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DEPARTMENT OF ENERGY

10 CFR Part 810

RIN 1994-AA07

Assistance to Foreign Atomic Energy Activities

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Final rule.

SUMMARY: On April 13, 2026, the Secretary of Energy (“Secretary”) issued a Determination generally authorizing the destination of Thailand for exports of controlled nuclear technology and assistance under DOE’s regulation on *Assistance to Foreign Atomic Energy Activities*. Accordingly, DOE is issuing this final rule to add Thailand to the generally authorized destinations list in appendix A.

DATES: This rule is effective on June 16, 2026.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Goorevich, Assistant Deputy Administrator, Office of Nonproliferation and Arms Control (NPAC), National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 586–6836, richard.goorevich@nnsa.doe.gov; Ms. Christina Pak, Office of the General Counsel, GC–74, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 531–7420, christina.pak@hq.doe.gov; or Mr. Zachary Stern, Office of the General Counsel, National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 586–8627, zachary.stern@nnsa.doe.gov.

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- II. Good Cause for Dispensing with Notice and Comment

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IV. Approval of the Office of the Secretary

I. Background and Discussion of Final Rule

On April 13, 2026, the Secretary issued a “determination and authorization pursuant to section 57 b.(2) of the *Atomic Energy Act of 1954*, as amended, regarding exports of nuclear technology and assistance to Thailand,” which was published in the **Federal Register** on May 14, 2026 (91 FR 27322). Section 57b.(2) of the *Atomic Energy Act of 1954*, as amended (“AEA”) (42 U.S.C. 2077(b)(2)), enables peaceful nuclear trade by helping to assure that nuclear technology exports from the United States will not be used for non-peaceful purposes.

Part 810 of title 10, Code of Federal Regulations (“Part 810”) implements section 57 b.(2) of the AEA, pursuant to which the Secretary has granted a general authorization for certain categories of activities that the Secretary has found to be non-inimical to the interest of the United States—including assistance or transfers of technology to the generally authorized destinations listed in appendix A to part 810. In light of the Secretary’s Determination to generally authorize Thailand to cover exports of part 810-controlled nuclear technology and assistance, DOE is amending the generally authorized destinations list in appendix A by adding Thailand.

II. Good Cause for Dispensing with Notice and Comment

In accordance with the *Administrative Procedure Act* (APA), an agency may waive the notice and comment procedure if it finds, for good cause, that it is “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 553(b). Additionally, 5 U.S.C. 553(d) provides that an agency may waive the 30-day delayed effective date upon finding of good cause.

DOE finds good cause that notice and comment for this rule is unnecessary due to the nature of the revisions. This final rule simply makes ministerial changes to appendix A by adding Thailand to the generally authorized destinations list. Comments cannot alter the regulation given that the generally authorized destination status for Thailand has already been made effective through the Secretarial Determination issued on April 13, 2026

and published on May 14, 2026, at 91 FR 27322.

Accordingly, DOE has concluded that there is good cause to publish this final rule without prior opportunity for public comment because the action merely aligns appendix A with the Secretarial Determination. A delay in effective date is unnecessary for these same reasons. Therefore, these amendments are published as final and are effective June 16, 2026.

III. Regulatory Review

A. Executive Order 12866

Executive Order (“E.O.”) 12866, “Regulatory Planning and Review,” requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (“OIRA”) in the Office of Management and Budget (“OMB”) has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this final rule is consistent with these principles.

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

B. Additional Executive Orders and Presidential Memoranda

DOE has examined this final rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154 “Unleashing American Energy,” E.O. 14192, “Unleashing Prosperity Through Deregulation,” and Presidential Memorandum, “Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis.”

C. National Environmental Policy Act

DOE has considered this final rule in accordance with the National Environmental Policy Act (NEPA), as amended, DOE’s NEPA implementing regulations, set forth in 10 CFR part 1021, and DOE’s NEPA Implementing Procedures published outside the Code of Federal Regulations on June 30, 2025. DOE has determined that NEPA does not apply to this action. The changes to appendix A to part 810 are ministerial. DOE has determined that this rulemaking is a Federal action, but it is not “major” and therefore not subject to NEPA. This action is one to which NEPA does not apply because it does not fall within the definition of “major Federal action” in section 110(10) of NEPA, 42 U.S.C. 4336e(10). For more information, please see appendix A of 10 CFR part 1021 (“A5, Interpretive rulemakings with no change in environmental effect”) and appendix A of DOE’s NEPA Implementing Procedures, A5, Interpretive rulemakings with no change in environmental effect (June 30, 2025). *D. Regulatory Flexibility Act.*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that, by law, must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As discussed previously, DOE has determined that providing notice and opportunity for public comment on this final rule is unnecessary. Therefore, no regulatory flexibility analysis has been prepared for this final rule.

The changes to appendix A are summarized in section I of this

document. DOE has reviewed the changes under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The changes update the list of generally authorized destinations. They do not expand the scope of activities currently regulated under part 810.

DOE estimates that approximately 10 percent of the entities impacted by part 810 are small businesses, which generally fall within two North American Industry Classification System codes: engineering services (541330) and computer systems designs services (541512). Often, their requests for authorization include the transfer of computer codes or other similar products. Generally speaking, small businesses reported that their initial filing of a part 810 request for authorization required up to 40 hours of legal assistance, but follow-on reporting and requests required significantly less assistance.

The requirements for small businesses exporting nuclear technology abroad would not substantively change because the revisions to this rule do not add new burdens or duties to small businesses. The obligations of any person subject to the jurisdiction of the United States who engages directly or indirectly in the development or production of special nuclear material outside the United States have not changed in a manner that would provide any significant economic impact on small businesses. This rulemaking change no longer requires such persons to obtain specific authorization before making such transfers to Thailand, and this change is not expected to have any significant impact. This rulemaking no longer requires such persons to obtain specific authorization before making such transfers to Thailand, which is expected to ease the burden on small businesses.

On the basis of the foregoing, DOE certifies this final rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking.

E. Paperwork Reduction Act

This final rule imposes no information collection or recordkeeping requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

F. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and

Tribal governments, and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For regulatory actions likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy (2 U.S.C. 1532(a),(b)). DOE examined this rule according to UMRA and its statement of policy and has determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure by State, local, and Tribal government, in the aggregate, or by the private sector, of \$100 million or more in any year. Accordingly, no further assessment or analysis is required under UMRA.

G. Executive Order 13132

Executive Order 13132, “Federalism,” 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this final rule and has determined that it would not preempt State law and would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required under Executive Order 13132.

H. Treasury and General Government Appropriations Act, 1999

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

I. Executive Order 13211

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy, Supply,

Distribution, or Use,” 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any significant energy action. A “significant energy action” is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

J. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (February 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of this final rule prior to the effective date set forth at the outset of this rule. The report will state that it has been determined that the rule is not a “major rule” as defined by 5 U.S.C. 801 804(2).

IV. Approval of the Office of the Secretary

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

List of Subjects in 10 CFR Part 810

Foreign relations, Nuclear energy, Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on June 5, 2026, by Chris Wright, Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC on June 12, 2026.

Jennifer Hartzell,

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

For the reasons set forth in the preamble, the Department of Energy amends part 810 of chapter III of title 10 of the Code of Federal Regulations as set forth below.

PART 810—ASSISTANCE TO FOREIGN ATOMIC ENERGY ACTIVITIES

■ 1. The authority citation for part 810 continues to read as follows:

Authority: Secs. 57, 127, 128, 129, 161, 222, 232, and 234 AEA, as amended by the Nuclear Nonproliferation Act of 1978, Pub. L. 95–242, 68 Stat. 932, 948, 950, 958, 92 Stat. 126, 136, 137, 138 (42 U.S.C. 2077, 2156, 2157, 2158, 2201, 2272, 2280, 2282), the Intelligence Reform and Terrorism Prevention Act of 2004, Pub. L. 108–458, 118 Stat. 3768, and sec. 3116 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. 115–232; Sec. 104 of the Energy Reorganization Act of 1974, Pub. L. 93–438; Sec. 301, Department of Energy Organization Act, Pub. L. 95–91; National Nuclear Security Administration Act, Pub. L. 106–65, 50 U.S.C. 2401 *et seq.*, as amended.

Appendix A to Part 810 [Amended]

■ 2. Appendix A to part 810 is amended by adding an entry to the list for “Thailand” in alphabetical order to read as follows:

Appendix A to Part 810—Generally Authorized Destinations

* * * * *

Thailand

* * * * *

[FR Doc. 2026–12066 Filed 6–15–26; 8:45 am]

BILLING CODE 6450–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 703 and 749

RIN 3133–AF61

Records Preservation Program and Appendices—Record Retention Guidelines; Catastrophic Act Preparedness Guidelines

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: On March 11, 2026, the NCUA (or ‘agency’) published a proposed rule to solicit comments on ways to improve and update the vital records preservation program regulation and accompanying guidelines. Based on the comments received, and upon further consideration of the issues involved, the NCUA Board is publishing this final rule, mostly as proposed, to clarify the purpose of part 749, update the definitions, and remove unnecessary references to recommendations and guidance.

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

FOR FURTHER INFORMATION CONTACT:

Policy: Matt Huston, Policy Officer, Office of Examination and Insurance, at (571) 309–7684 or jhuston@ncua.gov; Legal: Gira Bose, Senior Staff Attorney, Office of General Counsel, at (703) 518–6562 or gbose@ncua.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The NCUA’s first vital records preservation program rule was promulgated in 1972 to ensure that duplicate vital records could be used for reconstruction purposes in the event of a catastrophe.¹ The rule has been periodically amended since that time.² While the Board believes part 749 continues to serve an important purpose, it has not been updated since 2007, and Appendix A, which was promulgated in 2001, has never been updated. In 2018, the NCUA’s Regulatory Reform Taskforce recommended that the Board review part 749 to identify if any changes or

¹ Records Preservation Program, 37 FR 19387 (Sept. 20, 1972) (establishing 12 CFR 749).

² See, NCUA Board Action Memorandum (Nov. 12, 1980); Records Preservation Program, 66 FR 40578 (Aug. 3, 2001); and Records Preservation Program and Appendices—Record Retention Guidelines; Catastrophic Act Preparedness Guidelines, 72 FR 14251 (Mar. 27, 2007).

improvements are needed.³ Over the next few years the Board received feedback that part 749 is unnecessarily burdensome and unclear to credit unions. In 2024, the Board issued an Advance Notice of Proposed Rulemaking (ANPR) on part 749 to inform any future changes the agency might make.⁴ This final rule builds on the comments received pursuant to the ANPR and the proposed rule issued in March 2026.⁵ The proposed rule primarily suggested removing Appendices A and B from the Code of Federal Regulations, in addition to tightening up the definitions used in part 749 and generally streamlining the regulation. Appendix A was added to part 749 as “suggested guidelines” based on the frequency of requests for assistance from credit unions. However, many commenters to the ANPR stated that, in practice, Appendix A is followed as if it were a requirement; thus, the Board concluded that Appendix A has become an obstacle to sound record retention practices and has resulted in credit unions retaining unused and obsolete records. The Board proposed removing Appendix B because, upon reconsideration, the benefit of having the guidance in proximity to the regulation does not outweigh the potential for misinterpretation.

B. Legal Authority

The Board is issuing this final rule pursuant to its authority under the Federal Credit Union Act (FCU Act). Under the FCU Act, NCUA is the chartering and supervisory authority for federal credit unions and the federal supervisory authority for federally insured credit unions (FICUs).⁶ The FCU Act grants NCUA a broad mandate to issue regulations governing both FCUs and all FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe rules and regulations for the administration of the FCU Act.⁷ Section 209 of the FCU Act is a plenary grant of regulatory authority to issue rules and

regulations necessary or appropriate to carry out its role as share insurer for all FICUs.⁸ Accordingly, the FCU Act grants the Board broad rulemaking authority to ensure that FICUs and the Share Insurance Fund remain safe and sound.

Part 749 also incorporates 15 U.S.C. 7001(d)—the Electronic Signatures in National and Global Commerce Act—which states that if a statute, regulation, or other rule of law requires a record be retained, that requirement is met by retaining an electronic record of the information in the record that accurately reflects the information in the record and remains accessible to all persons who are entitled to access by statute, regulation, or rule of law, for the period required by such statute, regulation, or rule of law, in a form that is capable of being accurately reproduced for later reference, whether by transmission, printing, or otherwise.

II. Final Rule

A. Overview

This final rule follows publication of the proposed rule and takes into consideration the comments received on the proposal. By the close of the public comment period on May 11, 2026, the Board had received 19 comments.⁹ These were submitted by seven credit unions, seven state and regional credit union leagues, two national credit union trade associations, one trade association for state credit union supervisors, and one individual member of the public who did not disclose a group affiliation. After careful consideration of the issues raised by the commenters, the Board has made two changes to the proposal, as discussed in section B. below.

B. Discussion of Public Comments

This section of the preamble discusses issues raised by commenters, and the Board’s responses to the comments.

Six commenters supported the proposal unconditionally. Eleven commenters expressed overall support but also provided feedback on issues raised in the proposal. Only one commenter opposed the proposal stating that reduced record retention would lead to the spoliation of certain types of records.

Commenters requested changes to the proposal in two main areas. First, part 749 currently requires credit unions to maintain a records preservation log with a list of items to be recorded as part of the log. The proposed rule did not alter this requirement. Second, the proposed

rule solicited feedback on adding a reference to part 749 on consulting with legal counsel when determining record retention timeframes.

On the requirement to maintain a records preservation log, one commenter expressed support for keeping the current provision. Another nine commenters recommended either removing the provision or revising it with an approach that gives a credit union more flexibility to determine what its individual records preservation log should incorporate and that works with the modern practice of electronic storage and automatic back up of data. Commenters stated that the final rule should not require credit unions to manually create or track information that is stored and tracked through automated systems.

Upon consideration of the comments, the Board agrees that the proposed rule text is unnecessarily prescriptive in mandating specific requirements and does not give a credit union the appropriate flexibility to create a records preservation log that will be most useful to the credit union. The Board believes it is important for a credit union and for the agency to know where vital records are stored. The purpose of a records preservation log is, therefore, to facilitate easy access when these records are needed. This is particularly important in the aftermath of a catastrophic event. But how the credit union structures such a log and what information it records in the log should be determined by the credit union. To be clear, the agency is not requiring or expecting credit unions to manually create or maintain this tool. As stated in the proposed rule, the log may be in electronic format if the credit union chooses. Therefore, paragraph 749.2(a)(3) is revised to read as follows:

a records preservation log as determined by the credit union that will aid in locating and easily accessing the vital records. The log may be in electronic or any other format as determined by the credit union.

Second, the preamble to the proposed rule asked whether the agency should include a reference in the regulation to consulting with legal counsel when setting minimum retention periods. Nine commenters provided feedback on this point. Six commenters stated that any reference to consulting with legal counsel should be clearly optional, nonbinding guidance, and should not create a supervisory expectation of consulting with legal counsel. Three commenters opposed any reference to such consultation in the rule. One commenter stated that any such reference could be communicated

³ Regulatory Reform Agenda, 83 FR 65926 (Dec. 21, 2018).

⁴ Records Preservation Program and Appendices—Record Retention Guidelines; Catastrophic Act Preparedness Guidelines, 89 FR 31117 (Apr. 24, 2024). See proposed rule for an overview of the ANPR and the comments received in response. Records Preservation Program and Appendices—Record Retention Guidelines; Catastrophic Act Preparedness Guidelines, 91 FR 11934 (Mar. 11, 2026).

⁵ Records Preservation Program and Appendices—Record Retention Guidelines; Catastrophic Act Preparedness Guidelines, 91 FR 11934 (Mar. 11, 2026).

⁶ 12 U.S.C. 1752–1775.

⁷ 12 U.S.C. 1766(a).

⁸ 12 U.S.C. 1789.

⁹ Two comments were duplicate submissions from the same commenter.

through a Letter to Credit Unions rather than in the Code of Federal Regulations. One comment from a credit union league stated that this is a service that it provides to its members, as do other leagues, at much less cost than outside counsel would charge. Finally, one commenter said that any reference to consulting with legal counsel would be interpreted as a requirement when this is a decision that should be left to a credit union's board of directors.

On further reflection, the Board has decided not to include a reference in the regulation to consulting with legal counsel when crafting record retention periods. While such consultation may be prudent for some credit unions, the reference was not intended to be taken as a requirement. As explained by commenters, however, the mere reference may in time be interpreted as a requirement by credit unions or examiners. And in light of the services provided by credit union leagues to their members, there may be sufficient industry-generated guidance available to assist with record retention periods that obviates the need for NCUA to include this reference in the regulation.

Other issues raised in the comments are addressed as follows. All commenters who opined on the proposal to remove Appendices A and B were supportive of the change. Commenters generally reiterated the concerns expressed by commenters to the ANPR stating that the appendices have become overly burdensome, are unreasonably prescriptive, and are confusing in practice because they operate as requirements even though they were intended to be nonbinding recommendations. The final rule repeals both appendices. A few commenters did state, however, that Appendix B contains helpful guidance on catastrophic act preparedness and the agency should publish its content in some other publication or on its website as an aid to any credit unions that choose to consult it. While this suggestion is beyond the scope of this rulemaking, the agency plans to publish the content of Appendix B for informational purposes for any credit union that finds it useful.

Two commenters asked that the agency provide guidance on what credit unions should do with certain documents that were referenced in Appendix A but fall outside part 749 because they are not records that would be needed to restore vital member services, such as a credit union's bylaws, charter, and other foundational documents. These documents are beyond the scope of part 749 but they are important documents, and credit

unions should be thoughtful in their approach to managing them. As stated in the preamble to the proposed rule, it should be reasonable for the Board and for a credit union's membership to expect that a credit union's leadership would retain key foundational documents of its own volition. While this request for guidance is beyond the scope of this rulemaking, the agency will consider this suggestion as it reviews the need for future guidance.

One commenter opposed the rule stating that records related to escheatment and beneficiary designation should be retained permanently. As stated in the regulation, a credit union may classify additional records as vital and maintain older versions of any vital records as it determines necessary. Also, as revised § 749.0 makes clear, nothing in this rulemaking relieves a credit union of any recordkeeping obligations under other laws and regulations.

Finally, this rule removes 12 CFR 703.105(d), which requires reports to be maintained in accordance with Appendix A to part 749. This is a technical amendment to remove the inconsistency that would otherwise arise between part 703 and the revised part 749.

III. Regulatory Procedures

A. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 ("Regulatory Planning and Review"), a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.¹⁰ Executive Order 13563 ("Improving Regulation and Regulatory Review") supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.¹¹ This final rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OIRA has determined that this final rule is not a "significant regulatory action" as defined by section 3(f) of Executive Order 12866.

Executive Order 14192 ("Unleashing Prosperity Through Deregulation") requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by

the elimination of existing costs associated with at least 10 prior regulations.¹² This final rule is not an E.O. 14192 regulatory action because this rule is not significant under E.O. 12866.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act¹³ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.¹⁴ For purposes of this analysis, NCUA considers small credit unions to be those having under \$100 million in assets.¹⁵ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions.

This final rule amends part 749 by clarifying the purpose of the regulation, updating the definitions, and removing unnecessary references to recommendations and guidance. Part 749 is a longstanding regulation that requires credit unions to establish a vital records preservation program to identify, store, and reconstruct vital records for the purpose of restoring vital member services after a catastrophic event. The preamble makes clear that the purpose of the rule is to reduce the regulatory burden of vital records preservation. It does so by streamlining the regulation so that only vital records are preserved and only for so long as they can be used to restore vital member services. The rule is based on industry feedback, particularly from small credit unions, that part 749, particularly Appendix A, is unnecessarily burdensome and unclear. The elimination of Appendix A, which recommends credit unions retain certain documents permanently, should reduce the costs of compliance with part 749. Accordingly, NCUA certifies the final rule will not have a significant economic impact on a substantial number of small credit unions.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency

¹² 90 FR 9065 (Feb. 6, 2025).

¹³ 5 U.S.C. 601 *et seq.*

¹⁴ 5 U.S.C. 605(b).

¹⁵ 80 FR 57512 (Sept. 24, 2015).

¹⁰ 58 FR 51735 (Oct. 4, 1993).

¹¹ 76 FR 3821 (Jan. 21, 2011).

may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The PRA applies to rulemaking in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement.

The final rule contains information collection recordkeeping requirements associated with establishing, retaining and maintaining a written vital records preservation program. This action will require revision of an existing information collection for approval under the PRA. The NCUA is proposing to extend, for three years, with revision, its information collection. The revision was submitted to OMB for approval under OMB control number 3133–0032.

Title of Information Collection: Records Preservation, 12 CFR part 749.
OMB Control Number: 3133–0032.
Estimated Number of Respondents: 4,339.
Estimated Number of Responses per Respondent: 1.
Estimated Annual Responses: 4,339.
Estimated Hours per response: Varies.
Estimated Total Annual Burden Hours: 8,726.

The NCUA estimates a total annual burden of 8,726 hours as follows:

NCUA SUMMARY OF ESTIMATED ANNUAL BURDEN
 [3133–0032]

Information collection activity	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Hours per response	Total estimated annual burden hours
Retain and maintain a written vital records preservation program.	Recordkeeping (On Occasion)	4,331	1	2	8,662
Establish a written program	Recordkeeping (One-time)	8	1	8	64
<i>Total Estimated Annual Burden (Hours).</i>					8,726

D. Executive Order 13132 on Federalism

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests.¹⁶ NCUA, an agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This final rule would apply to all FICUs, including state-chartered credit unions. The NCUA expects that any effect on states or on the distribution of power and responsibilities among the various levels of government will be minor. The changes to part 749 would mainly clarify the existing regulations and guidance in this area and are not intended to affect the division of responsibilities between the NCUA and state regulatory authorities with oversight of federally insured, state-chartered credit unions.

E. Assessment of Federal Regulations and Policies on Families

NCUA has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.¹⁷ This final rule relates to FICUs' vital records retention programs, and any effect on family well-being is expected to be indirect.

F. Congressional Review Act

The Congressional Review Act (CRA) generally provides for congressional review of agency rules.¹⁸ NCUA must submit a report to Congress and the Comptroller General when it issues a final rule, as defined by the CRA.¹⁹ An agency rule, in addition to being subject to congressional oversight, may also be subject to a delayed effective date if the rule is a "major rule." The Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), has determined that this rule is not a "major rule" within the meaning of the relevant sections of the CRA. NCUA will also file appropriate reports with Congress and the Comptroller General so this rule may be reviewed.

List of Subjects

12 CFR Part 703

Credit unions, Investments, Reporting and recordkeeping requirements.

12 CFR Part 749

Archives and records, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board, this 9th day of June, 2026.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board amends 12 CFR parts 703 and 749 as follows:

PART 703—INVESTMENT AND DEPOSIT ACTIVITIES

Subpart B—Derivatives

- 1. The authority citation for part 703 continues to read as follows:

Authority: 12 U.S.C. 1757(7), 1757(8), 1757(14), and 1757(15).

§ 703.105 [Amended]

- 2. Remove and reserve § 703.105(d).

PART 749—RECORDS PRESERVATION PROGRAM AND APPENDICES—RECORD RETENTION GUIDELINES; CATASTROPHIC ACT PREPAREDNESS GUIDELINES

- 3. The authority citation for part 749 continues to read as follows:

Authority: 12 U.S.C. 1756, 1766(a), 1784, 1786, 1789; 15 U.S.C. 7001(d).

- 4. Revise part 749 to read as follows:

PART 749—VITAL RECORDS PRESERVATION PROGRAM

Sec.
 749.0 Purpose and scope.

¹⁶ 64 FR 43255 (Aug. 4, 1999).

¹⁷ Public Law 105–277, 112 Stat. 2681 (1998).

¹⁸ 5 U.S.C. 801–808.

¹⁹ 5 U.S.C. 804(3).

- 749.1 Definitions.
 749.2 Vital records preservation program.
 749.3 Vital records center and third-party service providers.
 749.4 Format for vital records preservation.
 749.5 Format for records required by other NCUA regulations.

§ 749.0 Purpose and scope.

(a) This part describes the obligations of a federally insured credit union to maintain a vital records preservation program to identify, store, and reconstruct vital records in the event such records are destroyed.

(b) This part does not supersede records preservation requirements that may apply to a credit union pursuant to other law or regulation.

§ 749.1 Definitions.

For purposes of this part:

Vital member services are the essential financial services that a credit union provides to its members, such as member access to their accounts, share withdrawal and deposit facilities, and loan payments and disbursements.

Vital records are the most recent and current versions of the records a credit union needs to restore vital member services. These records are:

- (1) A list of share, deposit, and loan balances for each member's account as of the close of the most recent business day that:
 - (i) Shows each balance individually identified by a name or number,
 - (ii) Lists multiple loans of one account separately, and
 - (iii) Contains information sufficient to enable the credit union to locate each member, such as address and telephone number.
- (2) A financial report, which lists all of the credit union's asset and liability accounts, current as of the most recent month-end.
- (3) Bank reconciliements, current as of the most recent month-end.
- (4) A list of the credit union's accounts at financial institutions, insurance policies, and investments along with related contact information, current as of the most recent month-end.
- (5) Emergency contact information for employees, officials, regulatory offices, and vendors used to support vital records.
- (6) A credit union may classify additional records as vital and maintain older versions of any vital records as it determines necessary.

Vital records center is a storage facility, which may include another federally insured credit union, at any location far enough from the credit union's offices to avoid the simultaneous loss of both sets of records in the event of a catastrophic act.

§ 749.2 Vital records preservation program.

(a) The board of directors of a credit union is responsible for establishing a vital records preservation program within six months of its insurance certificate being issued. The program must be in writing and contain procedures for maintaining duplicate vital records at a vital records center. The procedures must include:

- (1) Designated staff responsible for vital records preservation,
- (2) A schedule for the storage and destruction of vital records, and
- (3) A records preservation log as determined by the credit union that will aid in locating and easily accessing the vital records. The log may be in electronic or any other format as determined by the credit union.

(b) A credit union that has some or all of its vital records maintained by an off-site data processor is considered to be in compliance for the storage of those records if the service agreement specifies the data processor safeguards against the simultaneous destruction of production and back-up information.

(c) Unless required by other law or regulation, older versions of vital records may be destroyed once their current versions are stored.

§ 749.3 Vital records center and third-party service providers.

A credit union must maintain, or contract with a third-party service provider to maintain, any equipment or software for its vital records center necessary for the credit union to access its records. If a credit union contracts with a third-party service provider to maintain its records, the credit union must maintain effective oversight of the third-party service provider to ensure the records meet the requirements of this section.

§ 749.4 Format for vital records preservation.

Preserved vital records may be in any format that can be used to reconstruct the credit union's vital records. The format used must accurately reflect the information in the record, remain accessible to all persons entitled to access by statute, regulation, or rule of law, and be capable of reproduction by transmission, printing, or otherwise.

§ 749.5 Format for records required by other NCUA regulations.

Where NCUA regulations require a credit union to retain certain writings, records, or information, the credit union may use any format that accurately reflects the information in the record, is accessible to all persons entitled to access by statute, regulation, or rule of

law, and is capable of being reproduced by transmission, printing, or otherwise. The credit union must maintain the necessary equipment or software to permit an examiner to access the records during the examination process.

[FR Doc. 2026-12058 Filed 6-15-26; 8:45 am]

BILLING CODE 7535-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2026-0007; Project Identifier MCAI-2025-01183-R; Amendment 39-23378; AD 2026-12-08]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Model AS350B2, AS350B3, EC130B4, and EC130T2 helicopters. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the airworthiness limitations section (ALS) of the existing maintenance manual (MM) or instructions for continued airworthiness (ICAs) and the existing approved maintenance or inspection program, as applicable. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 21, 2026. The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 21, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-0007; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA,

Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at regulations.gov under Docket No. FAA-2026-0007.

FOR FURTHER INFORMATION CONTACT:

Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946-4134; email: matthew.t.williams@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Helicopters Model AS350B2, AS350B3, EC130B4, and EC130T2 helicopters. The NPRM was published in the **Federal Register** on January 8, 2026 (91 FR 645). The NPRM was prompted by EASA AD 2025-0137, dated June 27, 2025; corrected October 29, 2025 (EASA AD 2025-0137) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that new or more restrictive airworthiness limitations have been developed. Additionally, the MCAI advises that the airworthiness limitations are identified as mandatory for continued airworthiness and that Airbus Helicopters has issued applicable ALS revisions to specify new and more restrictive life limits and maintenance tasks. The FAA is issuing this AD to prevent failure of critical parts and primary structural components, which, if not addressed, could result in loss of control of the helicopter.

In the NPRM, the FAA proposed to require revising the ALS of the existing MM or ICAs and the existing approved maintenance or inspection program, as applicable. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA-2026-0007.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters. One commenter was an individual, and the other commenter was anonymous. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Not Incorporate the MCAI by Reference

The individual commenter requested that the FAA not incorporate by reference EASA AD 2025-0137 for the basis of the FAA AD. The individual commenter stated that ADs that incorporate the MCAI by reference are time consuming for the operator and increase the likelihood of errors due to complexity of the required actions when using multiple references. The individual commenter also requested that the FAA begin publishing its own, complete, single-source AD, which had been done before using the concept of incorporating the MCAI by reference.

The FAA disagrees with both the request to not require compliance with EASA AD 2025-0137 in the FAA AD and the request to discontinue the method of requiring compliance with some foreign ADs issued by the foreign state of design authority. In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. FAA ADs that require compliance with foreign ADs have been utilized since 2018 for some products and since 2020 for Airbus Helicopters. Incorporating information by reference is a common method of federal rulemaking that is explicitly permitted under 1 CFR part 51. As stated in the Incorporation by Reference Handbook, June 2023 Edition, incorporation of relevant, usually technical information (such as the MCAI) promotes efficiency. The FAA did not change this AD as a result of this comment.

Request for More Information on Required Actions and Incorporated Material

The anonymous commenter requested further information regarding the compliance recording requirement. The anonymous commenter also stated that the required actions of the proposed AD are not communicated well due to the fact that the FAA AD does not incorporate several paragraphs from the MCAI and only incorporates paragraph

(3) of the MCAI. The anonymous commenter questions what actions the AD requires and how to record compliance with the AD. Additionally, the anonymous commenter stated that paragraph (3) of the MCAI applicability is questionable as owners and operators are not required to have an Aircraft Maintenance Program (AMP).

The FAA infers that the requester is seeking clarification on recording compliance for the proposed AD. This AD requires revising the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable. Once the ALS is revised, the AD has been fully complied with and the life limit or inspection change remains enforceable as a part of the ALS. Requiring revision of the ALS, rather than requiring individual repetitive inspections, is advantageous for operators. It allows them to record AD compliance once when they make the revision rather than after every inspection or replacement.

Additionally, the FAA only requires compliance with paragraph (3) of the incorporated material and therefore that is the only required action.

Furthermore, the FAA does not require revising the AMP and instead requires revising the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program. The FAA did not change this AD as a result of this comment.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025-0137, which specifies replacing components before exceeding their life limits and accomplishing all applicable maintenance tasks within thresholds and intervals specified in the ALS as

defined in EASA AD 2025–0137. Depending on the results of the maintenance tasks, EASA AD 2025–0137 specifies accomplishing corrective action(s) or contacting Airbus Helicopters for approved instructions and accomplishing those instructions.

Additionally, EASA AD 2025–0137 specifies revising the AMP by incorporating the limitations, tasks, and associated thresholds and intervals described in the specified ALS, as applicable. Revising the AMP constitutes terminating action for the requirement to record accomplishment of the actions of replacing components

before exceeding their life limits and accomplishing maintenance tasks within thresholds and intervals specified in the applicable ALS as specified in EASA AD 2025–0137 for demonstration of AD compliance on a continued basis.

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

Differences Between This AD and the MCAI

Where EASA AD 2025–0137 specifies revising the approved AMP within 12 months after the effective date of EASA AD 2025–0137, this AD requires revising the ALS of the existing approved maintenance or inspection program, as applicable, within 30 days after the effective date of this AD.

Costs of Compliance

The FAA estimates that this AD affects 1,163 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise ALS	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$98,855

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2026–12–08 Airbus Helicopters:

Amendment 39–23378; Docket No. FAA–2026–0007; Project Identifier MCAI–2025–01183–R.

(a) Effective Date

This airworthiness directive (AD) is effective July 21, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model AS350B2, AS350B3, EC130B4, and EC130T2 helicopters, certificated in any category.

Note 1 to paragraph (c): Helicopters with AS350B3e designation are Model AS350B3 helicopters.

(d) Subject

Air Transport Association (ATA) of America Code 04, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by new or more restrictive airworthiness limitations. The FAA is issuing this AD to prevent failure of critical parts and primary structural components, which, if not addressed, could result in loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2025–0137, dated June 27, 2025; corrected October 29, 2025 (EASA AD 2025–0137).

(h) Exceptions to EASA AD 2025–0137

(1) Where EASA AD 2025–0137 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt paragraphs (1), (2), (4), and (5) of EASA AD 2025–0137.

(3) Where paragraph (3) of EASA AD 2025–0137 specifies “Within 12 months after the effective date of this AD, revise the approved AMP”, this AD requires replacing that text with “Within 30 days after the effective date of this AD, revise the airworthiness limitations section of the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable”.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2025–0137 is on or before the applicable “limitations” and “associated thresholds” as incorporated by the requirements of

paragraph (3) of EASA AD 2025–0137 or within 30 days after the effective date of this AD, whichever occurs later.

(5) This AD does not adopt the “Remarks” section of EASA AD 2025–0137.

(i) Provisions for Alternative Actions and Intervals

After the action required by paragraph (g) of this AD has been done, no alternative actions and associated thresholds and intervals, including any life limits, are allowed unless they are approved as specified in the provisions of the Ref. Publications section of EASA AD 2025–0137.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: matthew.t.williams@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2025–0137, dated June 27, 2025; corrected October 29, 2025.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222 5110.

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

Issued on June 11, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–12050 Filed 6–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–0006; Project Identifier MCAI–2024–00735–R; Amendment 39–23379; AD 2026–12–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–11–08, which applied to all Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D, EC130B4, and EC130T2 helicopters. AD 2022–11–08 required incorporating into maintenance records certain requirements (airworthiness limitations). Since the FAA issued AD 2022–11–08, it was determined that new or more restrictive airworthiness limitations are necessary. This AD requires revising the airworthiness limitations section (ALS) of the existing maintenance manual (MM) or instructions for continued airworthiness (ICAs) and the existing approved maintenance or inspection program, as applicable. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 21, 2026. The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 21, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2026–0006; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu. It is also available at regulations.gov under Docket No. FAA–2026–0006.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at regulations.gov under Docket No. FAA–2026–0006.

FOR FURTHER INFORMATION CONTACT:

Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: matthew.t.williams@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–11–08, Amendment 39–22058 (87 FR 33632, June 3, 2022), (AD 2022–11–08). AD 2022–11–08 applied to all Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D, EC130B4, and EC130T2 helicopters. AD 2022–11–08 required incorporating into maintenance records certain requirements (airworthiness limitations). The FAA issued AD 2022–11–08 to prevent failure of critical parts which could result in the loss of control of the helicopter.

The NPRM was published in the **Federal Register** on January 8, 2026 (91 FR 648). The NPRM was prompted by EASA AD 2024–0133R1, dated June 27, 2025 (EASA AD 2024–0133R1) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. EASA AD 2024–0133R1 states that new or more restrictive airworthiness limitations have been developed. Additionally, EASA AD 2024–0133R1 advises that the airworthiness limitations and certification maintenance instructions are identified as mandatory for continued airworthiness and that AH [Airbus Helicopters] has issued applicable ALS revisions to specify new and more restrictive life limits and maintenance tasks, which includes repetitive checks and inspection requirements.

In the NPRM, the FAA proposed to require revising the ALS of the existing MM or ICAs and the existing approved maintenance or inspection program, as applicable.

The FAA is issuing this AD to prevent failure of critical parts and primary structural components, which if not addressed, could result in loss of control of the helicopter.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–0006.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters. One commenter was an individual and two commenters were anonymous. The anonymous commenters submitted identical comments, and thus the FAA will address these comments together. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

The individual commenter expressed support for the NPRM.

Request for More Information on Required Actions and Incorporated Material

The anonymous commenters requested further information regarding the compliance recording requirement. The anonymous commenters also requested further information regarding the airworthiness limitations section of the existing maintenance manual (*i.e.* revision level and date) that is to be revised, and how these manuals are to be revised to include digital manuals. The anonymous commenters also stated that the corrective actions of the proposed rule are not clear and concise.

The FAA infers that the requesters are seeking clarification on recording compliance for the proposed AD. This AD requires revising the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable. Once the ALS section is revised, the AD has been fully complied with and the life limit or inspection change remains enforceable as a part of the ALS. Requiring revision of the ALS, rather than requiring individual repetitive inspections, is advantageous for operators. It allows them to record AD

compliance once when they make the revision rather than after every inspection or replacement.

Additionally, the FAA makes incorporated by reference (IBR) material available in the AD docket when the final rule is published in the **Federal Register**, following formal approval of the IBR by the Office of the Federal Register. Materials may only be posted before the final rule's publication if they are already publicly available or if there is written consent from the owner of the IBR material. All relevant materials incorporated by reference will be accessible in the AD docket on [Regulations.gov](https://www.regulations.gov), which the public can access without registration or fees. This AD also specifies instructions for revising the maintenance manual or instructions for continued airworthiness by incorporating the limitations, tasks and associated thresholds and intervals described in the applicable ALS, which applies to either paper or digital versions.

Furthermore, this AD only requires compliance with paragraph (3) of the EASA AD, therefore the corrective actions paragraph is not adopted.

Therefore, the FAA did not change this AD as a result of this comment.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, including the MCAI referenced, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Relationship Between This AD and Other Relevant Rulemaking

EASA AD 2024–0133R1 specifies that the manufacturer revised the ALS, for Airbus Helicopters Model AS350B2, AS350B3, EC130B4, and EC130T2 helicopters as applicable. The revised ALS for each model now incorporates the new and more restrictive tasks and limitations. The FAA is evaluating this

issue and may take further rulemaking action to accommodate these ALS amendments.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0133R1, which specifies procedures for replacing components before exceeding their life limits and accomplishing all applicable maintenance tasks within thresholds and intervals specified in the ALS as defined in EASA AD 2024–0133R1. Depending on the results of the maintenance tasks, EASA AD 2024–0133R1 specifies accomplishing corrective action(s) or contacting Airbus Helicopters for approved instructions and accomplishing those instructions.

Additionally, EASA AD 2024–0133R1 specifies revising the Aircraft Maintenance Programme (AMP) by incorporating the limitations, tasks, and associated thresholds and intervals described in the specified ALS, as applicable. Revising the AMP constitutes terminating action for the requirement to record accomplishment of the actions of replacing components before exceeding their life limits and accomplishing maintenance tasks within thresholds and intervals specified in the applicable ALS as required by EASA AD 2024–0133R1 for demonstration of AD compliance on a continued basis.

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

Differences Between This AD and the MCAI

Where EASA AD 2024–0133R1 specifies revising the approved AMP within 12 months after the effective date of EASA AD 2024–0133R1, this AD requires revising the ALS of the existing approved maintenance or inspection program, as applicable, within 30 days after the effective date of this AD.

EASA AD 2024–0133R1 applies to Airbus Helicopters Model AS350BB, whereas this AD does not because that model does not have an FAA type certificate.

Costs of Compliance

The FAA estimates that this AD affects 963 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise ALS	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$81,855

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:
- Authority:** 49 U.S.C. 106(g), 40113, 44701.
- § 39.13 [Amended]**
- 2. The FAA amends § 39.13 by:
- a. Removing Airworthiness Directive 2022–11–08, Amendment 39–22058 (87 FR 33632, June 3, 2022); and
- b. Adding the following new airworthiness directive:
- 2026–12–09 Airbus Helicopters:** Amendment 39–23379; Docket No. FAA–2026–0006; Project Identifier MCAI–2024–00735–R.
- (a) Effective Date**
- This airworthiness directive (AD) is effective July 21, 2026.
- (b) Affected ADs**
- This AD replaces AD 2022–11–08, Amendment 39–22058 (87 FR 33632, June 3, 2022).
- (c) Applicability**
- This AD applies to all Airbus Helicopters Model AS350B, AS350BA, AS350B1, and AS350D helicopters, certificated in any category.
- (d) Subject**
- Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.
- (e) Unsafe Condition**
- This AD was prompted by new and more restrictive airworthiness limitations. The FAA is issuing this AD to prevent failure of critical parts and primary structural components, which if not addressed, could result in loss of control of the helicopter.
- (f) Compliance**
- Comply with this AD within the compliance times specified, unless already done.
- (g) Required Actions**
- Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2024–0133R1, dated June 27, 2025 (EASA AD 2024–0133R1).
- (h) Exceptions to EASA AD 2024–0133R1**
- (1) Where EASA AD 2024–0133R1 refers to its effective date, this AD requires using the effective date of this AD.
- (2) This AD does not adopt paragraphs (1), (2), (4), and (5) of EASA AD 2024–0133R1.

- (3) Where paragraph (3) of EASA AD 2024–0133R1 specifies, “Within 12 months after the effective date of this AD, revise the approved AMP”, this AD requires replacing that text with “Within 30 days after the effective date of this AD, revise the airworthiness limitations section of the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable.”
- (4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0133R1 is on or before the applicable limitations and associated thresholds as incorporated by the requirements of paragraph (3) of EASA AD 2024–0133R1 or within 30 days after the effective date of this AD, whichever occurs later.
- (5) This AD does not adopt the “Remarks” section of EASA AD 2024–0133R1.
- (i) Provisions for Alternative Actions and Intervals**
- After the action required by paragraph (g) of this AD has been done, no alternative actions and associated thresholds and intervals, including any life limits, are allowed unless they are approved as specified in the provisions of the Ref. Publications section of EASA AD 2024–0133R1.
- (j) Alternative Methods of Compliance (AMOCs)**
- (1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *AMOC@faa.gov*.
- (2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.
- (k) Additional Information**
- For more information about this AD, contact Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: *matthew.t.williams@faa.gov*.
- (l) Material Incorporated by Reference**
- (1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0133R1, dated June 27, 2025.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222 5110.

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

Issued on June 11, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–12052 Filed 6–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–5387; Project Identifier MCAI–2024–00399–R; Amendment 39–23337; AD 2026–09–15]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–01–04 for all Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters. AD 2023–01–04 required, for helicopters with certain part-numbered tail rotor head (TRH) spider pitch change units installed, inspecting the pitch change spider nut (nut) for correct installation; marking a 2 to 5 mm wide black paint index mark and repetitively inspecting the alignment of the marking; and performing additional inspections and corrective actions if necessary. Since the FAA issued AD 2023–01–04, new or more restrictive airworthiness

limitations were issued, which terminated the requirement for the repetitive inspections of the black paint index marking. This AD requires the same actions as AD 2023–01–04, except for the repetitive black paint index marking inspections and prohibits installing certain parts unless certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 21, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 21, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2025–5387; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Airbus Helicopters material identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; website: airbus.com/en/products-services/helicopters/hcare-services/airbusworld.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at regulations.gov under Docket No. FAA–2025–5387.

FOR FURTHER INFORMATION CONTACT:

Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: matthew.t.williams@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–01–04, Amendment 39–22298 (88 FR 6618, February 1, 2023), (AD 2023–01–04). AD 2023–01–04 applied to Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D,

AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters. AD 2023–01–04 required, for helicopters with certain part-numbered TRH spider pitch change units installed, inspecting for correct installation of the nut; marking a 2 to 5 mm wide black paint index mark to identify the position of certain parts; and after the initial marking, repetitively inspecting the alignment of the marking; and additional inspections and corrective actions if necessary. Additionally, AD 2023–01–04 prohibited installing an affected part on a helicopter unless certain requirements were met. The FAA issued AD 2023–01–04 to detect improper installation of the nut and improper alignment of a black index marking.

The NPRM was published in the **Federal Register** on December 17, 2025 (90 FR 58512). The NPRM was prompted by European Union Aviation Safety Agency (EASA) AD 2021–0282R1, Revision 1, dated July 10, 2024 (EASA AD 2021–0282R1) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that the manufacturer revised the Airworthiness Limitations Section (ALS), as applicable, which now includes the repetitive black index marking checks (inspections).

In the NPRM, the FAA proposed to require the same actions as AD 2023–01–04, except the NPRM only proposed to require the initial black paint index marking inspection, not the repetitive inspections. The FAA also proposed to prohibit installing an affected part on a helicopter unless certain requirements are met.

You may examine the AD docket at regulations.gov under Docket No. FAA–2025–5387.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from an individual commenter. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Clarify Black Paint Index Mark Visual Inspection for New Units

The commenter requested that the FAA add language to paragraph (g)(2) of the proposed AD to clarify whether a 10 hour time-in-service visual inspection of the black paint index mark is required on a pitch change unit that is new or newly overhauled.

The FAA disagrees with the request to update paragraph (g)(2) of this AD but

agrees to clarify that the repetitive black paint index mark visual inspections are now integrated into the ALS for affected part numbers 350A33–2030–00, 350A33–2167–00, and 350A33–2167–01, in accordance with the applicable ALS. No changes were made to this AD as a result of this comment.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is

issuing this AD to address the unsafe condition on these products. Except for minor editorial changes and technical corrections in paragraph (h) to accurately reflect the parts installation limitations, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. AS350–05.01.03, and Airbus Helicopters ASB No. AS355–05.00.86, both Revision 1 and dated July 8, 2024, which include Figure 1 that identifies the position of the TRH pitch change unit and of the bearing spacer to be marked with a 2 to 5 mm wide black paint index mark. This material also specifies procedures for inspecting the

condition and installation of the nut; and inspecting the application and alignment of the black index mark on the TRH pitch change unit and the bearing spacer.
This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Differences Between This AD and the MCAI

The MCAI applies to Airbus Helicopters Model AS350BB, whereas this AD does not because that model does not have an FAA type certificate.

Costs of Compliance

The FAA estimates that this AD affects 972 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect the nut	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$82,620
Inspect alignment of marking	1 work-hour × \$85 per hour = \$85	0	85	82,620
Place black paint marking	1 work-hour × \$85 per hour = \$85	0	85	82,620

The FAA estimates the following costs to do any repairs/replacements that would be required based on the

results of the inspection. The agency has no way of determining the number of

helicopters that might need these repairs or replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspect the TRH pitch change unit	13 work-hours × \$85 per hour = \$1,105 ..	\$0	\$1,105.
Replace bushes	1 work-hour × \$85 per hour = \$85	5,918	6,003 per helicopter.
Replace a rotating plate	1 work-hour × \$85 per hour = \$85	27,375	27,460 per helicopter.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency’s authority.
The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or

develop on products identified in this rulemaking action.
Regulatory Findings
The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.
For the reasons discussed above, I certify that this AD:
(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Will not affect intrastate aviation in Alaska, and
(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.
List of Subjects in 14 CFR Part 39
Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.
The Amendment
Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:
PART 39—AIRWORTHINESS DIRECTIVES
■ 1. The authority citation for part 39 continues to read as follows:
Authority: 49 U.S.C. 106(g), 40113, 44701.
§ 39.13 [Amended]
■ 2. The FAA amends § 39.13 by:

- a. Removing Airworthiness Directive 2023–01–04, Amendment 39–22298 (88 FR 6618, February 1, 2023); and
- b. Adding the following new airworthiness directive:

2026–09–15 Airbus Helicopters:

Amendment 39–23337; Docket No. FAA–2025–5387; Project Identifier MCAI–2024–00399–R.

(a) Effective Date

This airworthiness directive (AD) is effective July 21, 2026.

(b) Affected ADs

This AD replaces AD 2023–01–04, Amendment 39–22298 (88 FR 6618, February 1, 2023).

(c) Applicability

This AD applies to all Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters, certificated in any category.

Note 1 to paragraph (c): Helicopters with AS350B3e designation are Model AS350B3 helicopters.

(d) Subject

Joint Aircraft System Component (JASC) Code 6420, Tail rotor head.

(e) Unsafe Condition

This AD was prompted by an occurrence reported where, during an inspection of a tail rotor head (TRH) pitch change unit, excessive play and excessive wear were detected, due to an unwanted rotating motion and updated airworthiness limitations and maintenance tasks. The FAA is issuing this AD to detect improper installation of the pitch change spider nut (nut) and improper alignment of a black index marking. The unsafe condition, if not addressed, could result in loss of the TRH pitch change control and consequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) For helicopters with TRH pitch change unit, part number (P/N) 350A33–2030–00, 350A33–2167–00, or 350A33–2167–01 installed, within 50 hours time-in-service (TIS) after the effective date of this AD, inspect the nut for correct installation. If the nut is missing or loose, before further flight, remove the bearing from the TRH pitch change unit and do the following:

(i) Inspect the TRH pitch change unit for corrosion. If there is any corrosion, before further flight, remove the affected part from service and replace with an airworthy part.

Note 2 to paragraph (g)(1)(i): Airbus Helicopters Mechanical Repair Manual (MRM) AS350 65–20–00–713, dated March 29, 2017, also known as Work Card 65–20–00–713 MRM, and Airbus Aircraft Maintenance Manual (AMM) AS350 65–21–00, 4–9b, dated May 16, 2019, also known as Task 65–21–00, 4–9 AMM, specify

disassembly and reassembly information for the TRH pitch change unit.

(ii) Inspect for rotation and wear on the faces of the bushes. For the purposes of this AD, indications of rotation and wear include tearing, peening, metal pick-up, and hammering. If there is any rotation or any wear on the faces of the bushes, before further flight, remove the bushes from service and replace with airworthy bushes.

(iii) Using 5X or higher power magnification, visually inspect the rotating plate and the rotating plate threads for damage. For the purposes of this AD, indications of damage include wear, deformation, stripping, galling, and corrosion. If there is any damage on the rotating plate or the rotating plate threads, before further flight, remove the rotating plate from service and replace with an airworthy rotating plate.

(iv) Identify the position of the TRH pitch change unit (item a) and of bearing spacer (item b) by marking a 2 to 5 mm wide black paint index mark (item C) with black paint as depicted in Figure 1, Section B–B, of Airbus Helicopters Alert Service Bulletin (ASB) No. AS350–05.01.03, (ASB AS350–05.01.03 Rev 1), or Airbus Helicopters ASB No. AS355–05.00.86 (ASB AS355–05.00.86 Rev 1), both Revision 1, and dated July 8, 2024, as applicable to the model helicopter.

(2) Within 10 hours TIS after the initial marking required by paragraph (g)(1)(iv) of this AD, visually inspect the alignment of the marking. An example of a properly aligned marking is depicted in Figure 1, Section B–B of ASB AS350–05.01.03 Rev 1 and ASB AS355–05.00.86 Rev 1, as applicable to the model helicopter. If the black paint index mark (item C) is misaligned, before further flight, inspect the TRH pitch change unit by accomplishing the actions required by paragraphs (g)(1)(i) and (ii) of this AD.

(h) Parts Installation Limitations

As of the effective date of this AD, do not install a TRH pitch change unit P/N 350A33–2030–00, 350A33–2167–00, or 350A33–2167–01 on any helicopter, unless you do the actions required by paragraphs (g)(1)(i) through (iv) of this AD before further flight after installation, and thereafter do the actions required by paragraph (g)(2) of this AD at the times specified in paragraph (g)(2) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the initial inspections and actions required by paragraph (g)(1) of this AD, if those actions were performed before the effective date of this AD using Airbus Helicopters ASB No. AS350–05.01.03, or ASB No. AS355–05.00.86, both Revision 0, and dated December 16, 2021.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly

to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD and email to: AMOC@faa.gov.

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

(k) Additional Information

(1) For more information about this AD, contact Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: matthew.t.williams@faa.gov.

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (l)(3) of this AD.

(l) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin (ASB) No. AS350–05.01.03, Revision 1, dated July 8, 2024.

(ii) Airbus Helicopters ASB No. AS355–05.00.86 Revision 1, dated July 8, 2024.

(3) For Airbus Helicopters material identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; website: airbus.com/en/products-services/helicopters/hcare-services/airbusworld.

(4) You may view this material at the FAA, Office of the Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on June 11, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–12048 Filed 6–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2025–2542; Project Identifier MCAI–2024–00397–R; Amendment 39–23356; AD 2026–10–16]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–19–13, which applied to all Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters. AD 2022–19–13 required incorporating into existing maintenance records certain requirements (airworthiness limitations). Since the FAA issued AD 2022–19–13, a determination was made that new or more restrictive airworthiness limitations are necessary. This AD requires revising the airworthiness limitations section (ALS) of the existing maintenance manual (MM) or instructions for continued airworthiness (ICAs) and the existing approved maintenance or inspection program, as applicable. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 21, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 21, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2025–2542; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu;

website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2025–2542.

FOR FURTHER INFORMATION CONTACT:

Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: matthew.t.williams@faa.gov.

SUPPLEMENTARY INFORMATION:**Background**

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–19–13, Amendment 39–22182 (87 FR 57814, September 22, 2022) (AD 2022–19–13). AD 2022–19–13 applied to all Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters. The FAA issued AD 2022–19–13 to address the failure of certain parts, which could result in the loss of control of the helicopter.

The NPRM was published in the **Federal Register** on September 15, 2025 (90 FR 44353). The NPRM was prompted by EASA AD 2024–0134, dated July 10, 2024 (EASA AD 2024–0134) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that new or more restrictive airworthiness limitations and repetitive check requirements have been developed. Additionally, the MCAI advises that the airworthiness limitations are identified as mandatory for continued airworthiness and that Airbus Helicopters has issued applicable ALS revisions to specify new and more restrictive life limits and maintenance tasks, which include repetitive checks and inspection requirements.

In the NPRM, the FAA proposed to require revising the ALS of the existing MM or ICAs and the existing approved maintenance or inspection program, as applicable. The FAA is issuing this AD to prevent failure of critical parts and primary structural components, which if not addressed, could result in loss of control of the helicopter.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–2542.

Relationship Between This AD and Other Relevant Rulemaking

EASA AD 2021–0193 notes that the requirements of EASA AD 2010–0006, dated January 7, 2010 (EASA AD 2010–0006) (which prompted FAA AD 2011–22–05 R1, Amendment 39–17765 (79 FR 14169, March 13, 2014) (AD 2011–22–05 R1)); and EASA AD 2015–0094, dated May 29, 2015 (EASA AD 2015–0094) (which prompted FAA AD 2016–25–20, Amendment 39–18746 (81 FR 94954, December 27, 2016) (AD 2016–25–20)); have been incorporated into the applicable ALS specified in EASA AD 2021–0193.

Accordingly, this AD does not supersede AD 2011–22–05 R1 or AD 2016–25–20. Rather, the FAA has determined that a standalone AD is more appropriate to address the changes in EASA AD 2024–0134, which superseded EASA AD 2021–0193. Therefore, accomplishment of the required actions in this AD terminates all of the requirements of AD 2011–22–05 R1 and AD 2016–25–20 for Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters only.

Discussion of Final Airworthiness Directive**Comments**

The FAA received comments from three commenters. The commenters were the Citizens Rulemaking Alliance and two individuals. The two individuals supported the NPRM without change. The following presents the comments received on the NPRM from the Citizens Rulemaking Alliance and the FAA's response to each comment.

Request To Issue an NPRM or Justify Forgoing Notice and Comment

The Citizens Rulemaking Alliance requested that the FAA either convert this action to an NPRM with a 30-day delayed effective date or provide its justification for finding good cause to bypass notice and comment procedures. The commenter asserted the FAA has not adequately justified use of the good cause exemption to bypass notice and comment and the 30-day delayed effective date.

The FAA notes the comment was submitted in response to an NPRM for which the FAA provided a 45-day comment period. This final rule is effective 35 days after its publication in the **Federal Register**. Therefore, the FAA did not change this AD as a result of this comment.

Request To Comply With the Paperwork Reduction Act (PRA)

The Citizens Rulemaking Alliance requested that the FAA revise the proposed AD to comply with the PRA if reporting is required or remove any reporting provisions until PRA requirements are satisfied, or make any reporting provisions voluntary. If reporting is not required, the commenter requested the FAA clarify that in the AD.

The FAA notes this AD does not require reporting. If an AD were to require reporting, the preamble of the AD would include a paragraph titled “Paperwork Reduction Act” that would provide the applicable OMB control number, required PRA statements, and the estimated time to collect the required information (burden). Any costs associated with the reporting requirement would be included in the Costs of Compliance section in the preamble of the final rule. Therefore, the FAA did not change this AD as a result of this comment.

Request To Make Incorporation by Reference (IBR) Materials Reasonably Available

The Citizens Rulemaking Alliance stated that the FAA’s current practices for IBR frequently fail to meet the legal and regulatory standards for reasonable availability. The commenter called on the FAA to guarantee that all IBR materials are easily and freely accessible to the public and affected parties for both commenting and compliance purposes. The commenter requested the FAA either obtain the copyright holder’s consent to place the IBR material in the public docket or include a summary of

the essential technical steps within the AD text to allow compliance without purchasing proprietary material. They also requested that this access be documented in the rulemaking record.

The FAA notes that EASA AD 2024–0134, which is incorporated by reference in this AD, is available to the public on the EASA website at ad.easa.europa.eu, as explained in the preamble and regulatory text of the proposed AD. This material was also posted in the AD docket upon publication of the NPRM. Therefore, the FAA did not change this AD as a result of this comment.

Request To Consider Impact on Small Entities

The Citizens Rulemaking Alliance requested that the FAA provide the factual basis for its Regulatory Flexibility Act (RFA) certification that the AD will not have a significant economic impact on a substantial number of small entities and consider less burdensome alternatives for small operators.

FAA has considered the AD’s impact on small businesses and provides the following factual basis for its RFA certification.

The Regulatory Flexibility Act of 1980, Public Law 96–354, 94 Stat. 1164 (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121, 110 Stat. 857, Mar. 29, 1996) and the Small Business Jobs Act of 2010 (Public Law 111–240, 124 Stat. 2504, Sept. 27, 2010), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term

“small entities” comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

Small Entities to Which This AD Applies

The FAA used the definition of small entities in the RFA for this analysis. The RFA defines small entities as small businesses, small governmental jurisdictions, or small organizations. In 5 U.S.C. 601(3), the RFA defines “small business” to have the same meaning as “small business concern” under section 3 of the Small Business Act. The Small Business Act authorizes the Small Business Administration (SBA) to define “small business” by issuing regulations.

The SBA (2023) has established size standards for various types of economic activities, or industries, under the North American Industry Classification System (NAICS). These size standards generally define small businesses based on the number of employees or annual receipts. Note that the SBA definition of a small business applies to the parent company and all affiliates as a single entity.

To identify small entities, the FAA first identified the primary NAICS of the entity or parent company, and then used data from different sources (*e.g.*, company annual reports, Bureau of Transportation Statistics) to determine whether the entity meets the applicable size standard. The FAA provides the estimated number of small entities (plus 3 individuals) affected by this AD:

NUMBER OF SMALL ENTITIES AFFECTED BY INDUSTRY AND COST SIGNIFICANCE

NAICS Code	Description	Number of small entities affected	Average annual revenue	Cost per AD/annual revenue
236116	New Multifamily Housing Construction	1	\$61,020	0.14%
423860	Transportation Equipment and Supplies [except Motor Vehicle] Merchant Wholesalers.	2	162,900	0.05
481211	Nonscheduled Chartered Passenger Air Transportation.	7	1,181,754	0.01
481219	Other Nonscheduled Air Transportation	4	733,405	0.02
488119	Other Airport Operations	3	28,645,000	0.00
488190	Other Support Activities for Air Transportation.	5	1,760,390	0.01
523910	Miscellaneous Intermediation	1	261,830	0.03
532411	Commercial Air, Rail, and Water Transportation Equipment Rental and Leasing.	2	999,999	0.02
541512	Computer Systems Design Services	1	241,120	0.04
541611	Administrative Management and General Management Consulting Services.	1	999,999	0.01
541922	Commercial Photography	1	750,000	0.01
813910	Business Associations	1	1,160,000	0.01
921110	Executive Offices	1	226,340	0.04

RFA Conclusions

While FAA has determined that this AD affects a substantial number of small entities, the compliance cost relative to annual revenue is minimal. The estimated compliance cost per entity is a one-time labor cost of \$85 to revise the ALS of the maintenance manual. Therefore, as provided in section 605(b) and based on the foregoing, the FAA has determined that the financial impacts of this AD are not disproportionate to small entities. Therefore, the FAA did not change this AD as a result of this comment.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any

comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0134. This material specifies replacing components before exceeding their life limits and accomplishing all applicable maintenance tasks within thresholds and intervals specified in the ALS as defined in EASA AD 2024–0134. Depending on the results of the maintenance tasks, EASA AD 2024–0134 requires accomplishing corrective action(s) or contacting Airbus Helicopters for approved instructions and accomplishing those instructions.

Additionally, EASA AD 2024–0134 specifies revising the Aircraft

Maintenance Programme (AMP) by incorporating the limitations, tasks, and associated thresholds and intervals described in the specified ALS, as applicable. Revising the AMP constitutes terminating action for the requirement to record accomplishment of the actions of replacing components before exceeding their life limits and accomplishing maintenance tasks within thresholds and intervals specified in the applicable ALS as specified in EASA AD 2024–0134 for demonstration of AD compliance on a continued basis.

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

Costs of Compliance

The FAA estimates that this AD affects 34 helicopters of the U.S. registry. The FAA estimates the following costs to comply with this AD.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise ALS	1 work-hour × \$85 per hour ¹ = \$85	\$0	\$85	\$2,890

¹ FAA estimated operators will incur \$85 in costs per labor hour, which is the weighted average fiscal year (FY) 2026 fully loaded wage of an aircraft mechanic (\$69.85) working 60% of the labor hours and a general and operations manager (\$108.15) working 40% of the labor hours. The FAA estimated these wages by taking the average of the FY 2024 Bureau of Labor Statistics (BLS) air transportation industry average wage for aircraft mechanics and general and operations managers (See: *Occupational Employment and Wage Statistics Query System*, BLS (May 2024), data.bls.gov/oes/); multiplying each wage by a fringe benefit factor of 1.42 (See: *Employer Cost for Employee Compensation—December 2024*, BLS (2024), bls.gov/news.release/archives/eccec_03142025.pdf); and adjusting these 2024 wages to 2026 dollars using an implicit Gross Domestic Product (GDP) Price Deflator of 2.8% (See: *Gross Domestic Product: Implicit Price Deflator*, FRED (2026) fred.stlouisfed.org/series/GDPDEF).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by:
 - a. Removing Airworthiness Directive 2022–19–13, Amendment 39–22182 (87 FR 57814, September 22, 2022) (AD 2022–19–13); and
 - b. Adding the following new airworthiness directive:

2026–10–16 Airbus Helicopters:
Amendment 39–23356; Docket No. FAA–2025–2542; Project Identifier MCAI–2024–00397–R.

(a) Effective Date

This airworthiness directive (AD) is effective July 21, 2026.

(b) Affected ADs

(1) This AD replaces AD 2022–19–13, Amendment 39–22182 (87 FR 57814, September 22, 2022).

(2) This AD affects AD 2011–22–05 R1, Amendment 39–17765 (79 FR 14169, March 13, 2014) (AD 2011–22–05 R1); and AD 2016–25–20, Amendment 39–18746 (81 FR 94954, December 27, 2016) (AD 2016–25–20).

(c) Applicability

This AD applies to all Airbus Helicopters Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by new or more restrictive airworthiness limitations. The FAA is issuing this AD to prevent failure of critical parts and primary structural components, which if not addressed, could result in loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2024–0134, dated July 10, 2024 (EASA AD 2024–0134).

(h) Exceptions to EASA AD 2024–0134

(1) Where EASA AD 2024–0134 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt paragraphs (1), (2), (4), and (5) of EASA AD 2024–0134.

(3) Where paragraph (3) of EASA AD 2024–0134 specifies “Within 12 months after the effective date of this AD, revise the approved AMP”, this AD requires replacing that text with “Within 30 days after the effective date of this AD, revise the airworthiness limitations section of the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable”.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0134 is on or before the applicable “limitations” and “associated thresholds” as incorporated by the requirements of paragraph (3) of EASA AD 2024–0134 or within 30 days after the effective date of this AD, whichever occurs later.

(5) This AD does not adopt the “Remarks” section of EASA AD 2024–0134.

(i) Provisions for Alternative Actions and Intervals

After the action required by paragraph (g) of this AD has been done, no alternative actions and associated thresholds and intervals, including life limits, are allowed unless they are approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2024–0134.

(j) Terminating Action for ADs 2011–22–05 R1 and 2016–25–20

(1) Accomplishing the actions required by this AD terminates all requirements of AD 2011–22–05 R1 for Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters only.

(2) Accomplishing the actions required by this AD terminates all requirements of AD 2016–25–20 for Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters only.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Additional Information

For more information about this AD, contact Matthew Williams, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4134; email: matthew.t.williams@faa.gov.

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0134, dated July 10, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records

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

Issued on June 11, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–12051 Filed 6–15–26; 8:45 am]

BILLING CODE 4910–13–P

POSTAL SERVICE**39 CFR Part 20****International Mailing Services: Price Changes**

AGENCY: Postal Service.

ACTION: Final action.

SUMMARY: On April 9, 2026, the Postal Service published notice of mailing services price adjustments with the Postal Regulatory Commission (PRC). The PRC concluded that the price adjustments contained in the Postal Service’s notification may go into effect on July 12, 2026. The Postal Service will revise Notice 123, *Price List*, to reflect the new mailing services prices.

DATES: *Effective:* July 12, 2026.

FOR FURTHER INFORMATION CONTACT: Dale Kennedy at 202–268–6592 or Tonya Franklin-Whetts at 202–268–6308.

SUPPLEMENTARY INFORMATION:**I. Proposed Rule and Response**

On April 9, 2026, the Postal Service filed a notice with the PRC in Docket No. R2026–1 of mailing services price adjustments, including the elimination of the Customs Clearance and Delivery Fee for Inbound Letter Post letters and flats, to be effective on July 12, 2026. On April 16, 2026, the Postal Service published notification of proposed price changes in the **Federal Register** entitled “International Mailing Services: Proposed Price Changes” (91 FR 20393). The notification included the changes that the Postal Service would adopt for certain services covered by *Mailing Standards of the United States Postal Service*, International Mail Manual (IMM®) and publish in the Notice 123, *Price List*, available on Postal Explorer® at pe.usps.com. The Postal Service received no comments.

II. Order of the Postal Regulatory Commission

In PRC Order No. 9584 issued on May 27, 2026, in PRC Docket No. R2026–1, the PRC concluded that the international prices in the Postal Service’s notice in Docket No. R2026–1

may go into effect on July 12, 2026. The new prices will be posted accordingly in Notice 123, *Price List*, on Postal Explorer at pe.usps.com.

III. Summary of Changes
First-Class Mail International®
The price for a single-piece postcard will be \$1.75 worldwide. The First-Class

Mail International® (FCMI) letter nonmachinable surcharge will remain \$0.49. The FCMI single-piece letter and flat prices will be as follows:

LETTERS				
Weight not over (oz.)	Price groups			
	1	2	3–5	6–9
1	\$1.75	\$1.75	\$1.75	\$1.75
2	2.35	2.60	3.50	3.50
3	2.95	3.50	5.25	5.25
3.5	3.50	4.15	5.75	5.75

FLATS				
Weight not over (oz.)	Price groups			
	1	2	3–5	6–9
1	\$3.30	\$3.30	\$3.30	\$3.30
2	3.75	4.35	4.65	4.65
3	4.25	5.45	6.05	6.05
4	4.65	6.45	7.35	7.35
5	5.15	7.55	8.75	8.75
6	5.65	8.65	10.15	10.15
7	6.15	9.75	11.55	11.55
8	6.65	10.85	12.95	12.95
12	7.60	13.00	15.75	15.75
15.994	8.55	15.15	18.55	18.55

International Extra Services and Fees

The Postal Service will remove Customs Clearance and Delivery Fee for

Inbound Letter Post letters and flats and increase prices and fees for certain market dominant international extra services as noted:

- *Certificate of Mailing* service: Fees for Certificate of Mailing service for FCMI will increase as follows:

CERTIFICATE OF MAILING—FIRST-CLASS MAIL INTERNATIONAL

Individual pieces	Fee
Individual article (PS Form 3817)	\$2.55
Duplicate copy of PS Form 3817 or PS Form 3665 (per page)	2.55
Firm mailing sheet (PS Form 3665), per piece (minimum 3)	0.75
Bulk quantities	
For first 1,000 pieces (or fraction thereof)	14.25
Each additional 1,000 pieces (or fraction thereof)	1.80
Duplicate copy of PS Form 3606	2.55

- *Registered Mail®* service: The fee for international Registered Mail service for FCMI will increase to \$25.00.
- *Return Receipt* service: The fee for international Return Receipt service for FCMI will increase to \$7.20.
- *International Business Reply™ Mail Service*: The price for International Business Reply Service (IBRS) cards will increase to \$2.65, and the price for IBRS envelopes (up to 2 ounces) will increase to \$3.30.

The removal of Customs Clearance and Delivery Fee for Inbound Letter Post letters and flats, and the new prices will

be listed in the updated Notice 123, *Price List*.

Kevin Rayburn,
Attorney, Ethics and Legal Compliance.
[FR Doc. 2026–12071 Filed 6–15–26; 8:45 am]
BILLING CODE 7710–12–P

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
50 CFR Part 17
[FXES1111090FEDR–267–FF09E21000]

Endangered and Threatened Wildlife and Plants; Two Species Not Warranted for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.
ACTION: Notification of findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce

findings that two species are not warranted for listing as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best scientific and commercial data available, we find that it is not warranted at this time to list the Sangre

de Cristo peaclam (*Pisidium sanguinichristi*) and black-backed tanager (*Stilpnia peruviana*). However, we ask the public to submit to us at any time any new information relevant to the status of either of the species mentioned above or their habitats.

DATES: The findings in this document were made on June 16, 2026.

ADDRESSES: Detailed descriptions of the bases for these findings are available on the internet at <https://www.regulations.gov> under the following docket numbers:

Species	Docket No.
Sangre de Cristo peaclam	FWS-R2-ES-2026-1453
black-backed tanager	FWS-HQ-ES-2026-1454

Those descriptions are also available by contacting the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any

new information, materials, comments, or questions concerning these findings to the appropriate person, as specified

under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Species	Contact Information
Sangre de Cristo peaclam	Mark Horner, New Mexico Ecological Services Field Office, 505-657-2054, mark_horner@fws.gov .
black-backed tanager	Rachel London, Manager, Branch of Delisting and Foreign Species, Ecological Services Program, Headquarters, 703-358-2171, rachel_london@fws.gov .

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1533(b)(3)(B)), we are required to make a finding on whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted ("12-month finding"). We must make a finding that the petitioned action is: (1) not warranted; (2) warranted; or (3) warranted but precluded by other listing activity. We must publish a notification of these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife

and Plants (Lists). The Act defines "species" as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines an "endangered species" as a species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)) and a "threatened species" as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, the Secretary of the Interior (Secretary) may determine whether any species is an endangered species or a threatened species because of any of the following five factors:

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
- (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any

negative effects or may have positive effects.

We use the term "threat" to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term "threat" includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term "threat" may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an "endangered species" or a "threatened species." In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an "endangered

species” or a “threatened species” only after conducting this cumulative analysis and describing the expected effect on the species.

The Act does not define the term “foreseeable future,” which appears in the statutory definition of “threatened species.” Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis, which is further described in the 2009 Memorandum Opinion on the foreseeable future from the Department of the Interior, Office of the Solicitor (M–37021, January 16, 2009; “M–Opinion,” available online at <https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M-37021.pdf>). The foreseeable future extends as far into the future as the U.S. Fish and Wildlife Service can make reasonably reliable predictions about the threats to the species and the species’ responses to those threats. We need not identify the foreseeable future in terms of a specific period of time. We will describe the foreseeable future on a case-by-case basis, using the best scientific and commercial data available and taking into account considerations such as the species’ life-history characteristics, threat projection timeframes, and environmental variability. In other words, the foreseeable future is the period of time over which we can make reasonably reliable predictions. “Reliable” does not mean “certain;” it means sufficient to provide a reasonable degree of confidence in the prediction, in light of the conservation purposes of the Act.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the Sangre de Cristo peaclam or black-backed tanager meet the Act’s definition of an “endangered species” or a “threatened species,” we considered and thoroughly evaluated the best scientific and commercial data available regarding the past, present, and future stressors and threats. We reviewed the petition, information available in our files, and other available published and unpublished information for the species. Our evaluation may include information from recognized experts; Federal, State, and Tribal governments; academic institutions; foreign governments; private entities; and other members of the public.

In accordance with the regulations at 50 CFR 424.14(h)(2)(i), this document announces the not-warranted findings on petitions to list the two species. We have also elected to include brief summaries of the analyses on which these findings are based. We provide the

full analyses, including the reasons and data on which the findings are based, in the decisional files for the Sangre de Cristo peaclam and black-backed tanager. Below, we describe the documents containing these analyses.

The species assessment forms for the Sangre de Cristo peaclam and black-backed tanager each contain more detailed biological information, a thorough analysis of the listing factors, a list of literature cited, and an explanation of why we determined that these species do not meet the Act’s definition of an “endangered species” or a “threatened species.” To inform our status review, we completed a species status assessment (SSA) report for the black-backed tanager. This SSA report contains a thorough review of the taxonomy, life history, ecology, current status, and projected future status for this species. No SSA was completed for the Sangre de Cristo peaclam. This supporting information can be found on the internet at <https://www.regulations.gov> under the appropriate docket number (see ADDRESSES, above).

Sangre de Cristo Peaclam

Previous Federal Actions

On June 25, 2007, we received a petition from Forest Guardians (now WildEarth Guardians) to list 475 species, including the Sangre de Cristo peaclam, as an endangered or threatened species under the Act. On December 16, 2009, we published a 90-day finding (74 FR 66866) that the petition presented substantial information indicating that listing may be warranted for the Sangre de Cristo peaclam. This document constitutes our 12-month finding on the June 25, 2007, petition to list the Sangre de Cristo peaclam under the Act.

Summary of Finding

The Sangre de Cristo peaclam is a small freshwater clam thought to occur exclusively in Middle Fork Lake, a cirque lake in the Sangre de Cristo Mountains, Taos County, New Mexico, at nearly 11,000 feet (ft) (3,353 meters (m)) elevation. The initial species’ description claimed that the Sangre de Cristo peaclam is found in mud along emergent grasses in sheltered embayments along the edge and outlet of the lake and suggested the species may occur in other portions of the southern Rocky Mountains. However, surveys consisting of over 750 voucher samples from Middle Fork Lake alone, including surveys initiated by the New Mexico Department of Game and Fish in the mid-1990s, have failed to find any

additional occurrences. The 1987 description notes that the Sangre de Cristo peaclam was locally abundant, a finding inconsistent with subsequent sampling efforts.

Sphaeriid clams can be problematic to distinguish morphologically due to a limited number of shared ancestral traits and high levels of intraspecific phenotypic variation. Therefore, recent research has focused on a genetic approach to potentially clarify the taxonomy of the Sangre de Cristo peaclam. Whole body samples were collected from 14 sites in New Mexico and west Texas, including Middle Fork Lake. Two independent genetic markers capable of accurately identifying a species’ uniqueness were then used to evaluate the validity of the Sangre de Cristo peaclam as a distinct species.

The results showed that the genetic sequences from Middle Fork Lake were effectively identical to those of both described and undescribed species listed in GenBank, a publicly available genetic database. This means there were very few differences in the genetic markers between the Middle Fork Lake samples and species already described in the scientific literature (*e.g.*, *Euglesa fallax*, *E. compressa*, *E. variabilis*, *E. casertana*, *E. walkeri*, *E. floresiana*, *E. subtruncata*, *Sphaerium lacustre*, *S. occidentale*, and *S. indicum*). One genetic marker from Middle Fork Lake matched (99–100 percent identical) samples from San Gregorio and Pioneer Lakes, which are about 150 kilometers (km) (93.2 miles (mi)) and 10 km (6.2 mi) away, and matched exclusively with *E. variabilis* and *E. casertana*. Another genetic marker from Middle Fork Lake also matched (99–100 percent identical) samples from eight other locations in the region.

A phylogenetic analysis (*i.e.*, an evolutionary tree that models the relationships and common ancestors of a group of organisms based on genetic data) of a combination of both markers showed analogous results with multiple, well-supported clades (branches). The only monophyletic clade (a branch with a single species) is from Perch Lake, which was most closely related to an undescribed species and *E. floresiana*, *E. casertana* or *E. subtruncata*. The samples from Middle Fork Lake are found in two statistically supported clades, one of which also included individuals from San Gregorio Lake, and the other of which also included individuals from Pioneer Lake in northern New Mexico.

The results of the various genetic analyses strongly suggest that the Sangre de Cristo peaclam is not supported as a valid taxon. Instead, individuals that

had been previously identified as Sangre de Cristo peaclam are most likely a member of either the most widely distributed non-marine mollusk in the world, *E. casertana*, or *E. variabilis*, which occurs throughout North America.

In conclusion, genetic evidence strongly indicates that the Sangre de Cristo peaclam is not a valid taxon. Additionally, since the initial species description in 1987, hundreds of samples have been examined genetically or morphologically and have failed to identify any specimen from Middle Fork Lake that are clearly Sangre de Cristo peaclam despite claims that the species was locally abundant. Thus, we consider specimens previously identified as Sangre de Cristo peaclam to actually be a more widespread cosmopolitan species rather than a narrow endemic limited to Middle Fork Lake. The best scientific data available present clear evidence that the Sangre de Cristo peaclam is not a unique species.

Thus, after assessing the best available information, we find that the Sangre de Cristo peaclam is not supported as a valid taxon, but rather a member of a widely dispersed cosmopolitan species, likely to be *E. casertana* or *E. variabilis*. Therefore, the Sangre de Cristo peaclam is not warranted for listing because it is not a listable entity under the Act. A detailed discussion of the basis for these findings can be found in the Sangre de Cristo peaclam species assessment form and other supporting documents on <https://www.regulations.gov> under Docket No. FWS-R2-ES-2026-1453 (see ADDRESSES, above).

Black-Backed Tanager

Previous Federal Actions

On May 6, 1991, we received a petition from the International Council for Bird Preservation (now BirdLife International) to list 53 different bird species, including the black-backed tanager (*Stilpnia peruviana*), as an endangered or threatened species under the Act. On December 16, 1991, we published a 90-day finding that the petition contained substantial information indicating that listing may be warranted for all species (56 FR 65207). On May 21, 2004, we published our resubmitted petition findings that listing the black-backed tanager was warranted but precluded by higher priority actions, and we added the entity to our list of candidate species (69 FR 29354). We subsequently published 11 candidate notices of review between 2007 and 2025 which continued to find that the species was warranted but

precluded by higher priority actions (72 FR 20184, April 23, 2007; 73 FR 44062, July 29, 2008; 74 FR 40540, August 12, 2009; 76 FR 25150, May 3, 2011; 78 FR 24604, April 25, 2013; 81 FR 71457, October 17, 2016; 84 FR 54732, October 10, 2019; 86 FR 43470, August 9, 2021; 87 FR 26152, May 3, 2022; 88 FR 41560, June 27, 2023; 90 FR 48912, October 31, 2025). At the time of the petition, the black-backed tanager was classified as *Tangara peruviana*. However, the black-backed tanager was later placed in the genus *Stilpnia*, and we now treat *Tangara peruviana* as a synonym. This document constitutes our 12-month finding on the May 6, 1991, petition to list the black-backed tanager under the Act.

Summary of Finding

The black-backed tanager is endemic to the Atlantic Forest along the southeastern coast of Brazil, and while the extent of the species' historical range is not known, it is estimated to currently occupy 11 to 100 locations throughout an extant range that measures approximately 72,500 square kilometers (km²) (28,000 square miles (mi²)).

The black-backed tanager mainly occupies coastal sandbank forests, restinga (coastal scrubland), and lowland forests (up to ~700 m (2,297 ft) in elevation), and its diet consists primarily of fruit, and to a smaller extent, invertebrates found in canopy vegetation. The species is also known to visit other habitat types when certain fruit-bearing plants are ripening (e.g., secondary forest, edge habitat near pastures, gardens, and orchards).

We have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the black-backed tanager, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these threats. The primary threat affecting the black-backed tanager's biological status is habitat loss from deforestation and sea level rise.

The black-backed tanager is "not rare" within suitable habitat, but because the species breeds in coastal habitats, its viability is closely tied to the persistence of these habitats within its range. Protected areas overlap with 21.5 percent of the black-backed tanager's extant range, and 49.4 percent of the remaining restinga within that range. These protected areas maintain very low illegal deforestation rates (0.08–0.1 percent) and provide adequate legal protection to the black-backed tanager's remaining suitable habitat. However,

small-scale illegal deforestation has caused the loss of 0.69 percent of the remaining restinga within the species' range since 2010. This equates to an annual loss of approximately 0.05 percent of restinga within the black-backed tanager's range, which if projected into the future, could result in an additional loss of 1.25 percent of restinga habitat over the next 25 years. However, because one of the main tree species that black-backed tanagers feed on (Brazilian peppertree, *Schinus terebinthifolia*) persists in disturbed environments, it is likely that the species' viability will not be significantly impacted by small-scale deforestation in the future. Furthermore, multiple ongoing restoration efforts are actively restoring degraded habitat within the black-backed tanager's range and contributing to improving the species' current condition. So, while small-scale illegal deforestation may continue to occur, the amount of deforested habitat is likely to be offset in the future by these ongoing restoration initiatives such that we expect the total amount of suitable habitat available for the species to likely be stable or increasing.

Because the black-backed tanager mainly occupies coastal habitats, both sea level rise and temperature increases resulting from climate change are projected to impact the species' viability in the future. Restingas are projected to be one of the more climatically stable habitat types in the Atlantic Forest biome and are projected to lose 7 percent of their area by 2070 due to temperature increases resulting from climate change. In addition, coastal Brazil is expected to experience a median range of sea level rise of 0.22–0.25 m by 2050, for shared socioeconomic pathway (SSP)2–4.5 and SSP5–8.5 respectively. Because restingas consist mostly of pioneer plants, they may be able to retreat further inland as sea levels rise. However, many restingas in highly developed areas will be unable to retreat further inland due to existing urban structures, removing the possibility that some restingas within the black-backed tanager's range adapt to sea level rise. Furthermore, it is unknown how restingas may tolerate increased flooding and saltwater intrusion, both of which may lead to additional habitat loss and degradation. The black-backed tanager is known to opportunistically feed on ripening fruits in more inland areas and has even established residency in some higher elevation areas. Therefore, while it is unknown exactly how restingas will adapt to

changing environmental conditions, the species has demonstrated the ability to persist in more inland habitats and is therefore likely capable of withstanding small-scale losses of coastal habitat. Considering the potential effects of additional small-scale habitat loss, the likely stability or net gain of suitable habitat via restoration efforts, and the species' ability to adapt to shifting environmental conditions, the black-backed tanager will likely have either stable or slightly reduced viability into the foreseeable future.

We also evaluated whether the black-backed tanager is endangered or threatened throughout a significant portion of its range. We did not find any portion of the black-backed tanager's range for which both (1) the portion is "significant;" and (2) the species is in danger of extinction in that portion, either now or likely to become so within the foreseeable future. Thus, after assessing the best available scientific and commercial data available, we conclude that the black-backed tanager is not in danger of extinction throughout a significant portion of its range, or likely to become so within the foreseeable future.

Based on the best scientific and commercial data available, we determine that the black-backed tanager does not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. Therefore, we find that listing the black-backed tanager is not warranted at this time. A detailed discussion of the basis for this finding can be found in the black-backed tanager species assessment form and other supporting documents on <https://www.regulations.gov> under Docket No. FWS-HQ-ES-2026-1454 (see **ADDRESSES**, above).

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review in listing actions under the Act, we solicited independent scientific reviews of the information contained in the black-backed tanager SSA report from three experts and received peer review from two independent peer reviewers. Results of this structured peer review process can be found at <https://www.regulations.gov> under Docket No. FWS-HQ-ES-2026-1454. We incorporated the results of this review, as appropriate, into the SSA report, which is the foundation for this finding. We did not solicit peer review for the Sangre de Cristo peacclam

because there was no SSA drafted for the species.

New Information

We request that you submit any new information concerning the taxonomy of, biology of, ecology of, status of, or stressors to the Sangre de Cristo peacclam or black-backed tanager to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor these species and make appropriate decisions about their conservation and status. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts.

References

A complete list of the references used in these petition findings is available in the relevant species assessment form, which is available on the internet at <https://www.regulations.gov> in the appropriate docket (see **ADDRESSES**, above) and upon request from the appropriate person (see **FOR FURTHER INFORMATION CONTACT**, above).

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Brian R. Nesvik,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2026-12077 Filed 6-15-26; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[RTID 0648-XF466; Docket No. 260611-0141]

Pacific Halibut Fisheries of the West Coast; Annual Management Measures for the 2026 Area 2A Pacific Halibut Directed Commercial Fishery

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

ACTION: Final rule.

SUMMARY: NMFS is implementing annual management measures for the 2026 non-Tribal directed commercial Pacific halibut fishery that operates south of Point Chehalis, WA, (lat. 46°53.30' N) in the International Pacific Halibut Commission's (IPHC) Regulatory Area 2A off Washington,

Oregon, and California. Annual management measures include fishing periods and fishing period limits. This action is intended to conserve Pacific halibut, while providing fishing opportunity to achieve the Regulatory Area 2A allocation set by the IPHC.

DATES: Effective June 15, 2026.

FOR FURTHER INFORMATION CONTACT:

Louis Forristall, West Coast Region, NMFS, (503) 230-5410, louis.forristall@noaa.gov

SUPPLEMENTARY INFORMATION:

Background

The Northern Pacific Halibut Act of 1982 (16 U.S.C. 773-773k; Halibut Act) gives the Secretary of Commerce responsibility for implementing the provisions of the Convention between Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Halibut Convention), signed in Ottawa, ON, on March 2, 1953, as amended by a Protocol Amending the Convention, signed in Washington, DC, on March 29, 1979. This responsibility includes the responsibility to adopt regulations to carry out the Halibut Act (16 U.S.C. 773c).

The Halibut Act provides that the regional fishery management council with authority for the geographic area concerned may develop regulations governing Pacific halibut fishing in U.S. waters that are in addition to, and not in conflict with, approved IPHC regulations (16 U.S.C. 773c(c)). Such regulations "shall only be implemented with the approval of the Secretary of Commerce" (16 U.S.C. 773c(c)). The Pacific Fishery Management Council (Council) developed a catch sharing plan (CSP) guiding the allocation of halibut across the various sectors for the IPHC's Regulatory Area 2A. While the full CSP is not published in the **Federal Register**, it is made available on the Council's website at https://www.pcouncil.org/managed_fishery/pacific-halibut/.

Under the Halibut Act, the Secretary of State, with the concurrence of the Secretary of Commerce, may accept or reject, on behalf of the United States, regulations recommended by the IPHC in accordance with the Halibut Convention (16 U.S.C. 773b). Following acceptance by the Secretary of State, the annual management measures recommended by the IPHC are published in the **Federal Register** through a NMFS rulemaking to provide notice of their immediate regulatory effectiveness and to inform persons subject to the regulations of their

restrictions and requirements (50 CFR 300.62).

This final rule implements management measures for the 2026 non-Tribal directed commercial Pacific halibut fishery in Area 2A that are not part of the annual IPHC regulations. The rule finalizes management measures that were developed through the Council's public process over multiple meetings. Additionally, the final rule adopts, without changes, the management measures from the proposed rule published on March 25, 2026 (91 FR 14516) (Proposed Rule).

Fishery Allocation

At its annual meeting held January 19–22, 2026, the IPHC adopted a Regulatory Area 2A catch limit, referred to as the fishery constant exploitation yield (FCEY), of 1.54 million pounds (lb) or 698.5 metric tons (mt), net weight (*i.e.*, the weight of Pacific halibut that is without gills and entrails, head-off, washed, and without ice and slime), of Pacific halibut. The FCEY is derived from the 2026 total constant exploitation yield (TCEY) of 1.65 million lb (748 mt), net weight, for Regulatory Area 2A, which includes commercial discards and bycatch projections calculated using a formula developed by the IPHC. On March 23, 2026, the Secretary of State accepted, with concurrence from the Secretary of Commerce, the annual management measures, Regulatory Area 2A TCEY, Regulatory Area 2A FCEY, and commercial and recreational fishery

allocations (in net weight) that were adopted by the IPHC. These management measures, catch limits, and allocations were subsequently published in the **Federal Register** in the Proposed Rule. Based on the FCEY for Regulatory Area 2A and the allocation framework in the Council's CSP, NMFS proposed a non-Tribal directed commercial fishing allocation for the 2026 fishing season of 261,211 lb (118.5 mt) net weight. The directed commercial fishing allocation for the 2026 fishing season in this final rule is unchanged from that in the Proposed Rule.

Fishing Periods

Fishing periods, often referred to as fishery openers, are the time during the IPHC's annual commercial halibut season when non-Tribal directed commercial fishing for Pacific halibut in Regulatory Area 2A is allowed. This action implements two 58-hour fishing periods. The first fishing period will begin on June 23, 2026 at 8 a.m. (0800) Pacific Daylight Time (PDT) and close on June 25, 2026 at 6 p.m. (1800) PDT. The second fishing period will occur 2 weeks later, beginning on July 7, 2026, at 8:00 a.m. (0800) PDT and closing on July 9, 2026, at 6:00 p.m. (1800) PDT. If another fishing period is necessary to attain the allocation, NMFS intends to open a third 58-hour fishing period on July 21, 2026 at 8 a.m. (0800) PDT that would close on July 23, 2026 at 6 p.m. (1800) PDT, through inseason action. If subsequent fishing periods are

necessary to reach the allocation, NMFS intends to have them follow the same pattern, occurring 2 weeks after the previous fishing period (beginning on August 4, beginning on August 18, *etc.*), as announced by inseason action. If NMFS determines that additional fishing periods are warranted, and if for any reason a fishing period cannot be scheduled on this 2-week schedule, NMFS intends to skip a fishing period to follow the outlined every 2-week schedule. NMFS will use email addresses obtained from 2026 Pacific halibut directed commercial fishery permit applications for email notice of inseason actions. Fishing periods may be added inseason consistent with 50 CFR 300.63(e)(1)(iii).

Fishing Period Limits

A fishing period limit, also called a vessel catch limit, is the maximum amount of Pacific halibut that may be retained and landed by a vessel during one fishing period. Each vessel may retain no more than the applicable fishing period limit of Pacific halibut for its vessel size class, which is determined by vessel length. NMFS is implementing the directed commercial fishing period limits, shown in table 1 below, for the first two fishing periods.

Fishing period limits are intended to ensure that the Area 2A directed commercial fishery does not exceed its allocation, while also providing fair and equitable access across participants to an attainable amount of harvest.

TABLE 1—FISHING PERIOD LIMITS FOR THE INITIAL FISHING PERIODS IN 2026 OF THE REGULATORY AREA 2A PACIFIC HALIBUT NON-TRIBAL DIRECTED COMMERCIAL FISHERY

Vessel class	Length range in feet (meters)	Fishing period limit in lb (mt)
A–C	1–35 (0.3–10.9)	2,000 (0.907)
D–E	36–45 (11.0–13.9)	3,400 (1.542)
F–G	46–55 (14.0–16.9)	4,300 (1.950)
H	56+ (17.0+)	5,000 (2.268)

Note: Fishing period limits are in dressed weight (head-on, with ice and slime). If a vessel's size is between lengths, its length will be rounded up for the purpose of fishing period limits.

If NMFS determines that more than two fishing periods are warranted, NMFS will set the fishing period limits for subsequent fishing periods equal across all vessel classes through inseason action consistent with 50 CFR 300.63(e)(1)(iii). Fishing period limits for the second 2026 fishing period may also be adjusted through inseason action consistent with 50 CFR 300.63, if necessary to avoid exceeding the allocation. Inseason actions will be noticed via email to the affected public, published in the **Federal Register**, and

appear on the NMFS website. Inseason actions will be effective upon the date and time of either the receipt of notice of the direct email or publication in the **Federal Register**, whichever occurs first.

Comments and Responses

NMFS published the Proposed Rule on March 25, 2026 and accepted public comment on the 2026 Area 2A non-Tribal Pacific halibut directed commercial fishery annual management measures through April 24, 2026. NMFS received one public comment. The

comment spoke generally in opposition to fish consumption; however, the comment was not directly responsive to this rulemaking. The comment did not warrant any changes to the Proposed Rule.

Classification

This final rule is consistent with section 5 of the Halibut Act, which gives relevant regional fishery management councils the authority to develop regulations governing Pacific halibut fishing in U.S. waters that are in

addition to, and not in conflict with, approved IPHC regulations, and that “shall only be implemented with the approval of the Secretary” (16 U.S.C. 773c(c)).

This action is exempt from review under Executive Order (E.O.) 12866. This final rule is also exempt from the requirements of E.O. 14192 because it is a routine fishing action. A Treaty Tribal summary impact statement under section 5(b)(2)(B) and (c)(2) of E.O. 13175 was not required for this final rule because this action does not impose substantial direct compliance costs on Treaty Tribal Governments and this action does not preempt Treaty Tribal law. A Treaty Tribal summary impact statement is not required and has not been prepared.

NMFS determined that the 30-day delay in the date of effectiveness requirement does not apply pursuant to 5 U.S.C. 553(d)(1) and (3), and the annual management measures for the 2026 directed commercial fishery will take effect upon the filing of this rule with the Office of Federal Register. Pursuant to 5 U.S.C. 553(d)(1), this rule relieves a restriction on fishing. The fishery participants will be restricted from fishing if this rule does not take effect by June 23, 2026. Therefore, having this rule take effect upon filing with the Office of the Federal Register will relieve a restriction on fishery participants pursuant to 5 U.S.C. 553(d)(1).

Additionally, there is good cause under 5 U.S.C. 553(d)(3) for this rule to take effect upon filing with the Office of the Federal Register. Pursuant to 5 U.S.C. 553(d)(3), delaying the effective date of the annual management measures contained in this rule would be contrary to the public interest as it would prevent the directed commercial fishery in Area 2A from beginning on time. Accordingly, waiving the 30-day delay in effectiveness will benefit the public because it will provide additional opportunity for commercial Pacific halibut fishermen in 2026 and thus increase the likelihood of full utilization of the 2026 allocations in Area 2A.

This rule implements Area 2A non-Tribal directed commercial fishery management measures as published in the Proposed Rule and is based on Council recommendations that followed a multi-meeting public Council process. The non-Tribal directed commercial fishery has an average of 76 vessels participate annually, and similar participation is expected in 2026. This seasonal fishery is typically open for approximately 7 days per year, spread over 2 months, and concludes in late

August. The fishery is important to many commercial fishermen on the U.S. West Coast. In 2025, the ex-vessel revenue from the fishery was \$2.37 million. A 30-day delay in the effectiveness of the measures in this rule would result in the directed commercial fishery not being opened on its intended timeline and, thus, the fishery not being open on the dates that the affected public is expecting. Business decisions have likely been made surrounding the fishery’s anticipated opening date. Further, due to the short nature of this summer fishery, pushing the start date is not considered a viable option because such a delay would disrupt normal fishing operations. Thus, a delayed effective date for this rule would be contrary to the public interest as it could have a substantial adverse economic impact on fishery participants and fishing communities.

A delayed effective date is also not necessary to provide sufficient notice to the fishing community. This rule does not establish any new or unique regulations, nor otherwise make changes that would require fishery participants to purchase new gear or make other time-consuming adjustments. By contrast, this rule implements routine fishery management measures that are similar year-to-year. Further, the rule contains management measures for the fishery that were recommended by the Council following a multi-meeting public process, which included industry participation, and the final rule is unchanged from the Proposed Rule. Therefore, a 30-day delay in effectiveness is not needed to give the regulated community time to adjust to the rule.

In conclusion, NMFS finds that the 30-day delay in effective date does not apply to this final rule pursuant to 5 U.S.C. 553(d)(1) and (3).

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities for purposes of the Regulatory Flexibility Act. The factual basis for the certification was published in the Proposed Rule and is not repeated here. No comments were received regarding this certification. As a result, a final regulatory flexibility analysis was not required for this action and none was prepared.

This final rule does not create any information collection requests nor necessitate revision of existing approved information collection requests under

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: June 12, 2026.

Samuel D. Rauch, III,

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

[FR Doc. 2026–12131 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 260116–0030]

RIN 0648–BO30

Fisheries Off West Coast States; Extension of Emergency Action To Temporarily Increase 2026 Harvest Specifications and Sector Allocations for Shortspine Thornyhead, Canary Rockfish, and Petrale Sole

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

ACTION: Temporary rule; extension of emergency action.

SUMMARY: This temporary rule extends emergency measures that increase 2026 harvest specifications and sector allocations for shortspine thornyhead, canary rockfish, and petrale sole in the Pacific Coast groundfish fishery. This increase in harvest specifications is based on new, recently discovered information from the latest catch-only projections, which show a higher biomass of these species available for harvest than determined by stock assessments used to set the 2025–2026 harvest specifications and management measures. This action is necessary to alleviate significant direct economic loss caused by restrictive annual catch limits for these species.

DATES: Effective July 20, 2026, through December 31, 2026.

ADDRESSES: A plain language summary of this emergency rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2025-0900>.

Electronic Access

This emergency rule is accessible via the internet at the Office of the Federal Register website at <https://ecfr.federalregister.gov/>. A Supplemental Environmental Assessment that addresses National Environmental Policy Act (NEPA) requirements may be obtained from the

West Coast Groundfish Actions NEPA website at <https://www.fisheries.noaa.gov/west-coast/laws-policies/groundfish-actions-nepa-documents>. Additional background information is available at the Pacific Fishery Management Council's (Council) website at <http://www.pcouncil.org/groundfish/fishery-management-plan/groundfish-amendments-in-development/>.

FOR FURTHER INFORMATION CONTACT: Meghan Roberts, 206–526–4048, or meghan.roberts@noaa.gov.

SUPPLEMENTARY INFORMATION: The Pacific Coast groundfish fishery in the U.S. exclusive economic zone seaward of Washington, Oregon, and California is managed under the Pacific Coast Groundfish Fishery Management Plan (Groundfish FMP). The Council developed the Groundfish FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The Secretary of Commerce approved the Groundfish FMP and implemented the provisions of the plan through federal regulations at 50 CFR part 660, subparts C through G. The Groundfish FMP manages species of roundfish, flatfish, rockfish, sharks, and skates.

On January 22, 2026, NMFS published an emergency rule (91 FR 2714) that temporarily increases 2026 harvest specifications and sector allocations for shortspine thornyhead, canary rockfish, and petrale sole in the Pacific Coast groundfish fishery. A full description of the issue can be found in the emergency rule (91 FR 2714, January 22, 2026). NMFS held a public comment

period on the emergency rule for 30 days from January 21, 2026, to February 23, 2026, and received two non-substantive comments. Without extension, the emergency rule would expire on July 20, 2026.

Industry representatives provided testimony on the significant economics constraints caused by the 2025 ACLs for shortspine thornyhead, canary rockfish, and petrale sole at several Council meetings in 2025 (see agenda item E.3.a, Supplemental GAP Report 1 from June 2025 and agenda item G.8.a, Supplemental GAP Report 1 from September 2025 at <https://www.pcouncil.org/> for detailed information on species-specific constraints). This issue remains relevant throughout the remainder of the 2025–2026 harvest specifications management cycle, which ends this calendar year. The emergency motivating this action will be permanently addressed by the Council's 2027–2028 groundfish harvest specifications action, which, if approved by NMFS, would be effective in January 2027. Therefore, consistent with section 305(c)(3) of the Magnuson-Stevens Act, NMFS finds good cause to extend the emergency measures until December 31, 2026.

Emergency Measures

In alignment with the Council's September 2025 recommendation, the January 2026 emergency rule temporarily increased the 2026 overfishing limit (OFL), acceptable biological catch (ABC), annual catch limit (ACL), harvest guidelines (HG), tribal set-asides, and sector allocations for shortspine thornyhead, canary rockfish, and petrale sole, effective

January 21, 2026. This temporary rule will extend these increased harvest specifications through December 31, 2026. These increased harvest specifications include the implementation of alternative harvest control rules (HCRs) for canary rockfish and shortspine thornyhead. For canary rockfish, this extension of the emergency rule eliminates the buffer between the 2026 ABC and ACL that is applied when the stock is in the precautionary zone (*i.e.*, the “40–10” rule¹) and sets the ABC equal to the ACL. For shortspine thornyhead, this rule implements a phase-in ABC control rule that reduces the buffer between the OFL and ABC. Per the National Standard 1 guidelines (see 50 CFR 600.310(f)(2)(ii)(A)), Councils can develop and recommend to NMFS ABC control rules that allow for changes in catch limits to be phased in over time to help stabilize catch levels as stock assessments are updated.

Finally, this action would increase the off-the-top deductions from ACLs for Tribal harvest; increase the set-aside for bycatch in the at-sea Pacific whiting sectors, which is deducted from the trawl allocation; and increase the non-trawl allocation for petrale sole, until December 31, 2026. The new harvest specifications, Tribal set-asides, and sector allocations are provided below in table 1. This emergency rule will not change any other aspect of the 2025–2026 harvest specifications and management measures. For additional explanation on the rationale and effects of this emergency rule extension, see the original emergency rule published on January 22, 2026 (91 FR 2714).

TABLE 1—REVISED 2026 HARVEST SPECIFICATIONS, TRIBAL SET-ASIDES, AND ALLOCATIONS IN METRIC TONS

Species	OFL	ABC	ACL	Tribal	HG	Trawl allocation	At-sea	Shorebased trawl allocation	Non-trawl allocation
Shortspine thornyhead	970	902	897	54.4	820.6	582.6	76.3	506	238
Canary rockfish	673	626	626	54.7	558.4	403.7	21.9	382	154.7
Petrale sole	2,676	2,489	2,489	322.5	2,138	2,104.6	5.6	2,099	33.4

Classification

NMFS is issuing an extension of this emergency rule pursuant to section 305(3)(c) of the Magnuson-Stevens Act. The NMFS Assistant Administrator has determined that this emergency rule is consistent with the Pacific Coast Groundfish FMP, section 305(c) and other provisions of the Magnuson-

Stevens Act, the Administrative Procedure Act (APA), and other applicable law. Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries finds prior notice and public comment is not required because it would be impracticable and contrary to the public interest. The reasons justifying promulgation of this rule on an emergency basis, coupled with the

fact that the public had the opportunity to comment on the original emergency rule, make solicitation of additional comment unnecessary, impractical, and contrary to the public interest. This rule must be in place before the expiration of the original emergency rule to avoid immediate, significant adverse economic impacts to fishery participants and fishing communities.

¹ The 40–10 HCR is applied when a stock's biomass falls below the management target of 40 percent unfished biomass; the further the stock's

biomass is below the 40 percent threshold, the greater the reduction in ACL relative to the ABC. When a stock's biomass raises above the

management target of 40 percent, the 40–10 rule automatically no longer applies.

The new, increased harvest specifications and alternative HCRs are not expected to present conservation concerns in the fishery, as they are informed by new best scientific information available, which indicates that there is a higher biomass of all three species available for harvest than was projected in the 2023 stock assessments used to set 2025–2026 harvest specifications and which the Council's Scientific and Statistical Committee has deemed sufficient to support the new catch limits. For the reasons outlined above, NMFS finds it impracticable and contrary to the public interest to provide prior notice and public comment on these emergency measures.

Additionally, this rule is excepted from the 30-day delayed effectiveness provision of the APA under 5 U.S.C. 553(d)(1) because it removes a restriction in the form of the pre-existing, restrictive 2026 shortspine thornyhead, canary rockfish, and petrale sole specifications.

This action is being taken pursuant to the emergency provision of the Magnuson-Stevens Act and is exempt

from Office of Management and Budget review.

This emergency rule is exempt from Executive Order 14192 because it is a routine fishing action.

The Regulatory Flexibility Act does not apply to this emergency rule because prior notice and opportunity for public comment is not required.

This emergency/interim rule contains no information collection requirements under the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Fishing vessels.

Dated: June 9, 2026.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 660 as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 773 *et seq.*, and 16 U.S.C 7001 *et seq.*

■ 2. In § 660.50, revise paragraphs (f)(4), (18), and (21) to read as follows:

§ 660.50 Pacific Coast treaty Indian fisheries.

* * * * *

(f) * * *

(4) *Canary rockfish*. The Tribal harvest guideline is 54.7 mt per year.

* * * * *

(18) *Petrable sole*. The Tribal harvest guideline is 322.5 mt per year.

* * * * *

(21) *Thornyheads*. The Tribal harvest guideline for shortspine thornyhead is 54.4 mt per year and the Tribal harvest guideline for longspine thornyhead is 30 mt per year.

* * * * *

■ 3. In tables 2a and 2b to part 660, subpart C, revise the entries for “Canary Rockfish”, “Petrable Sole”, and “Shortspine Thornyhead” to read as follows:

* * * * *

TABLE 2a TO PART 660, SUBPART C—2026, AND BEYOND, SPECIFICATIONS OF OFL, ABC, ACL, ACT, AND FISHERY HG (WEIGHTS IN METRIC TONS). CAPITALIZED STOCKS ARE REBUILDING

Species/stock	Area	OFL	ABC	ACL ^a	Fishery HG ^b
* * *	* * *	* * *	* * *	* * *	* * *
Canary Rockfish	Coastwide	673	626	626	558.4
* * *	* * *	* * *	* * *	* * *	* * *
Petrable Sole	Coastwide	2,676	2,489	2,489	2,138
* * *	* * *	* * *	* * *	* * *	* * *
Shortspine Thornyhead ^c	Coastwide	970	902	897	820.6
* * *	* * *	* * *	* * *	* * *	* * *

^a Annual catch limits (ACLs), annual catch targets (ACTs) and harvest guidelines (HGs) are specified as total catch values.

^b Fishery HGs means the HG or quota after subtracting Pacific Coast treaty Indian Tribes allocations and projected catch, projected research catch, deductions for fishing mortality in non-groundfish fisheries, and deductions for EFPs from the ACL or ACT. These deductions, as well as any HG sharing agreements between states and/or sectors, are published in the SAFE.

* * * * *

^c Shortspine thornyhead has a commercial ACT of 55 mt for north of 34° 27' N lat.

* * * * *

TABLE 2b TO PART 660, SUBPART C—2026, AND BEYOND, ALLOCATIONS BY SPECIES OR SPECIES GROUP

Species/stock & complexes	Area	Fishery HG or ACT	Trawl		Non-trawl	
			%	mt	%	mt
* * *	* * *	* * *	* * *	* * *	* * *	* * *
Canary rockfish	Coastwide	558.4	72.3	403.7	27.7	154.7

TABLE 2b TO PART 660, SUBPART C—2026, AND BEYOND, ALLOCATIONS BY SPECIES OR SPECIES GROUP—Continued

Species/stock & complexes	Area	Fishery HG or ACT	Trawl		Non-trawl	
			%	mt	%	mt
* * *	* * *	* * *				
Petrale sole	Coastwide	2,138		2,104.6		33.4
* * *	* * *	* * *				
Shortspine thornyhead	Coastwide	820.6	71	582.6	29	238
* * *	* * *	* * *				

* * * * *

■ 4. In § 660.140, in table 1 to paragraph (d)(1)(ii)(D), revise the entries for “Canary rockfish”, “Petrale sole”, and “Shortspine thornyhead” to read as follows:

(d) * * *

(1) * * *

(ii) * * *

(D) * * *

§ 660.140 Shorebased IFQ Program.

* * * * *

TABLE 1d TO PARAGRAPH (d)(1)(ii)(D)—SHOREBASED TRAWL ALLOCATIONS FOR 2025 AND 2026

IFQ species	Area	2025 shorebased trawl allocation (mt)	2026 shorebased trawl allocation (mt)
* * *	* * *		
Canary rockfish	Coastwide	348	382
* * *	* * *		
Petrale sole	Coastwide	2,001	2,099
* * *	* * *		
Shortspine thornyhead	Coastwide	406	506
* * *	* * *		

* * * * *

[FR Doc. 2026-12108 Filed 6-15-26; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 91, No. 115

Tuesday, June 16, 2026

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

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4262

RIN 1212-AB61

Technical Amendments: Special Financial Assistance

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Proposed rule.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is proposing technical corrections, clarifications, and improvements to the restrictions and conditions in its regulation on special financial assistance. These changes would clarify (a) the permissibility of investing special financial assistance in certain securities and (b) the condition requiring PBGC approval for settling withdrawal liability claims. The amendments also would repeal a provision that enabled plans that received special financial assistance to request the reallocation of employer contributions to pay for health benefit costs.

DATES: Comments must be submitted on or before August 17, 2026, to be assured of consideration.

ADDRESSES: Comments may be submitted by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green "SUBMIT A PUBLIC COMMENT" button beneath this rulemaking's title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket.

- **Email:** reg.comments@pbgc.gov. Refer to 1212-AB61 in the subject line.

- **Mail or Hand Delivery:** Legislative and Regulatory Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101.

Commenters are strongly encouraged to submit comments electronically.

Commenters who submit comments by mail should allow sufficient time for mailed comments to be received before the close of the comment period.

All submissions must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and the Regulation Identifier Number (RIN) for this rulemaking (RIN 1212-AB61). Comments received will be posted without change to PBGC's website, www.pbgc.gov, including any personal information provided. Do not submit comments that include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments may be submitted anonymously.

Copies of comments may also be obtained by writing to Disclosure Division (disclosure@pbgc.gov), Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101 or calling 202-326-4040 during normal business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services. You may also follow the search instructions on <https://www.regulations.gov> to view public comments.

FOR FURTHER INFORMATION CONTACT:

Abigail Davidow (davidow.abigail1@pbgc.gov), Deputy Assistant General Counsel, Legislative and Regulatory Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101; 202-229-6418. If you are deaf or hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose and Authority

This proposed rule would make technical corrections, clarifications, updates, and improvements to PBGC's regulation on Special Financial Assistance by PBGC (29 CFR part 4262) (PBGC's SFA regulation) to improve and facilitate the operation of PBGC's special financial assistance (SFA) program.

PBGC's legal authority for this rulemaking is derived from (a) section 4002(b)(3) of the Employee Retirement Income Security Act of 1974 (ERISA),

which authorizes PBGC to issue regulations to carry out the purposes of title IV of ERISA, and (b) section 4262 of ERISA (Special Financial Assistance by the Corporation), which (1) permits PBGC to provide for how SFA and earnings thereon are to be invested and (2) permits PBGC, in consultation with the Secretary of the Treasury, to impose reasonable conditions by regulation or other guidance on an eligible multiemployer plan that receives SFA.

B. Major Provisions

The major provisions of this proposed rulemaking would amend PBGC's SFA regulation to:

- Clarify the permissibility of investing SFA in certain assets;
- Clarify the condition, imposed on a plan that receives SFA requiring PBGC approval for a proposed settlement of withdrawal liability; and
- Eliminate a provision that enables a plan that receives SFA to request the reallocation of employer contributions to pay for health benefit costs.

II. Background

PBGC administers the SFA program for eligible financially distressed multiemployer plans under section 4262 of ERISA and PBGC's SFA regulation. The amendments in this proposed rule would apply to the SFA program.

The proposed amendments and improvements to PBGC's SFA regulation are discussed below. PBGC invites comment on these proposals.

III. Permissible Investments of Special Financial Assistance

Section 4262(I) of ERISA requires that SFA received, and any earnings thereon (SFA funds), be used to make benefit payments and pay plan expenses, and that such SFA funds be held separately from other plan assets. Section 4262(I) also requires that SFA funds be invested in investment grade bonds or other investments permitted by PBGC. Section 4262.14 of PBGC's SFA regulation describes the permitted investments for SFA funds, referred to as permissible investments. Section 4262.14(b) of PBGC's SFA regulation identifies permissible investments as either investments in return-seeking assets or investments in investment grade fixed income securities and cash.

While administering the SFA program, PBGC has received practitioner questions on, or otherwise

uncovered uncertainty about, whether certain investments are permissible investment grade fixed income securities and the nature of permitted derivative exposure. PBGC issued guidance to address the questions, which PBGC is now proposing to codify in its SFA regulation. The following discussion covers the questions, PBGC's guidance, and the proposed changes to the SFA regulation.

A. Commonly Held Fixed Income Investments

Under § 4262.14(d)(1) of PBGC's SFA regulation, investments in investment grade fixed income securities and cash include "[a] bond or other debt security that pays a fixed amount or fixed rate of interest, is denominated in U.S. dollars, sold in an offering registered under the Securities Act of 1933, and is investment grade. . . ." These criteria are very similar to those used for inclusion in large aggregate bond indexes used as benchmarks by a broad spectrum of investors. Practitioners expressed uncertainty about whether certain Total Loss Absorbing Capacity (TLAC) bonds are permissible. Many TLAC bonds are commonly held and included in large aggregate bond indexes. In some circumstances, TLAC bonds may convert to equity, raising the question of whether they are a "bond, or other debt security." Other TLACs may change the interest paid for certain periods, under certain circumstances, creating uncertainty about whether they "pay a fixed amount or fixed rate of interest." One example of such an instrument is a fixed-to-float security. Fixed-to-float securities pay a fixed interest rate for a period of time before switching to a variable rate. These bonds may be called in by the issuer before switching to a variable rate, but would otherwise drop out of the index and simultaneously would no longer be considered permissible.

On July 16, 2024, PBGC updated a set of frequently asked questions (FAQs) about the SFA program to provide examples of securities included in large, aggregate U.S. bond indexes that meet the criteria for permissible investment grade fixed income securities under the statute and regulation. Examples of securities included in large, aggregate U.S. bond indexes that may meet the criteria for permissible investment grade fixed income securities are U.S. Treasury bonds, U.S. Government Agency bonds, U.S. Corporate bonds, asset-backed debt securities, mortgage-backed debt securities, commercial mortgage-backed debt securities, fixed-to-float securities during the fixed rate period, and step-up bonds, which pay

an initial interest rate that increases according to a predetermined schedule. The FAQs also provided examples of securities that do not meet the definition of permissible investment grade fixed income, including fixed-to-float securities during any period when they pay a variable rate interest, high yield bonds, traditional convertible bonds, preferred stock, collateralized loan obligations, annuity purchases, and contingent capital securities, such as contingent convertible bonds, which typically have a mechanical trigger based on capital ratios for conversion or write down of value.

PBGC now seeks to codify this guidance in its SFA regulation. For that reason, PBGC's proposed rule would amend the definition of permissible investment grade fixed income in § 4262.14(d)(1) of PBGC's SFA regulation to make clear that a bond or other debt security that pays a fixed amount or fixed rate of interest during the entire period that it is owned or that pays predetermined interest according to a schedule is permissible. A security that is convertible to equity will be considered a debt security (and therefore eligible to be a permissible investment) if it is convertible to equity solely by action of a Federal agency or other regulator.

B. Investments Exempt From Registration in Fixed Income

Several plans and practitioners have asked PBGC about whether SFA funds may be invested in certain fixed income securities that are exempt from registration requirements under the Securities Act of 1933. Of particular interest are securities issued or guaranteed by banks (exempt under section 3(a)(2) of the Securities Act of 1933) and securities issued by nonprofits (exempt under section 3(a)(4) of the Securities Act of 1933).

PBGC understands that, though exempt securities typically make up a small portion of fixed income investments, they are relatively common in portfolios of pension plans and are included in large, aggregate U.S. bond indexes. As discussed earlier, PBGC FAQs have clarified that bonds included in these indexes generally will be considered permissible investment grade fixed income investments. Further, upon evaluating various illustrative SFA asset investment portfolios, PBGC accepts that not all securities have a readily available method to verify the security's registration status under the Securities Act of 1933 and that the costs to plans to determine such status may be unduly burdensome.

Taking into consideration the requirements imposed on plans and the risks associated with holding the identified securities, PBGC is proposing to amend the definition of permissible investment grade fixed income in section 4262.14(d)(1) of PBGC's SFA regulation to permit investment in a bond or other debt security that is exempt from registration under sections 3(a)(2) or 3(a)(4) of the Securities Act of 1933 if it is investment grade.

C. Permissible Derivative Exposure

Section 4262.14(h) of PBGC's SFA regulation covers permissible derivative exposure for SFA plans and states that "[p]ermissible investments must not be supplemented by, and permissible fund vehicles cannot include, derivatives or otherwise be leveraged in a way that could increase the risk of the permissible investment beyond the risk associated with the market value of the un-leveraged permissible investment." In addition, § 4262.14(h) of PBGC's SFA regulation currently states that "[a]ny notional derivative exposure, other than exposure gained through a permissible fund vehicle described under paragraph (g) of this section, must be supported by liquid assets that are cash or cash equivalents denominated in U.S. dollars."

On November 4, 2024, PBGC posted an updated FAQ covering the types of derivative exposure, outside of permissible fund vehicles, that are permissible in portfolios of SFA funds. In doing so, it provided examples. The guidance states that SFA funds should generally not be invested in derivatives but that permissible derivative exposure includes, for a short period of time, derivative positions that substitute for and closely replicate permissible physical securities when those physical securities are not immediately available in the market. Further, the FAQ clarifies that derivative positions intended to change the risk related to potential future events, such as changes in interest rates, yield curve shape, or bond and equity prices, are not permissible.

PBGC is proposing to amend § 4262.14(h) of PBGC's SFA regulation to clarify the intended application of the provision, consistent with its FAQ.

IV. Condition on Withdrawal Liability Settlements

To ensure that SFA is used to pay benefits and the expenses related to those benefit payments, section 4262(m)(1) of ERISA expressly authorizes PBGC, in consultation with the Secretary of the Treasury, to impose reasonable conditions, relating to certain aspects of plan terms or

operations, on any eligible multiemployer plan that receives SFA. These conditions are specified in § 4262.16 of PBGC's SFA regulation.

PBGC's SFA regulation imposes a condition on settling withdrawal liability.¹ More specifically, § 4262.16(h)(1) requires that, for a certain period of time (what is referred to as the SFA coverage period), a plan "must obtain PBGC approval for a proposed settlement of withdrawal liability if the amount of the liability settled is greater than \$50 million." This \$50 million amount is calculated as the lesser of "(i) The allocation of unfunded vested benefits to the employer under section 4211 of ERISA; or (ii) The present value of withdrawal liability payments assessed for the employer discounted using the interest assumptions under § 4044.54 of this chapter."

Thus, if a plan wishes to settle a withdrawal liability claim during its SFA coverage period, it must make a present value determination in accordance with § 4262.16(h)(1)(ii) of PBGC's SFA regulation to determine if the value of the proposed settlement exceeds \$50 million. Doing so involves an actuarial calculation to determine the value of future withdrawal liability payments to the plan as of a specific date referred to as the determination date, using the plan's interest assumption in effect on that date.

Practitioners have asked PBGC questions about how to determine the determination date under § 4262.16(h)(1)(ii) of PBGC's SFA regulation. Because the calculation is sensitive to the interest assumption in effect on the determination date,² the determination date can be determinative of whether the amount of liability settled is greater than \$50 million.

After considering alternatives, PBGC is proposing to fix the determination date as of the last day of the plan year preceding the withdrawal. This date coincides with the most recent date benefits are valued to determine the employer's share of unfunded vested

benefits in the withdrawal liability calculation under section 4211 of ERISA.

One alternative PBGC considered was the "first day of the plan year following the plan year in which the withdrawal occurs," which is the date the withdrawal liability payment schedule is calculated under section 4219(c)(1)(A)(i) of ERISA. PBGC decided against this alternative because this date can be well after the date of withdrawal (*i.e.*, when an employer withdraws early in a plan year). Also, because the value of withdrawal liability payments as of that date may be unknown until sometime after that date, plans could be prevented from expediently determining whether a withdrawal liability settlement offer exceeds \$50 million, which determines whether PBGC approval would be required for the settlement.

For these reasons, this proposed rule would amend § 4262.16(h)(1)(ii) of PBGC's SFA regulation to require that the value of withdrawal liability payments assessed be determined as of the last day of the plan year preceding the withdrawal.

V. Condition on Reallocation of Contributions

PBGC's SFA regulation imposes a condition relating to the allocation of contributions. Under § 4262.16(e)(1), broadly speaking and not including certain good-faith practices enumerated in paragraphs (e)(1)(i) through (iv), during the SFA coverage period, a decrease in the proportion of income (contributions, investment returns, etc.) or an increase in the proportion of expenses allocated to a plan that receives SFA is prohibited. This prohibition applies to written or oral agreements or practices (other than a written agreement in existence on March 11, 2021, to the extent not subsequently amended or modified) under which income or expenses are divided or to be divided between a plan that receives SFA and one or more other employee benefit plans. This condition is to ensure that plan trustees do not inappropriately reallocate contributions away from the plan that receives SFA to other benefit programs or inappropriately reallocate expenses from other benefit programs to the plan.

The regulation also includes a procedure to request an exception to this prohibition under narrow circumstances. The exception was intended to accommodate circumstances arising after March 11, 2021, beyond the control of the plan sponsor and the bargaining parties (*e.g.*, health benefit cost increases due to

legislative changes) that would justify a good faith reallocation of income or expenses between employee benefit plans. Thus, § 4262.16(e)(2) of PBGC's SFA regulation currently states that, beginning 5 years after the end of the plan year in which a plan receives payment of SFA, a plan may apply for an exception by demonstrating to the satisfaction of PBGC that, taking into account the value of any proposed reallocation, the plan that received SFA will avoid insolvency and that the reallocation is needed due to a significant increase in health benefit costs due to a change in Federal law.

PBGC has determined that this exception procedure, which could allow SFA funds to be diverted to welfare plans, is inconsistent with the best reading of the underlying statute,³ which clearly contemplates that SFA should be used to make benefit payments from, and pay expenses for, eligible multiemployer pension plans. It is also inconsistent with PBGC's statutory purposes to encourage the continuation and maintenance of voluntary private pension plans for the benefit of their *participants* and to provide for the timely and uninterrupted payment of pension benefits to participants. Accordingly, PBGC proposes to remove the exception procedure in current § 4262.16(e)(2) and to reorganize § 4262.16(e).

VI. Compliance With Rulemaking Guidelines

A. Executive Orders 12866, 13563, and 14192

The Office of Management and Budget (OMB) has determined that this proposed rule is not a "significant regulatory action" under Executive Order 12866. Accordingly, OMB has not reviewed the proposed rule under Executive Order 12866.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Although this is not a significant regulatory action under Executive Order 12866, PBGC has examined the economic and policy implications of this proposed rule and has concluded that there will be no significant economic impact as a result of these amendments to PBGC's SFA regulation. Many of the amendments codify

¹ Withdrawal liability represents a withdrawing employer's proportionate share of the plan's unfunded benefit obligations and is an important source of funding for the plan. To assess withdrawal liability, the plan sponsor must determine the withdrawing employer's: (1) allocable share of the plan's unfunded vested benefits (UVBs) (the value of nonforfeitable benefits that exceeds the value of plan assets) as of the end of the plan year before the employer's withdrawal, or as otherwise provided under section 4211 of ERISA, and (2) annual withdrawal liability payment and amortization period under section 4219.

² This is because the value of a future withdrawal liability payment discounted using a higher interest rate will be lower than if it were discounted using a lower interest rate, all else being equal.

³ American Rescue Plan (ARP) Act of 2021 (Pub. L. 117-2).

clarifications already issued by PBGC in sub-regulatory guidance. Making these clarifications more transparent will decrease uncertainty among plan sponsors and their service providers. The clarifications will also prevent delays of withdrawal liability settlements and unnecessary divestment. In addition, some cost savings will be realized through simpler annual statement of compliance filings and elimination of exception filings.

Section 6 of Executive Order 13563 requires agencies to rethink existing regulations by periodically reviewing their regulatory program for rules that “may be outmoded, ineffective, insufficient, or excessively burdensome.” These rules should be modified, streamlined, expanded, or repealed as appropriate. PBGC has identified the amendments in this final rule as consistent with the principles for review under Executive Order 13563. PBGC believes codifying its previously issued guidance provides further clarity to the public and that the amendments will improve and clarify its existing regulations.

Executive Order 14192 requires agencies to identify at least ten existing regulations to be repealed when the agency issues a new regulation and that new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with prior regulations. As OMB explains in its memorandum, “Guidance Implementing Section 3 of Executive Order 14192, Titled ‘Unleashing Prosperity Through Deregulation,’” an “Executive Order 14192 regulatory action” is a significant regulatory action (as defined in section 3(f) of Executive Order 12866) that would impose total costs greater than zero. Because this proposed rule is not a significant regulatory action under Executive Order 12866, it is not an Executive Order 14192 regulatory action. However, PBGC believes this rule, if finalized, qualifies as an “Executive Order 14192 deregulatory action” (as defined in M–25–20) because of expected cost savings associated with both removing restrictions on investments and eliminating the option to reallocate employer contributions to health care.

PBGC estimates that easing investment restrictions on fixed-to-float securities and securities exempt from registration would result in annualized cost savings of approximately \$18.4 million. This estimate reflects PBGC’s observation of typical market practice regarding benchmark construction and advisory fee differentials for non-standard mandates, applied to the

projected SFA asset base and an estimated proportion of affected plans ($(\$10 \text{ million for one-time setup costs} + \$450 \text{ million for ongoing advisory fee impact}) \times 0.6$ (reflecting an estimated 60 percent of the 200 plans expected to receive SFA) $\div 15$ (reflecting a straight-line decline in advisory-fee impacts to \$0 over 15 years)). Furthermore, PBGC estimates that eliminating the procedure to grant an exception to the condition prohibiting the reallocation of contributions would result in fewer expected determination requests submitted to PBGC. PBGC estimates there would have been at least 10 requests for an exception from the condition prohibiting the reallocation of contributions, and by eliminating this procedure, PBGC estimates a total annual cost savings of \$250,000 ($10 \times \$25,000$ per request). Therefore, this rulemaking, if finalized, would result in \$18.65 million in total annual cost savings.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act⁴ (RFA) imposes certain requirements respecting rules that are subject to the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act, or any other law,⁵ and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the proposed rule describing the impact of the rule on small entities and seek public comment on such impact. Small entities include small businesses, organizations, and governmental jurisdictions.⁶

For purposes of the RFA requirements with respect to this proposed rule, PBGC considers a small entity to be a plan with fewer than 100 participants.⁷ This is substantially the same criterion PBGC uses in other regulations⁸ and is consistent with certain requirements in

title I of ERISA⁹ and the Code¹⁰, as well as the definition of a small entity that PBGC and the Department of Labor (DOL) have used for purposes of the RFA.¹¹

PBGC believes that assessing the impact of the final rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business based on size standards promulgated by the Small Business Administration (13 CFR 121.201) pursuant to the Small Business Act. PBGC therefore requests comments on the appropriateness of the size standard used in evaluating the impact on small entities of this proposed rule.

Based on its proposed definition of small entity, PBGC certifies under section 605(b) of the RFA that the amendments in this proposed rule would not have a significant economic impact on a substantial number of small entities. As explained above under “Executive Orders 12866 and 13563,” the proposed amendments offer clarifications or conform the regulation to statutory changes and thus are neutral in their impact. For instance, the clarification of the date as of which the value of withdrawal liability payments is calculated does not impose any new requirements, and, by choosing a date on which the sponsor is already determining present value amounts for purposes of determining withdrawal liability, should simplify the process of determining the present value. While it is possible that individual small plans would be impacted by this change, the overall effect on small plans, or plans of any size, would not be significant. Accordingly, as provided in section 605 of the RFA, sections 603 and 604 do not apply.

C. Paperwork Reduction Act

This proposed rule contains collections of information that PBGC has submitted to OMB for review and approval under the Paperwork Reduction Act (PRA). OMB’s decision

⁴ 5 U.S.C. 601 *et seq.*

⁵ The applicable definition of “rule” is found in section 601 of the RFA. *See* 5 U.S.C. 601(2).

⁶ The applicable definitions of “small business,” “small organization,” and “small governmental jurisdiction” are found in section 601 of the RFA. *See* 5 U.S.C. 601.

⁷ PBGC consulted with the Small Business Administration’s Office of Advocacy before making this determination. Memorandum received from the U.S. Small Business Administration, Office of Advocacy on March 9, 2021.

⁸ *See, e.g.*, special rules for small plans under part 4007 (Payment of Premiums).

⁹ *See, e.g.*, section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants.

¹⁰ *See, e.g.*, section 430(g)(2)(B) of the Code, which permits plans with 100 or fewer participants to use valuation dates other than the first day of the plan year.

¹¹ *See, e.g.*, PBGC’s proposed rule on Reportable Events and Certain Other Notification Requirements, 78 FR 20039, 20057 (Apr. 3, 2013) and DOL’s final rule on Procedures Governing the Filing and Processing of Prohibited Transaction Exemption Applications, 89 FR 4662, 4690 (Jan. 24, 2024).

regarding these information collection requests will be available at www.reginfo.gov. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Many of the changes PBGC expects to make are revisions to filing instructions, where necessary or helpful, to incorporate the clarifications in the proposed rule. Therefore, PBGC estimates that the proposed rule will have a small reduction on the hour and cost burden of reporting as described below.

The collection of information under part 4262 is approved under OMB control number 1212-0074 (expires May 31, 2027). The current information collection requirements have an estimated annual hour burden of 864 hours and a cost burden of \$1,931,800.

PBGC's Annual Statement of Compliance instructions would be updated to reflect the changes in this proposed rule to make clear that plans need not attempt to evaluate the registration status of a security exempt from registration under sections 3(a)(2) or 3(a)(4) of the Securities Act of 1933. The clarifications incorporated into the instructions would replace or augment existing language but would not create additional filing burden. The proposed elimination of the procedure to grant an exception to the condition prohibiting the reallocation of contributions would result in fewer expected determination requests submitted to PBGC. PBGC estimates it would have received at least 10 requests for an exception from the condition prohibiting the reallocation of contributions at an estimated total cost savings of \$250,000 (10 × \$25,000 per request).

List of Subjects in 29 CFR Part 4262

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

For the reasons stated in the preamble, PBGC proposes to amend 29 CFR part 4262 as follows:

PART 4262—SPECIAL FINANCIAL ASSISTANCE BY PBGC

■ 1. The authority citation for part 4262 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1432.

■ 2. Amend § 4262.14 of PBGC's SFA regulation by revising paragraphs (d)(1) and (h) to read as follows:

§ 4262.14 Permissible investments of special financial assistance.

* * * * *

(d) * * *

(1) A bond or other debt security that pays a fixed amount or fixed rate of interest during the entire period that it is owned or that pays predetermined rates of interest according to a schedule, is denominated in U.S. dollars, is a security registered under the Securities Act of 1933 or is a security exempt from registration under section 3(a)(2) or 3(a)(4) of the Securities Act of 1933 that does not include embedded features that result in returns or risks that differ materially from those of a fixed-rate or predetermined-rate debt security, and is investment grade as described under paragraph (f) of this section. For the purposes of this paragraph, a security that is convertible to equity will be considered a debt security only if it is convertible solely by action of a Federal agency or other regulator.

* * * * *

(h) Permissible investments must not be supplemented by, and permissible fund vehicles cannot include, derivatives or otherwise be leveraged in a way that could increase the risk of the permissible investment beyond the risk associated with the market value of the un-leveraged permissible investment. Outside of a permissible fund vehicle, permissible exposure to derivatives includes, for a short period of time, derivative positions that substitute for and closely replicate permissible physical securities when those physical securities are not immediately available in the market. The relevant facts and circumstances will determine the appropriate length of time that the plan may hold such derivative positions. Any notional derivative exposure, other than exposure gained through a permissible fund vehicle described under paragraph (g) of this section, must be supported by liquid assets that are cash or cash equivalents denominated in U.S. dollars. Derivative positions that are intended to change the risk related to potential future events are not permissible.

(i) *Example.* The following example provides an illustration of appropriate exposure to otherwise impermissible derivatives.

(1) At the time a pension plan receives SFA, a fixed income manager does not identify enough investible corporate bonds that are consistent with the plan's investment objectives and that are available on the market. For a few weeks after the plan's receipt of SFA, the investment manager accesses fixed income exposure through long positions in exchange traded Treasury futures. The notional value of Treasury futures plus the market value of physical securities in the plan's SFA

account do not exceed the total market value of physical securities, had they been available. This example would constitute permissible exposure.

* * * * *

■ 3. Amend § 4262.16 of PBGC's SFA regulation by:

■ a. Revising paragraphs (e) and (h)(1)(ii);

■ b. Adding new subparagraph (h)(1)(iii).

The revisions read as follows:

§ 4262.16 Conditions for special financial assistance.

* * * * *

(e) *Allocating contributions and other practices—*(1) *In general.* During the SFA coverage period, a decrease in the proportion of income or an increase in the proportion of expenses allocated to a plan that receives special financial assistance pursuant to a written or oral agreement or practice (other than a written agreement in existence on March 11, 2021, to the extent not subsequently amended or modified) under which the income or expenses are divided or to be divided between a plan that receives special financial assistance and one or more other employee benefit plans is prohibited.

(2) The prohibition in this paragraph (e) does not apply to a good faith allocation of:

(i) Contributions pursuant to a reciprocity agreement;

(ii) Costs of securing shared space, goods, or services, where such allocation does not constitute a prohibited transaction under ERISA or is exempt from such prohibited transaction provisions pursuant to section 408(b)(2) or 408(c)(2) of ERISA, or pursuant to a specific prohibited transaction exemption issued by the Department of Labor under section 408(a) of ERISA;

(iii) The actual cost of services provided to the plan by an unrelated third party; or

(iv) Contributions where the contributions to a plan that receives special financial assistance required for each base unit are not reduced, except as otherwise permitted by paragraph (d) of this section.

* * * * *

(h) * * *

(1) * * *

(ii) The present value of withdrawal liability payments assessed for the employer, discounted to the last day of the plan year preceding the plan year in which the withdrawal occurs, using the interest assumptions under § 4044.54 of this chapter that applied as of that date.

(iii) For purposes of paragraph (h)(1)(ii), that present value must be

aggregated with the present value of withdrawal liability payments assessed that are the subject of any prior or contemporaneous settlement or proposed settlement during the SFA coverage period involving the same employer or any trade or business (whether or not incorporated) treated as a single employer with that employer under section 4001(b)(1) of ERISA, to the extent arising from the same withdrawal or from a series of related withdrawals (including partial withdrawals), transactions, or arrangements. Settlements, transactions, or arrangements undertaken with a principal purpose of avoiding the approval requirement under this paragraph are treated as related for purposes of this paragraph (h)(1)(ii).

* * * * *

Jack Lund,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2026-12100 Filed 6-15-26; 8:45 am]

BILLING CODE 7709-02-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2026-0562]

RIN 1625-AA09

Drawbridge Operation Regulation; Wishkah River, Aberdeen, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating schedule that governs the Puget Sound and Pacific railroad bridge (PS&P) across the Wishkah River, mile 0.1 in Aberdeen, WA. Based on infrequent drawbridge openings, Genesee & Wyoming Inc. (GWRR), the bridge owner, is requesting to change the default draw position from the fully open position to the fully closed-to-navigation position. In addition, the proposed rule will require 24-hour notice for all drawbridge openings. Based on these proposed changes in operating schedule, there would no longer need to always have a bridge operator on site. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must reach the Coast Guard on or before July 16, 2026.

ADDRESSES: You may submit comments identified by docket number USCG-

2026-0562 at <https://www.regulations.gov>.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Steven Fischer, Northwest District Bridge Administrator, Coast Guard; telephone 206-220-7282, email, d13-smb-d13-bridges@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
GWRR Genesee & Wyoming Inc.
PS&P Puget Sound and Pacific

II. Background, Purpose and Legal Basis

GWRR owns and operates the PS&P railroad bridge across the Wishkah River at mile 0.1. GWRR is requesting a change to the existing operating regulation due to minimal waterway use. GWRR requested that we change the regulation to maintain the subject bridge's draw in the closed-to-navigation position to marine vessels and fully open the draw in the open-to-navigation position with a minimum of 24-hours' notice from marine vessels. GWRR's bridge logs show that marine vessel openings have decreased to 1 or 2 per year over the past ten years. The PS&P railroad bridge is regulated to operate in accordance with 33 CFR 117.1065(b) and is a swing bridge with a vertical clearance of eight feet above high water in the closed-to-navigation position. The lower low water tidal range at Aberdeen, WA, is 9 feet, and charted river depth is 16 feet.

III. Discussion of Proposed Rule

The Coast Guard proposes a change to 33 CFR 117.1065(b) to maintain the PS&P railroad bridge in the closed-to-navigation position, and that GWRR will fully open the swing span with a minimum of 24-hours' notice. When the draw is to be opened or closed the drawtender must sound one prolonged blast followed by one short blast. GWRR's bridge logs show that marine vessel openings have decreased to 1 or 2 openings per year over the past ten years. This proposed change will continue to service the mariner's

reasonable needs. This bridge provides a vertical clearance of eight feet above high tide when the draw is in the closed-to-navigation position. This section of the Wishkah River has no alternate routes.

This regulatory action determination is based on the ability for the PS&P railroad bridge, at Wishkah River mile 0.1, to fully open on signal after a minimum of 24-hours by telephone or VHF radio channel 13. The Coast Guard has made this finding because the proposed change allows any vessel that needs a drawbridge opening to transit through the PS&P railroad bridge with proper advance notice.

This proposed rule also plans to remove the requirement for the drawtender to sound two prolonged blasts every minute when the draw of the bridge is closed and the visibility at the drawtender's station is less than one mile up or down the channel. This requirement will no longer be needed when the default drawbridge position will be in the closed-to-navigation position.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on these statutes and Executive Orders.

A. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons.

While some owners or operators of vessels intending to transit the bridge may be small entities, the Coast Guard has not identified any vessel operators that will be caused significant economic impact as result of the proposed rule change. As noted earlier, only one or two vessels required openings of the drawbridge annually over the last 10 years. They would be able to continue to request openings of the drawbridge with a 24-hour notice.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity

and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

B. Collection of Information

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

C. Federalism and Indian Tribal Governments

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

Also, the Coast Guard has communicated and met with the Quinault Indian Nation and requested that any concerns be provided. To date, the Coast Guard has not received a formal response and intends to determine that there are “no tribal implications” under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments). This is because the proposed action would not have a substantial direct effect on one or more Indian tribes, nor would it affect the relationship between the Federal Government and Indian tribes, or the distribution of power and responsibilities between them. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

D. Unfunded Mandates Reform Act

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

E. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321 *et seq.*). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

V. Public Participation and Request for Comments

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

Submitting comments. We encourage you to submit comments at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2026–0562 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the

Comment option. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you go to the online docket and sign up for email alerts through the “Subscribe” option, you will be notified when comments/updates are posted, or a final rule is published.

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

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and DHS Delegation No. 00170.1. Revision No. 01.4

■ 2. Amend § 117.1065 by revising paragraph (b) to read as follows:

§ 117.1065 Wishkah River.

* * * * *

(b) The draw of the Puget Sound and Pacific railroad bridge, mile 0.1 at Aberdeen, shall be maintained in the closed-to-navigation position. Vessels requesting the bridge’s draw to be opened for navigation shall make a request at least 24 hours in advance by telephone or VHF radio channel 13. Please refer to the Coast Pilot in the Grays Harbor, Washington section for updated contact requirements. When the draw is to be opened or closed the

drawtender shall sound one prolonged blast followed by one short blast.

* * * * *

Arex B. Avanni,

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

[FR Doc. 2026–12054 Filed 6–15–26; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 26–113; DA 26–568; FR ID 350860]

Radio Broadcasting Services; Selmer, Tennessee

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document the Federal Communications Commission (Commission) requests comments on a proposal to amend the Table of FM Allotments, by deleting vacant Channel 288A at Selmer, Tennessee, because it does not comply with the minimum distance separation requirements of the Commission's rules. A staff engineering analysis determines that Channel 288A at Selmer, Tennessee is short-spaced to Station WVNA–FM by nine kilometers, and there are no alternate channels available to alleviate the existing spacing conflict that would comply with the Commission's spacing requirements. The proposed Selmer deletion is consistent with the Commission's policy that it will not retain a vacant FM channel that would not comply with the Commission's spacing requirements.

DATES: Comments must be filed on or before July 24, 2026, and reply comments on or before August 10, 2026.

ADDRESSES: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section above. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). You may submit comments, identified by

[docket number and/or rulemaking number], by any of the following methods:

- **Electronic Filers:** Comments may be filed electronically using the internet by accessing the ECFS: <https://www.fcc.gov/ecfs>.

- **Paper Filers:** Parties who choose to file by paper must file an original and one copy of each filing.

- Filings can be sent by hand or messenger delivery, by commercial courier, or by the U.S. Postal Service. All filings must be addressed to the Secretary, Federal Communications Commission.

- Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8:00 a.m. and 4:00 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

- Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

- Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express must be sent to 45 L Street NE, Washington, DC 20554.

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

FOR FURTHER INFORMATION CONTACT:

Rolanda F. Smith, Media Bureau, (202) 418–2054, Rolanda-Faye.Smith@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making (NPRM), in MB Docket No. 26–113, adopted June 8, 2026, and released June 9, 2026. The full text of this document is available online at <https://www.fcc.gov/ecfs>. The full text of this document is also available at <https://docs.fcc.gov/public/attachments/DA-26-568A1.pdf>.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. This document does not contain proposed information

collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

The Providing Accountability Through Transparency Act requires each agency, in providing notice of a rulemaking, to post online a brief plain-language summary of the proposed rule. Accordingly, the Commission will publish the required summary of this NPRM on <https://www.fcc.gov/proposed-rulemakings>.

Members of the public should note that from the time a NPRM is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.202 [Amended]

■ 2. In § 73.202(b), amend table 1 (Table of FM Allotments) under Tennessee by removing the entry for “Selmer”.

[FR Doc. 2026–12043 Filed 6–15–26; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 91, No. 115

Tuesday, June 16, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Administration

Agency Information Collection
Activities: Child and Adult Care Food Program (CACFP) National Disqualified List

AGENCY: Food and Nutrition Administration (FNA), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection.

This collection is an extension, without change, of a currently approved collection for maintaining the National Disqualified List of institutions, day care home providers, and individuals that have been terminated or otherwise disqualified from Child and Adult Care Food Program (CACFP) participation. These federal requirements affect eligibility under the CACFP.

DATES: Written comments must be received on or before August 17, 2026.

ADDRESSES: Comments may be sent to: Jessica Saracino, Director, Program Monitoring and Operational Support Branch, Child Nutrition Division, Food and Nutrition Administration, U.S. Department of Agriculture, 1320 Braddock Place, Fourth Floor, Alexandria, VA, 22314. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov>, and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Suzanne Diggs at Suzanne.diggs@usda.gov or (703) 305–2096.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Child and Adult Care Food Program (CACFP) National Disqualified List.

Form Number: FNS–843 and FNS–844.

OMB Number: 0584–0584.

Expiration Date: September 30, 2026.

Type of Request: Extension, without change, of a currently approved collection.

Abstract: The Food and Nutrition Administration administers the Child Nutrition Act of 1966, as amended (42 U.S.C. 1771, *et seq.*). Section 243(c) of Public Law 106–224, the Agricultural Risk Protection Act of 2000, amended section 17(d)(5) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766 (d)(5)(E)(i) and (ii)) by requiring the Department of Agriculture to maintain a list of institutions, day

care home providers, and individuals that have been terminated or otherwise disqualified from Child and Adult Care Food Program participation. The law also requires the Department to make the list available to State agencies for their use in reviewing applications to participate in the program and to sponsoring organizations to ensure that they do not employ as principals any persons who are disqualified from the program. Forms FNS–843 Report of Disqualification from Participation—Institutions and Responsible Principals/Individuals and FNS–844 Report of Disqualification from Participation—Individually Disqualified Responsible Principal/Individual or Day Care Home Provider are used to collect and maintain this data via a web-based system constructed to update and maintain the list of disqualified institutions and individuals so that no State agency or sponsoring organization may approve any entity on the National Disqualified List to ensure the integrity of the Program. This statutory mandate has been incorporated into § 226.6(c)(7) of the Program regulations. In addition, the recordkeeping burden associated with maintaining documentation related to institutions and providers terminated for cause at the State agency level is captured under the Information Collection for the CACFP, OMB Control Number 0584–0055 Child and Adult Care Food Program (CACFP), expiration date October 31, 2027. Therefore, there is no recordkeeping burden associated with this collection.

Affected Public: State, Local, and Tribal Government. State Agencies are the respondents.

Estimated Number of Respondents: 56.

Estimated Number of Responses per Respondent: 28.

Estimated Total Annual Responses: 1,568.

Estimate Time per Response: 0.50.

Estimated Total Annual Burden: 784.

Affected public	Instrument	Estimated number of respondents	Number of responses per respondent	Total annual responses	Estimated total hours per response	Estimated total burden
Reporting						
State Agencies	FNS–843	56	6	336	.50	168
State Agencies	FNS–844	56	22	1,232	.50	616

Affected public	Instrument	Estimated number of respondents	Number of responses per respondent	Total annual responses	Estimated total hours per response	Estimated total burden
Total Estimated Reporting Burden.		56	28	1,568	0.50	784

Patrick A. Penn,

Acting Administrator, Food and Nutrition Administration, U.S. Department of Agriculture.

[FR Doc. 2026–12094 Filed 6–15–26; 8:45 am]

BILLING CODE 3410–30–P

Dated: June 12, 2026.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2026–12072 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–316–2026]

Foreign-Trade Zone 44; Application for Subzone; Perlen Packaging LLC; Whippany, New Jersey

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the State of New Jersey Department of State, grantee of FTZ 44, requesting subzone status for the facility of Perlen Packaging LLC, located in Whippany, New Jersey. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on June 12, 2026.

The proposed subzone (3.44 acres) is located at 135 Algonquin Parkway, Whippany, New Jersey. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 44.

In accordance with the FTZ Board's regulations, Juanita Chen of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is July 27, 2026. Rebuttal comments in response to material submitted during the foregoing period may be submitted through August 10, 2026.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–70–2026]

Foreign-Trade Zone (FTZ) 230, Notification of Proposed Production Activity; TN Americas LLC; (Nuclear Fuel Containers); Kernersville, North Carolina

TN Americas LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Kernersville, North Carolina within Subzone 230L. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on June 11, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished products include DN30 nuclear fuel containers (duty rate is duty-free).

The proposed foreign-status materials/components include: cold-rolled stainless steel plates; hot-rolled stainless steel plates; stainless steel bars; stainless steel pipe fittings; foam materials; microporous insulated panels; acrylic based sealant; seals of vulcanized rubber (duty rate ranges from duty-free to 6.5%).

The request [also] indicates that certain materials/components are subject to duties under section 122 of the Trade Act of 1974 (Section 122) or section 232 of the Trade Expansion Act of 1962 (section 232) depending on the country of origin. The applicable section 122 and section 232 decisions require subject merchandise to be admitted to

FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is July 27, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Christopher Williams at christopher.williams@trade.gov.

Dated: June 11, 2026.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2026–12073 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–71–2026]

Foreign-Trade Zone (FTZ) 207, Notification of Proposed Production Activity; QubicaAMF Worldwide, LLC; (Bowling Equipment); Mechanicsville, Virginia

QubicaAMF Worldwide, LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Mechanicsville, Virginia within FTZ 207. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on June 5, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished products include: hardware tool kits; monitor frames; lane cleaning machines; pulley assemblies; motor assemblies; bowling pinspotter machines; bowling bumper assemblies; bowling ball return

assemblies; and, cleaning broom assemblies (duty rate ranges from duty-free to 4%).

The proposed foreign-status materials/components include: lubricating oils; plastic tracks; polyvinyl tubes; plastic tubes; plastic hoses; adhesive tapes; vinyl tapes; polyethylene plastic guarding; plastic polyurethane sheets with hook-and-loop fastener; polyurethane foam strips; HDPE plastic strips; plastic caps; plastic mixing tanks; plastic handles; plastic gaskets; plastic latches; plastic guide blocks; plastic cover housings; plastic bushings sleeves; rubber belts; rubber seals; rubber vibration insulators; MDF plywood; printed manuals; warning labels; synthetic strings; transmission belts; microfiber dust cloths; game tokens; steel weldments; steel shafts; hollow steel tubes; steel chains; steel chain links; steel round link chains; steel cotter ins; steel self threading screws; steel shoulder bolts; steel threaded machine screws; steel socket head bolts; steel locking nuts; steel thumb screws; steel non-threaded washers; steel pivot pins; steel helical springs; steel framing and mounts; aluminum rivets; steel tools; motor crank; tools for furniture installs; steel hinges; base metal steel latches; base metal steel fittings; base metal mounts; base metal brackets; reciprocating pumps; cooling fans; blower fans; handheld tools; enclosed computer units with input/outputs; computer processing units, complete systems; computer processing units, individual; server controller boxes; magnetic stripe readers; electronic boards; storage devices; lane machines; solenoid assemblies; bearing shaft assemblies; radial bearings; needle roller bearings; uniball bearings; ball bearing housings; power shafts; flanged bearings; ball bearing shafts; gear boxes; chain left shafts; motor brake kits; pulley assemblies; universal joints; coupling spiders; chain sprockets; coupling spiders; gear pinions; support pins; metal gaskets; direct current motors; alternating current motors; linear actuators; universal power supplies; power supplies for LCD; power supply kits; magnetic latches; magnetic clutches; solenoid kits; single line wired telephones; scoring electronics; computer speakers; bowling scoring devices speakers; magnetic cards; computer software; solid state drives; television video converter boxes; digital cameras; LED lights; printed circuit boards; fuses; automatic circuit breakers; relay switches; relay kits; motor switches; Bayonet Neill-Concelman connectors; termination

plugs; terminal sockets; fuse holders; dimmer switches; electrical photosensors; electrical cables for scoring; electrical power cables; electrical cables without connectors; electrical copper wires; wire ducts; lenses; circuit testers; optical sensors; string measuring devices; bowling pinspotter sub-assemblies; bowling bumper sub-assemblies; and, bowling ball return sub-assemblies (duty rate ranges from duty-free to 19.9¢/kg + 10.8%%).

The request indicates that certain materials/components are subject to duties under section 122 of the Trade Act of 1974 (Section 122), section 232 of the Trade Expansion Act of 1962 (section 232), or section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 122, section 201, section 232, and section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign (PF) status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is July 27, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Brian Warnes at brian.warnes@trade.gov.

Dated: June 12, 2026.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2026-12104 Filed 6-15-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S-230-2026]

Approval of Subzone Status; Fisher BioServices; Frederick, Maryland

On April 22, 2026, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Board of County Commissioners of Washington County, grantee of FTZ 255, requesting subzone status subject to the existing activation limit of FTZ 255, on behalf of Fisher BioServices, in Frederick, Maryland.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (91 FR 22490, April 27, 2026). The FTZ staff examiner reviewed the

application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 255C was approved on June 11, 2026, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 255's 2,000-acre activation limit.

Dated: June 11, 2026.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2026-12075 Filed 6-15-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-533-884]

Glycine From India: Final Results of Countervailing Duty Administrative Review; 2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies were provided to certain producers and exporters of glycine from India during the period of review (POR) January 1, 2023, through December 31, 2023.

DATES: Applicable June 16, 2026.

FOR FURTHER INFORMATION CONTACT: Amber Hodak or Preston Cox, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-8034 or (240) 956-8630, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 3, 2025, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited interested parties to comment.¹ Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.² Additionally, due to a backlog of documents that were electronically filed

¹ See *Glycine from India: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2023*, 90 FR 48028 (October 3, 2025) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.³ Between March 24 and May 28, 2026, Commerce extended the time period for issuing these final results by 60 days.⁴ Accordingly, the deadline for these final results is now June 8, 2026.⁵

For a complete description of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.⁶ The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/frnotices>.

Scope of the Order ⁷

The product covered by the *Order* is glycine from India. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.⁸

Analysis of Comments Received

All issues raised by interested parties in briefs are addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is included as appendix to this notice.

Changes Since the Preliminary Results

Based on the comments received from interested parties and record information, we made certain changes from the *Preliminary Results* regarding

the subsidy calculations for Kumar Industries, India (Kumar). For a discussion of these changes, see the Issues and Decision Memorandum.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce finds that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁹ For a full description of the methodology underlying all of Commerce's conclusions, including any determination that relied upon the use of adverse facts available, pursuant to sections 776(a) and (b) of the Act, see the Issues and Decision Memorandum.

Rate for Non-Individually Examined Companies

The Act and Commerce's regulations do not directly address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. Generally, Commerce looks to section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in a CVD investigation. Section 777A(e)(2) of the Act provides that "the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}."

Under section 705(c)(5)(A)(i) of the Act, the all-others rate is normally an amount equal to the weighted average countervailable subsidy rates established for each of the companies individually investigated, excluding any rates that are zero, *de minimis* (*i.e.*, less than 0.5 percent), or determined entirely on the basis of facts available. Where the countervailable subsidy rates for each of the individually examined companies is zero, *de minimis*, or based entirely on facts available, section 705(c)(5)(A)(ii) of the Act provides that Commerce may use "any reasonable method to establish an all-others rate for exporters and producers not individually investigated, including averaging the weighted average countervailable subsidy rates

determined for the exporters and producers individually investigated."¹⁰

In this administrative review, Commerce calculated an individual estimated countervailable subsidy rate for Kumar, the sole individually examined respondent in this review. Because this individually calculated subsidy rate is not zero, *de minimis*, or based entirely on facts otherwise available, we are assigning the subsidy rate calculated for Kumar to the company under review that was not selected for individual examination (*i.e.*, Bajaj Healthcare Limited (Bajaj Healthcare)), pursuant to section 705(c)(5)(A)(i) of the Act.¹¹

Final Results of Review

As a result of this review, we determine the following net countervailable subsidy rates exist for the POR, January 1, 2023, through December 31, 2023:¹²

Company	Subsidy rate (percent <i>ad valorem</i>)
Kumar Industries, India	45.33
Bajaj Healthcare Limited	45.33

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Assessment

Consistent with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Commerce intends to issue assessment instructions to CBP regarding Kumar and Bajaj Healthcare

³ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁴ See Memoranda, "Extension of Deadline for Final Results of Countervailing Duty Administrative Review," dated March 24, 2026; and "Extension of Deadline for Final Results of Countervailing Duty Administrative Review," dated May 28, 2026.

⁵ Commerce's practice dictates that, where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005). We note that the calculated deadline would be June 6, 2026; however, because that date is a Saturday, the current deadline is June 8, 2026.

⁶ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Glycine from India; 2023," dated concurrently with, and hereby adopted by, this memorandum (Issues and Decision Memorandum).

⁷ See *Glycine from India and the People's Republic of China: Countervailing Duty Orders*, 84 FR 29173 (June 21, 2019) (*Order*).

⁸ See Issues and Decision Memorandum.

⁹ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

¹⁰ See, e.g., *Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review*, 75 FR 37386, 37387 (June 29, 2010).

¹¹ Bajaj Healthcare is the only company that was not selected for individual examination. See *Preliminary Results PDM* at 4.

¹² Commerce continues to determine that Advance Chemical Corporation, Rexistize Rasayan Industries, Reliance Corporation, and Rudraa International are cross-owned with Kumar. See *Preliminary Results PDM* at 16–17; see also *Glycine from India: Final Results of the Countervailing Duty Administrative Review; 2022*, 89 FR 95180 (December 2, 2024); and *Glycine from India: Preliminary Results of Countervailing Duty Administrative Review; 2018–2019*, 86 FR 37738 (July 16, 2021).

no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act and 19 CFR 351.107(e), Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as follows: (1) the cash deposit rate for the companies listed above will be equal to the company-specific estimated individual countervailable subsidy rates determined in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) if both the producer and exporter of the subject merchandise have company-specific estimated subsidy rates assigned, and their rates differ, then the applicable cash deposit rate will be the higher of these two rates; (3) if either the producer or the exporter, but not both, of the subject merchandise has a company-specific estimated subsidy rate assigned, the applicable cash deposit rate will be that company's company-specific rate; and (4) the cash deposit rate for all other producers and exporters will be continue to be 5.01 percent, the all-others subsidy rate established in the investigation.¹³ These cash deposit instructions, when imposed, shall remain in effect until further notice.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is sanctionable violation.

¹³ See *Order*.

Notification to Interested Parties

Commerce is issuing the final results and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: June 8, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. Use of Facts Otherwise Available and Application of Adverse Inferences
- V. Subsidies Valuation
- VI. Analysis of Programs
- VII. Discussion of the Issues
 - Comment 1: Whether Commerce Should Apply Adverse Facts Available (AFA) to Kumar and its Cross-Owned Affiliates
 - Comment 2: Whether Commerce Should Adjust Kumar's Sales Denominators and Kumar's Benefit Calculation for Pre- and Post-Shipment Finance Program
 - Comment 3: Whether Commerce Should Apply AFA to Kumar with Respect to Rudraa International
 - Comment 4: Whether the Duty Drawback (DDB) Program is Countervailable
 - Comment 5: Whether the Pre- and Post-Shipment Finance Program is Countervailable
 - Comment 6: Whether the Remission of Duties and Taxes on Export Products (RoDTEP) is Countervailable
 - Comment 7: Whether the State Government of Gujarat (SGOG) Provision of Water for Less Than Adequate Remuneration (LTAR) is Countervailable
- VIII. Recommendation

[FR Doc. 2026–12103 Filed 6–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–992]

Monosodium Glutamate From the People's Republic China: Final Results of Antidumping Duty Administrative Review; 2023–2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable June 16, 2026.

SUMMARY: On February 11, 2026, the U.S. Department of Commerce (Commerce) published the preliminary results of the 2023–2024 administrative review of the antidumping duty (AD) order on monosodium glutamate (MSG)

from the People's Republic of China (China) covering the period of review (POR) November 1, 2023, through October 31, 2024. We find that Ajinoriki MSG (Malaysia) Sdn Bhd (Ajinoriki) is not eligible to receive a separate rate and is, therefore, considered part of the China-wide entity.

FOR FURTHER INFORMATION CONTACT:

Thomas Cloyd, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1246.

SUPPLEMENTARY INFORMATION:

Background

On February 11, 2026, Commerce published in the **Federal Register** the *Preliminary Results* and invited interested parties to comment.¹

Scope of the Order

The scope of the *Order* covers MSG, whether or not blended or in solution with other products.² For a complete description of the scope of the *Order*, see the appendix to this notice.

Analysis of Comments Received

On March 3, 2026, we received comments from the Ajinomoto Health & Nutrition North America, Inc (petitioner) regarding the *Preliminary Results*.³ The petitioner identified an error regarding the rate for the China-wide entity listed in the *Preliminary Results*, which mistakenly indicated the China-wide rate to be 40.41 percent.⁴ The correct rate applicable to the China-wide entity, however, is 56.54 percent, pursuant to Commerce's findings in the *2017–2018 Administrative Review*.⁵ Because the petitioner was the sole party to comment on the *Preliminary Results*, which we have summarized and addressed in this notice, no decision memoranda accompany this notice.

¹ See *Monosodium Glutamate from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2023–2024*, 91 FR 6188 (February 11, 2026) (*Preliminary Results*).

² See *Monosodium Glutamate from the People's Republic of China: Second Amended Final Determination of Sales at Less Than Fair Value and Amended Antidumping Duty Order*, 80 FR 487 (January 6, 2015) (*Order*).

³ See Petitioner's Letter, "Comments on Preliminary {Results}," dated March 3, 2026.

⁴ See *Preliminary Results*.

⁵ See *Monosodium Glutamate from the People's Republic of China: Final Results of Antidumping administrative Review; 2017–2018*, 85 FR 9736 (February 20, 2020) (*2017–2018 Administrative Review*).

Final Results of Review

In the *Preliminary Results*, Commerce determined that Ajinoriki failed to submit a Separate Rate Application in a timely manner and, therefore, denied Ajinoriki separate rate status.⁶ As corrected from the *Preliminary Results*, Ajinoriki is subject to the currently applicable rate of 56.54 percent for the China-wide entity.⁷ Furthermore, Commerce finds that, because no party requested a review of the China-wide entity for the POR, the China-wide entity is not under review, and the China-wide entity's rate (*i.e.*, 56.54 percent) is not subject to change.

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with the final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce finds that the sole producer or exporter of MSG subject to review is part of the China-wide entity and the China-wide entity is not under review, there are no calculations to disclose for these final results.

Assessment Rates

Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries in this review, in accordance with section 751(a)(2)(C) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b)(1).

Commerce intends to issue appropriate assessment instructions directly to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

The assessment rate for Ajinoriki will be equal to the weighted-average dumping margin for the China-wide entity, *i.e.*, 56.54 percent.⁸

Cash Deposit Requirements

For all shipments of subject merchandise from China, entered, or withdrawn from warehouse, for consumption on or after the publication

date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) for subject merchandise exported by a company with a separate rate from a previously completed segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate, or producer-exporter-specific rate, for that exporter, (2) for all exporters of subject merchandise that have not been found to be entitled to a separate rate, *i.e.*, the China-wide entity, the cash deposit rate will continue to be 56.54 percent.⁹ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

These final results are being issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: June 11, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The scope of this *Order* covers monosodium glutamate (MSG), whether or not blended or in solution with other

products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15% or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in this investigation regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging.

MSG in monohydrate form has a molecular formula of C₅H₈NO₄Na·H₂O, a Chemical Abstract Service (CAS) registry number of 6106-04-3, and a Unique Ingredient Identifier (UNII) number of W81N5U6R6U. MSG in anhydrous form has a molecular formula of C₅H₈NO₄Na, a CAS registry number of 142-47-2, and a UNII number of C3C196L9FG.

Merchandise covered by the scope of this *Order* is currently classified in the Harmonized Tariff Schedule (HTS) of the United States at subheading 2922.42.10.00. Merchandise subject to the *Order* may also enter under HTS subheadings 2922.42.50.00, 2103.90.72.00, 2103.90.74.00, 2103.90.78.00, 2103.90.80.00, and 2103.90.90.91. The tariff classifications, CAS registry numbers, and UNII numbers are provided for convenience and customs purposes; however, the written description of the scope is dispositive.

[FR Doc. 2026-12101 Filed 6-15-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Solicitation of nominations for membership for the Environmental Technologies Trade Advisory Committee.

SUMMARY: Pursuant to Section 2313(c) of the Export Enhancement Act of 1988, as amended, 15 U.S.C. 4728(c), and in accordance with the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C. 1001 *et seq.*, the Department of Commerce (the Department) requests nominations for membership for the Environmental Technologies Trade Advisory Committee (ETTAC or Committee). The ETTAC is a non-discretionary committee that provides consensus advice to the Environmental Trade Promotion Working Group of the Trade Promotion Coordinating Committee (TPCC), reporting through the Secretary of Commerce in his capacity as Chair of the TPCC, regarding

⁶ See *Preliminary Results*, 91 FR at 6189.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

the development and administration of programs to expand U.S. exports of environmental technologies, goods, and services and products that comply with U.S. environmental, safety, and related requirements. U.S. natural resources management and environmental technologies, including water and wastewater treatment, waste management and recycling, and air quality monitoring and control solutions, enable the buildout of critical infrastructure and the operation of U.S. manufacturing across all industry sectors. They are essential in advancing U.S. economic and national security goals through promoting fair and balanced trade, U.S. manufacturing competitiveness, secure domestic supply chains, and energy dominance. U.S. environmental technologies goods and services are globally competitive, contributing approximately \$60 billion in U.S. exports annually and employing an estimated 1.9 million Americans. ETTAC guidance is vital to advancing the America First Trade Policy agenda, including informing U.S. government programs and activities to expand U.S. natural resource management and environmental technologies exports.

DATES: Nominations for membership must be received on or before 5:00 p.m. Eastern Daylight Time (EDT) on August 7, 2026. After that date, the International Trade Administration (ITA) may continue to accept nominations under this notice to fill any vacancies that may arise.

ADDRESSES: Applications should be submitted via ITA's Environmental Technologies Trade Advisory Committee web page: <https://www.trade.gov/ettac>.

After submission of an application through the link provided on the web page, applicants will be required to submit additional documentation in response to an automated email. Please send any questions regarding the application process or eligibility to envirotech@trade.gov.

FOR FURTHER INFORMATION CONTACT: Megan Hyndman, Designated Federal Officer, Office of Energy & Environmental Industries, (202) 482-1297; email Megan.Hyndman@trade.gov; or Evelina Scott, Secondary Designated Federal Officer, (202) 597-0342; email Evelina.Scott@trade.gov. ETTAC materials are posted online at <https://www.trade.gov/ettac>.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ETTAC was established pursuant to Section 2313(c) of the Export Enhancement Act of 1988, as amended,

15 U.S.C. 4728(c). The ETTAC provides consensus advice to the Environmental Trade Promotion Working Group of the Trade Promotion Coordinating Committee, reporting through the Secretary of Commerce in his capacity as Chair of the TPCC, regarding the development and administration of programs to expand U.S. exports of environmental technologies, goods, and services and products that comply with U.S. environmental, safety, and related requirements. Environmental technologies, goods, and services may include, but are not limited to:

- Air quality measuring, monitoring and control technologies;
- Emerging environmental technologies such as carbon capture, utilization, and storage and PFAS removal/destruction;
- Environmental engineering and consulting services;
- Environmental goods and services to support manufacturing, energy production, data centers, and critical infrastructure;
- Measuring, monitoring, and instrumentation devices and services;
- Process control and emission control technologies;
- Solid and hazardous waste management, resource efficiency, and recycling and materials recovery technologies;
- Water and wastewater treatment technologies; and/or
- Weather monitoring and forecasting, flood management, and coastal resilience solutions.

In particular, the Committee advises on matters including, but not limited to:

- (1) All matters concerning trade policy development and negotiations relating to U.S. environmental technologies exports;
- (2) The effect of U.S. Government policies, regulations, and programs, and foreign governments' policies and practices, on the export of U.S. environmental products, technologies, and services;
- (3) The competitiveness of U.S. industry and its ability to compete for environmental technologies, products, and services opportunities in international markets, including specific problems in exporting, and U.S. Government and joint public-private actions to assist environmental technologies companies in expanding their exports;
- (4) The identification of priority environmental technologies, products, and services markets with high immediate returns for U.S. exports, as well as emerging markets with a longer-term potential for U.S. exports;

(5) Strategies to increase private sector awareness and effective use of U.S. Government export promotion programs, and recommendations on how U.S. Government programs may be more efficiently designed and coordinated;

(6) The development of complementary industry and trade association export promotion programs and greater or more effective coordination of U.S. Government efforts with private sector organizations' environmental technologies industry export promotion efforts; and

(7) The development of U.S. Government programs to encourage U.S. producers of environmental technologies, products, and services to enter new foreign markets, in connection with which the Committee may advise on how to gather, disseminate, and promote awareness of information on environmental exports and related trade issues.

II. Membership

The ETTAC shall consist of approximately 30 to 45 members. Members shall represent U.S. environmental technologies manufacturing and services companies, U.S. trade associations, U.S. private sector organizations, States or associations representing the States, and civil society groups involved in the promotion of exports of environmental technologies products and services.

Members of the Committee are appointed by the Secretary, in accordance with applicable Department of Commerce guidelines, based on their ability to carry out the objectives of the Committee as set forth in the Committee's Charter and in a manner that ensures that the Committee is balanced in terms of points of view, industry subsector, geography, and company size. Race or sex shall not be considered in the selection of the Committee's membership. The Secretary shall appoint to the Committee at least one individual representing each of the following:

- (a) environmental businesses, including small businesses;
- (b) trade associations in the environmental sector;
- (c) private sector organizations involved in the promotion of environmental exports, including products that comply with U.S. environmental, safety, and related requirements;

(d) States (as defined in 15 U.S.C. 4721(j)(5)) and associations representing the States; and

(e) other appropriate interested members of the public, including labor representatives.

Members of the Committee serve at the pleasure of the Secretary from the date of appointment to the Committee to the date on which the Committee's charter terminates. Members of the Committee serve in a representative capacity, presenting the views and interests of a U.S. entity or U.S. organization, as well as their particular subsector; they are, therefore, not Special Government Employees. Each member of the Committee must be a U.S. citizen and must not be registered as foreign agents under the Foreign Agents Registration Act. No member may represent a company that is majority owned or controlled by a foreign government entity (or foreign government entities). Members of the Committee will not be compensated for their services or reimbursed for their travel expenses. The Department of Commerce invites applications for the ETTAC, consistent with the above membership requirements. To be considered for membership, submit the following information by 5:00 p.m. EDT on August 7, 2026, following the instructions listed in the **ADDRESSES** section.

Committee members are appointed by the Secretary of Commerce based on their individual qualifications and affiliation with an eligible organization. Each appointment is made to a specific individual and is non-transferable. Appointments may not be transferred to another person or organization and do not transfer if a member changes organizational affiliation.

III. Request for Applications

To be considered for ETTAC membership, interested persons should submit a nomination through the form provided on ITA's ETTAC web page: <https://www.trade.gov/ettac>.

The nomination form will request that applicants certify that they meet the following eligibility criteria:

1. The nominee must be a United States citizen.
2. The nominee must not be registered as a foreign agent under the Foreign Agents Registration Act of 1938, as amended.
3. The nominee must represent: a U.S. entity in the environmental technologies, goods, or services sector that is directly engaged in the export of goods or services or that provides services in direct support of the international trading activities of other entities; a State (as defined in 15 U.S.C. 4721(j)(5)) or association representing the States; or a U.S. organization in the

environmental technologies, good, or services sector that trades internationally, represents members that trade internationally, or, consistent with the needs of the ETTAC, has a demonstrated interest in international trade.

4. The nominee must be able to meet the expected time commitments of Committee work, including:

a. Attending Committee meetings approximately eight times throughout the charter (lasting one day each), including attending at least four in-person Committee meetings at the U.S. Department of Commerce. As a federal advisory committee, ETTAC meetings are generally open to the public, and members must be willing to discuss topics in a public setting. Tentative dates are provided below, but final dates, including the dates of in-person meetings, will be determined in consultation with 2026–2028 ETTAC members:

- February 9, 2027 (in-person attendance required)
- April 6, 2027
- June 1, 2027 (in-person attendance required)
- September 14, 2027
- December 7, 2027
- February 8, 2028 (in-person attendance required)
- April 25, 2028
- July 18, 2028 (in-person attendance required)

b. Undertaking additional work outside of full committee meetings including subcommittee conference calls or meetings as needed; and

c. Frequently drafting, preparing, or commenting on proposed recommendations to be evaluated at Committee meetings.

5. The nominee must provide an affirmative statement acknowledging that, if selected, the nominee will serve in a representative capacity to convey the perspectives and interests of the U.S. environmental technologies industry and to contribute recommendations that advance the overall competitiveness and growth of the sector, rather than the interests of any single company or organization.

After submission of the application form, nominees will receive an automated email requesting the nominee to directly submit relevant application documents. The Department of Commerce may also reach out to the nominee to request additional information. Nominees must monitor the email address and phone number provided via the application form to promptly respond to all requests for documentation to ensure consideration of the application.

Application Documents

The following documents are required to be submitted in response to the automated email after the submission of the nomination form. Nominees who do not provide these documents will not be considered for membership.

- Sponsor letter on the company's, association's, State's, or other organization's letterhead containing a brief description of why the Secretary of Commerce should consider the nominee for membership and how the nominee's membership on the ETTAC will support the development, implementation and administration of policies furthering the America First Trade Policy in advancing U.S. trade interests.

- Short biography of the nominee, including credentials;

- Brief description or profile of the company, association, State, or other organization to be represented and its business activities including, as applicable, its company size (number of employees and annual sales); U.S. manufacturing presence; and export markets it serves. If the organization to be represented is an association or otherwise maintains a relevant membership or client list, include the membership or client list demonstrating the organization's representation of U.S. and/or foreign entities.

- Unless the nominee will represent a State (as defined in 15 U.S.C. 4721(j)(5)) or association representing the States, information regarding the ownership or governing structure of the sponsoring organization, and whether it meets the criteria for a U.S. entity or U.S. organization below. If it does not, an explanation of how the sponsoring organization will represent U.S. interests and has a demonstrated interest in the export of U.S. goods or services;

(a) For purposes of this solicitation, the Secretary will give weight to applicants that will represent a U.S. entity that is a for-profit firm engaged in commercial, industrial, or professional activities that is incorporated in the United States (or is an unincorporated U.S. firm with its principal place of business in the United States) that is controlled by U.S. citizens or by other U.S. entities. An entity would not meet these criteria if 50 percent plus one share of its stock (if a corporation, or a similar ownership interest of an unincorporated entity) is known to be controlled, directly or indirectly, by non-U.S. citizens or non-U.S. entities. U.S.-incorporated subsidiaries of foreign-owned companies with U.S. operations should indicate how their

advisory participation reflects U.S. business interests.

(b) For purposes of this solicitation, the Secretary will give weight to applicants that will represent a U.S. organization that is an organization, including a trade association, labor union or organization, or nongovernmental organization (NGO), established under the laws of the United States, that is controlled by U.S. citizens, by another U.S. organization (or organizations), or by a U.S. entity (or entities), as determined based on its board of directors (or comparable governing body), membership, and funding sources, as applicable. To meet these criteria for a U.S. organization, more than 50 percent of the board of directors (or comparable governing body) and more than 50 percent of the membership of the organization to be represented must be U.S. citizens, U.S. organizations, or U.S. entities.

(c) An applicant who will represent an entity or organization known to have 10 percent or greater non-U.S. ownership of its shares or equity, non-U.S. board members, non-U.S. membership, or non-U.S. funding sources, as applicable, should demonstrate that this non-U.S. interest does not constitute control and will not adversely affect his/her ability to further the United States trade goals as a member of the ETTAC.

- Any additional documentation as helpful or necessary for the Secretary of Commerce to consider the nomination. Please do not send company, trade association, or organization brochures.

Selection Factors

The Secretary of Commerce will consider eligible applicants based on their ability to satisfy the following selection factors:

- Represent the interests of a sponsoring U.S. entity, State or association representing the States, or U.S. organization and its subsector on environmental technologies trade matters;
- Carry out the ETTAC's objectives as set forth in its Charter and in 15 U.S.C. 4728(c), including knowledge of matters relevant to U.S. exports of environmental technologies, goods, and services and products that comply with U.S. environmental, safety, and related requirements;
- Contribute to the development, implementation and administration of policies furthering the America First Trade Policy in advancing U.S. trade interests; and
- Provide balance in terms of points of view, industry subsector, geography, and company size.

Any questions regarding the application process or eligibility may be sent to envirotech@trade.gov. Nominees selected for appointment to the Committee will be notified by email.

Dated: June 11, 2026.

Man K. Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2026–12113 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–854]

Certain Steel Nails From Taiwan: Preliminary Results and Rescission, in Part, of Antidumping Duty Administrative Review; 2024–2025

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that Faithful Engineering Products Co., Ltd. (Faithful Engineering) and Top Forever Screws Co., Ltd. (Top Forever) made sales of subject merchandise at less than normal value (NV) during the period of review (POR), July 1, 2024, through June 30, 2025. In addition, we are rescinding the review with respect to 20 companies. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable June 16, 2026.

FOR FURTHER INFORMATION CONTACT:

Henry Wolfe, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0574.

SUPPLEMENTARY INFORMATION:

Background

On July 13, 2015, Commerce published the antidumping duty order on nails from Taiwan.¹ On June 30, 2025, Commerce published a notice of opportunity to request an administrative review of the *Order*.² On July 31, 2025, the domestic interested party, Mid Continent Steel & Wire Inc. (Mid

Continent) filed a timely request for review with respect to 22 companies.³ No other interested party requested an administrative review of the *Order*. Pursuant to this request, on August 22, 2025, Commerce published the *Initiation Notice* in the **Federal Register**.⁴

In the *Initiation Notice*, Commerce indicated that, in the event that it limited the respondents for individual examination in accordance with section 777A(c)(2) of the Tariff Act of 1930, as amended (the Act), Commerce intended to select respondents for individual examination based on U.S. Customs and Border Protection (CBP) data.⁵ On August 25, 2025, Commerce released CBP entry data to interested parties and provided interested parties the opportunity to comment on the CBP data and respondent selection.⁶ No interested parties filed comments regarding the CBP data or respondent selection.

On September 11, 2025, Commerce selected Faithful Engineering and Top Forever as mandatory respondents in this review.⁷ On September 15, 2025, Commerce issued the AD Questionnaire to Faithful Engineering and Top Forever.⁸ However, Faithful Engineering and Top Forever did not timely respond or request an extension of time to respond to Commerce's AD Questionnaire by the deadlines.⁹

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.¹⁰ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an

³ See Mid Continent's Letter, "Request for Administrative Review," dated July 31, 2025.

⁴ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 90 FR 41043, 41054 (August 22, 2025) (*Initiation Notice*).

⁵ *Id.*

⁶ See Memorandum "Release of Customs Data from U.S. Customs and Border Protection," dated August 22, 2025.

⁷ See Memorandum, "Respondent Selection," dated September 11, 2025.

⁸ See Commerce's Letters, "Request for Information," dated September 15, 2025 (AD Questionnaire).

⁹ See Memorandum, "Questionnaire Deadline for Faithful Engineering," dated September 15, 2025; see also Memorandum, "Questionnaire Deadline for Top Forever," dated September 15, 2025.

¹⁰ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

¹ See *Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders*, 80 FR 39994 (July 13, 2015) (*Order*).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 90 FR 27841, 27846 (June 30, 2025).

additional 21 days.¹¹ On June 8, 2026, Commerce extended the deadline for the preliminary results of this review an additional seven days.¹² Accordingly, the deadline for these preliminary results is now June 16, 2026.

Scope of the Order

The merchandise covered by the Order is steel nails. For a full description of the scope, see Appendix I.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an antidumping duty order where it concludes that there were no suspended entries of subject merchandise during the POR.¹³ Normally, upon completion of an administrative review, the suspended entries are liquidated at the antidumping duty assessment rate for the review period.¹⁴ Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the antidumping duty assessment rate calculated for the POR.¹⁵

Commerce notified all interested parties of its intent to rescind the instant review regarding the companies listed in Appendix II to this notice because there were no reviewable, suspended entries of subject merchandise from these companies during the POR and invited interested parties to comment.¹⁶ No party commented on this memorandum. In the absence of any suspended entries of subject merchandise from these companies during the POR, we are rescinding this administrative review for the companies listed in Appendix II to this notice, in accordance with 19 CFR 351.213(d)(3).

Methodology

Pursuant to sections 776(a)(1) and 776(a)(2)(A)–(C) of the Act, Commerce is preliminarily relying upon facts otherwise available to assign estimated dumping margins to mandatory respondents Faithful Engineering and

Top Forever because both companies were unresponsive to our requests for information, thereby withholding necessary information that was requested by Commerce, failing to provide the information requested by the specified deadlines in the form and manner requested, and significantly impeding the conduct of the review. Further, Commerce preliminarily finds that Faithful Engineering and Top Forever failed to cooperate by not acting to the best of their ability to comply with requests for information and, thus, Commerce is applying an adverse inference in selecting among the facts available, in accordance with section 776(b) of the Act. As adverse facts available, we are assigning these companies a rate of 78.17 percent, which is the highest rate applied in any segment of this proceeding.¹⁷ Based on this determination, there are no memoranda accompanying this notice.

Preliminary Results of Review

As a result of this review, we preliminarily determine that the following estimated weighted-average dumping margins exist for the period, July 1, 2024, through June 30, 2025:

Producer or exporter	Weighted-average dumping margin (percent)
Faithful Engineering Products Co., Ltd	78.17
Top Forever Screws Co., Ltd	78.17

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied total adverse facts available to the two companies subject to this review, in accordance with section 776 of the Act, there are no calculations to disclose.

¹⁷ See *Certain Steel Nails from Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Administrative Review; 2015–2016*, 82 FR 36744 (August 7, 2017), and accompanying Preliminary Decision Memorandum, unchanged in *Certain Steel Nails from Taiwan: Final Results of Antidumping Duty Administrative Review and Partial Rescission of Administrative Review; 2015–2016*, 83 FR 6163 (February 13, 2018).

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Pursuant to 19 CFR 351.309(c)(1)(ii), we have modified the deadline for interested parties to submit case briefs to Commerce to no later than 21 days after the date of the publication of this notice.¹⁸ Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.¹⁹ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.²⁰ All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs an executive summary for each issue raised in their briefs.²¹ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).²²

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing

¹⁸ See 19 CFR 351.309.

¹⁹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

²⁰ See 19 CFR 351.309(c)(2) and (d)(2).

²¹ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

²² See *APO and Service Procedures*.

¹¹ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

¹² See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated June 8, 2025.

¹³ See, e.g., *Diocetyl Terephthalate from the Republic of Korea: Rescission of Antidumping Administrative Review; 2021–2022*, 88 FR 24758 (April 24, 2023); see also *Certain Carbon and Alloy Steel Cut-to-Length Plate from the Federal Republic of Germany: Rescission of Antidumping Administrative Review; 2020–2021*, 88 FR 4157 (January 24, 2023).

¹⁴ See 19 CFR 351.212(b)(1).

¹⁵ See 19 CFR 351.213(d)(3).

¹⁶ See Memorandum, "Notice of Intent to Rescind Review, In Part," dated December 9, 2025.

will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, within 30 days after the date of publication of this notice. If a request for a hearing is made, Commerce intends to hold a hearing at a time and date to be determined.²³ Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Assessment Rates

Upon issuing the final results of this review, Commerce will determine, and U.S. CBP shall assess, antidumping duties on all appropriate entries covered by this review.²⁴ With respect to the companies for which we have rescinded this review in part, Commerce intends to instruct CBP to assess antidumping duties on all appropriate entries at rates equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the POR, in accordance with 19 CFR 351.212(c)(1)(i).

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not covered by this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company

participated; (3) if the exporter is not a firm covered in this review or another completed segment of this proceeding, but the manufacturer is, then the cash deposit rate will be the company-specific rate established for the completed segment for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 2.16 percent, the all-others rate established in the less-than-fair-value investigation.²⁵ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(4).

Dated: June 11, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistance Secretary for Enforcement and Compliance.

Appendix I

Scope of the Order

The merchandise covered by the *Order* is certain steel nails having a nominal shaft length not exceeding 12 inches. Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat,

projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of the *Order* are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of (i) medical, surgical, dental or veterinary furniture; and (ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (*e.g.*, furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of the *Order* are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision). Also excluded from the scope of the *Order* are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of the *Order* are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth

²³ See 19 CFR 351.310(d).

²⁴ See 19 CFR 351.212(b).

²⁵ See *Certain Steel Nails from Taiwan: Notice of Court Decision Not in Harmony With Final Determination in Less Than Fair Value Investigation and Notice of Amended Final Determination*, 82 FR 55090 (November 20, 2017).

symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of the *Order* are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of the *Order* are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to the *Order* are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to the *Order* also may be classified under HTSUS subheadings 7907.00.60.00, 8206.00.00.00, 7806.00.80.00, 7318.29.00.00, or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.

Appendix II

Companies for Which Commerce Is Rescinding the Administrative Review

1. Chunyu Factory Co., Ltd
2. Cool Shot Ltd.
3. Encore Green Co., Ltd
4. Fang Sheng Screw Co., Ltd
5. Fwang Tzay Enterprise Corp
6. Herstel Trading Limited
7. Home Value Co., Ltd.
8. Hsi Yi Enterprise Co. Ltd.
9. Hsin Ho Mfg. Co., Ltd.
10. Joker Industrial Co., Ltd.
11. Leading Hardware Corporation
12. Lu Chu Shin Yee Works Co., Ltd.
13. Panther T & H Industry Co., Ltd.
14. Perfect Seller Co., Ltd.
15. Phoenix Merchandise Inc.
16. Rexlen Corporation
17. Sanji Co., Ltd.
18. Sourcing Metrics Ltd.
19. TG Co., Ltd
20. Xiamen Huiyu Chemical Trading Co.

[FR Doc. 2026–12102 Filed 6–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–856]

Chromium Trioxide From the Republic of Türkiye: Postponement of Final Determination of Sales at Less-Than-Fair-Value Investigation and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is postponing the deadline for issuing the final determination in the less-than-fair-value

(LTFV) investigation of chromium trioxide from the Republic of Türkiye (Türkiye) until October 5, 2026, and is extending the provisional measures from a four-month period to a period of not more than six months.

DATES: Applicable June 16, 2026.

FOR FURTHER INFORMATION CONTACT:

Colin Thrasher, Office V, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3004.

SUPPLEMENTARY INFORMATION:

Background

On January 5, 2026, Commerce initiated the LTFV investigation of chromium trioxide from Türkiye.¹ The period of investigation is July 1, 2024, through June 30, 2025. On May 22, 2026, Commerce published the *Preliminary Determination* in this LTFV investigation.²

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(2) provide that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters or producers who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Further, 19 CFR 351.210(e)(2) requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period of not more than six months, in accordance with section 733(d) of the Act.

On May 20, 2026, pursuant to 19 CFR 351.210(e), the sole mandatory respondent in this investigation, Türkiye Şişe ve Cam Fabrikaları A.Ş. (Şişecam), requested that Commerce postpone the deadline for the final determination until no later than 135 days from the publication of the *Preliminary Determination*, and that

¹ See *Chromium Trioxide from India and the Republic of Türkiye: Initiation of Less-Than-Fair-Value Investigations*, 91 FR 234 (January 5, 2026).

² See *Chromium Trioxide from the Republic of Türkiye: Preliminary Affirmative Determination of Sales at Less than Fair Value*, 91 FR 30280 (May 22, 2026) (*Preliminary Determination*).

provisional measures be extended to a period not to exceed six months.³ In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the *Preliminary Determination* is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination until no later than 135 days after the date of the publication of the *Preliminary Determination*, and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will issue its final determination no later than October 5, 2026.⁴

Notification to Interested Parties

This notice is issued and published pursuant to section 735(a)(2)(A) of the Act and 19 CFR 351.210(g).

Dated: June 5, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2026–12099 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Parts Tariff Offset Program for Automobiles, MHDVs, and Engines

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public

³ See Şişecam's letter, "Şişecam's Final Determination Extension Request," dated May 20, 2026.

⁴ Commerce's practice dictates that, where a deadline falls on a weekend or Federal holiday, the appropriate deadline is the next business day. See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005).

comments were previously requested via the **Federal Register** on November 26, 2025, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: International Trade Administration, Commerce.

Title: Parts Tariff Offset Program for Automobiles, MHDVs, and Engines.

OMB Control Number: 0625–0283.

Form Number(s): None.

Type of Request: Regular submission, extension with a revision of a current information collection.

Number of Respondents: 50.

Average Hours per Response: 40 hours.

Burden Hours: 4,000.

Needs and Uses: On March 26, 2025, the President issued Proclamation 10908 (90 FR 14705), “Adjusting Imports of Automobiles and Automobile Parts Into the United States,” (Proclamation 10908) finding that imports of automobiles and certain automobile parts continue to threaten to impair the national security of the United States and imposing specified tariffs to adjust imports of automobiles and certain automobiles parts so that such imports will not threaten to impair national security pursuant to Section 232 of the Trade Expansion Act of 1962 (“Section 232”). Section 232 authorizes the President to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States so that such imports will not threaten to impair national security. Proclamation 10908 imposed a 25 percent tariff on certain imports of automobiles, effective April 3, 2025, and certain imports of automobile parts, effective May 3, 2025.

On April 29, 2025, the President issued Proclamation 10925 (90 FR 18899), which allowed for automobile manufacturers assembling automobiles in the United States to apply for an import adjustment offset amount, which would offset certain tariff liability under Proclamation 10908 on imports of automobile parts. Proclamation 10925 required that within 30 days of the date of the order the Secretary of the Department of Commerce (Commerce) shall establish a process by which automobile manufacturers could submit documentation supporting eligibility and a claim for an import adjustment offset amount.

On June 13, 2025, the International Trade Administration published a Notice titled “Procedures To Administer Import Adjustment Offset Amounts for Certain Imports of Automobile Parts Under Proclamation 10908, as

Amended” (90 FR 25027), which established procedures for automobile manufacturers to apply for and use the import adjustment offset amount established by Presidential Proclamation 10925 of April 29, 2025 (90 FR 18899), “Amendments to Adjusting Imports of Automobiles and Automobile Parts Into the United States” (Proclamation 10925) to incentivize domestic automobile production and reduce American reliance on imports of foreign automobiles and their parts.

Proclamation 10984 of October 17, 2025, “Adjusting Imports of Medium- and Heavy Duty Vehicles, Medium- and Heavy-Duty Vehicle Parts, and Buses Into the United States,” (Proclamation 10984) took similar action to address the threat imports of Medium- and Heavy-Duty Vehicles (MHDV) and Medium- and Heavy-Duty Vehicle Parts (MHDVPs) pose to the national security of the United States; that Proclamation also amended the offset rules established by Proclamation 10925.

Through this Offset Program automobile and MHDV manufacturers with final production in the United States have the opportunity to submit documentation to request an import adjustment offset amount for their parts. The import adjustment offset may only be used by importers of record authorized by that manufacturer, and the amount may only be used to offset tariff liability related to that manufacturer’s automobile and MHDV parts tariff liability under Proclamation 10908 or Proclamation 10984 and any future related Proclamations.

On May 15, 2026, the International Trade Administration published a Notice titled “Amending the Procedures To Administer Import Adjustment Offset Amounts for Certain Imports of Automobile Parts Under Proclamation 10908 to Include Medium- and Heavy-Duty Vehicle Parts” (May 15 Notice), which established amended procedures for automobile and medium- and heavy-duty vehicle (MHDV) manufacturers to apply for and use the import adjustment offset amounts established by Presidential Proclamation 10925 of April 29, 2025, “Amendments to Adjusting Imports of Automobiles and Automobile Parts Into the United States”, and Presidential Proclamation 10984 of October 17, 2025, “Adjusting Imports of Medium- and Heavy-Duty Vehicles, Medium- and Heavy-Duty Vehicle Parts, and Buses Into the United States.” Procedures to allow domestic manufacturers of automobile engines and MHDV engines to claim import adjustment offsets for imports of parts in a manner consistent with those

Proclamations have been established. The procedures exclude certain engine assembly operations determined to be limited production operations from being considered in the calculation of offsets.

During the normal extension period, ICR 0625–0283 underwent multiple revisions driven by evolving Administration policy priorities and implementation requirements, often with limited lead time. These revisions expanded the existing Offset Program to include medium- and heavy-duty vehicles (MHDVs), MHDV parts, and engines. To avoid the need for multiple future emergency approvals for every collection within the same program scope, this renewal incorporates those revisions and updates the title of the information collection to comprehensively reflect all categories covered under the Offset Program.

Affected Public: Business or other for-profit organizations.

Frequency: Twice annually.

Respondent’s Obligation: Voluntary.

Legal Authority: Proclamations 10908, 10925 and 10984.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the collection or the OMB Control Number 0625–0283.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–12092 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF691]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Surfclam and Ocean Quahog Advisory Panel will hold a public webinar meeting. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will be held on Tuesday, July 7, 2026, from 9 a.m. until 12 p.m.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the calendar prior to the meeting at <https://www.mafmc.org>.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331; <https://www.mafmc.org>.

FOR FURTHER INFORMATION CONTACT:

Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the Advisory Panel to develop a fishery performance report (FPR) for Atlantic surfclam and ocean quahog. The intent of the FPR is to provide structured input from the Advisory Panel for the specifications processes. The FPR will be used by the MAFMC's Scientific and Statistical Committee and Council when reviewing specifications for the 2027 and 2028 fishing years.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526-5251, at least 5 days prior to the meeting date.

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

Dated: June 12, 2026.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026-12112 Filed 6-15-26; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648-XF707]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to S50S/LNG and S499 Bulkheads Replacement Project at Naval Station Newport, Rhode Island

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of incidental harassment authorizations.

SUMMARY: In accordance with regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued two consecutive 1-year incidental harassment authorizations (IHAs) to the United States Navy (Navy) for authorization to take marine mammals incidental to construction activities associated with the S50S/LNG and S499 Bulkheads Replacement Project at Naval Station (NAVSTA) Newport, Rhode Island (RI).

DATES: The Year 1 IHA is effective for 1 year from the date of notification by the IHA-holder, not to exceed 1 year from the date of issuance (June 11, 2026). The Year 2 IHA is effective for 1 year from the date of notification by the IHA-holder, not to exceed 1 year from the date of expiration of the Year 1 IHA.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT:

Carter Esch, Office of Protected Resources, NMFS (301) 427-8401.

SUPPLEMENTARY INFORMATION:**MMPA Background and Determinations**

The MMPA prohibits the "take" of marine mammals, with certain exceptions. Among the exceptions is section 101(a)(5)(D) of the MMPA (16 U.S.C. 1361 *et seq.*) which directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking by harassment of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and the public has an opportunity to comment on the proposed IHA.

Specifically, NMFS shall issue an IHA if it finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe

the permissible methods of taking and other "means of effecting the least [practicable] adverse impact" on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as "mitigation"). NMFS must also prescribe requirements pertaining to the monitoring and reporting of such takings. The definitions of key terms, such as "take," "harassment," and "negligible impact," can be found in the MMPA and the NMFS' implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

On May 7, 2026, a notice of NMFS' proposal to issue two consecutive 1-year IHAs to the Navy for the taking of seven species of marine mammals incidental to construction activities supporting the S50S/LNG and S499 Bulkheads Replacement Project at NAVSTA in Newport, RI, was published in the **Federal Register** (91 FR 24817). In that notice, NMFS provided estimates of the numbers, type, and methods of incidental take proposed for each species or stock, as well as the mitigation, monitoring, and reporting measures that would be required should the IHAs be issued. The **Federal Register** notice also included analysis to support NMFS' preliminary conclusions and determinations that the IHAs, if issued, would satisfy the requirements of section 101(a)(5)(D) of the MMPA for issuance of the IHAs. The **Federal Register** notice included web links to review supporting documents including the draft IHAs, which would each be valid for the statutory maximum of 1 year from the date of effectiveness and will become effective upon written notification from the IHA Holder (*i.e.*, the Navy) to NMFS, but not beginning later than 1 year from the date of issuance or extending beyond 2 years from the date of issuance (Year 1), or beginning later than 1 year from the date of expiration of the Year 1 IHA (Year 2).

No comments were received during the public comment period. There are no changes to the specified activity, the species taken, the proposed numbers, type, or methods of take, or the mitigation, monitoring, or reporting measures in the notice of the proposed IHAs. No new information that would change any of the preliminary analyses, conclusions, or determinations in the notice of the proposed IHAs has become available since that notice was published, and therefore, the preliminary analyses, conclusions, and determinations included in the proposed IHAs are considered final.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHAs qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species. No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Authorization

Accordingly, consistent with the requirements of section 101(a)(5)(D) of the MMPA, NMFS has issued two consecutive 1-year IHAs to the Navy for authorization to take seven species of marine mammals incidental to construction activities supporting the S50S/LNG and S499 Bulkheads Replacement Project at NAVSTA in Newport, RI.

Dated: June 12, 2026.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2026–12111 Filed 6–15–26; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038–0096, Swap Data Recordkeeping and Reporting Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (“CFTC” or “Commission”) is announcing an opportunity for public comment on the proposed renewal of an information collection by the agency. Under the Paperwork Reduction Act (“PRA”), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on the information collections pertaining to the Commission’s swap data recordkeeping and reporting requirements. These rules impose recordkeeping and reporting requirements on the following entities: Swap Dealers (“SDs”), Major Swap Participants (“MSPs”), Swap Execution Facilities (“SEFs”), designated contract markets (“DCMs”), swap data repositories (“SDRs”), derivatives clearing organizations (“DCOs”), and swap counterparties that are neither swap dealers nor major swap participants (“non-SD/MSP counterparties”).

DATES: Comments must be submitted on or before August 17, 2026.

ADDRESSES: You may submit comments, specifically referencing “OMB Control No. 3038–0096,” by any of the following methods:

- **Regulations.gov:** Go to <https://www.regulations.gov> and press the “Search” button, then proceed as follows:
 1. Under Refine Documents Results—check the box to “Only show documents open for comment”;
 2. Under Agency—select “See More” and check the box for “Commodity Futures Trading Commission,” then press the Apply button;
 3. Identify this notice in the list of CFTC documents open for comment, press the “Comment” button to open the submission form, and follow the instructions on the form.

Alternatively, if you are viewing this notice on www.federalregister.gov, click the “Submit A Public Comment” button at the top of the page to open the

comment form. Follow the instructions on the form to submit your comment to Regulations.gov.

- **Mail:** Send to—Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

- **Hand Delivery/Courier:** Address to—CFTC Comment Submission, Attn: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

Please submit your comments using only one of these methods. To avoid possible delays with mail or in-person deliveries, submissions through Regulations.gov are encouraged.

All comments must be submitted in English or, if not, accompanied by an English translation. Do not include in your comment text or attachments any personal identifying information or business information that you do not want published online. Comments (regardless of submission method) will be published without review for, and without removal of, any personal identifying information or information your business may consider confidential.

If you wish to submit confidential information for the Commission’s consideration, please contact the CFTC personnel listed in this Notice under **FOR FURTHER INFORMATION CONTACT** before making any submission. Please also carefully review the Commission’s procedures in 17 CFR 145.9 for requesting confidential treatment under the Freedom of Information Act (FOIA) of information submitted to the Commission.

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, or redact all or any part of your comment submission. The CFTC also reserves the right, without further notification, to refuse to publish or to remove from public view all or any part of your submission to the extent it contains content inappropriate for publication in a comment file, such as—without limitation—obscene language, threats of violence, solicitations for commercial sales or illegal activity, or obvious spam. If a submission that is refused for or withdrawn from publication because of inappropriate content also contains comments on the merits of this notice, such submission will be retained in the record for the matter and will be considered as required under the Administrative Procedure Act, the Paperwork Reduction Act, and other applicable

laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT:

Owen Kopon, Associate Director, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581 (202) 418–5360; email: okopon@cftc.gov.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.*, Federal agencies must obtain approval from the Office of Management and Budget (“OMB”) for each collection of information they conduct or sponsor. “Collection of Information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed information collection including each proposed extension of an existing information collection, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of a proposed extension of the currently approved information collection listed below. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

Title: Swap Data Recordkeeping and Reporting Requirements (OMB Control No. 3038–0096). This is a request for an extension of a currently approved information collection.

Abstract: The collection of information is needed to ensure that the CFTC and other regulators have access to swap data as required by the Commodity Exchange Act, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”). The Dodd-Frank Act directed the CFTC to adopt rules providing for the reporting of data relating to swaps. In 2012, the CFTC adopted part 45, which imposes recordkeeping and reporting requirements relating to swaps. In 2020, a final rule adopting modifications to part 45 was adopted by the Commission.¹

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the CFTC, including whether the information will have a practical use;

- The accuracy of the CFTC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

Burden Statement: Part 45 of the Commission’s regulations establishes swap reporting and recordkeeping requirements for swap execution facilities (“SEFs”), designated contract markets (“DCMs”), swap data repositories (“SDRs”), derivatives clearing organizations (“DCOs”), swap dealers (“SDs”), major swap participants (“MSPs”), and non-SD/MSP/DCO counterparties (“non-SD/MSP counterparties”). The Commission estimates the burden of the collection of information as set out below.

Respondents/Affected Entities: Swap Dealers, Major Swap Participants, SEFs, DCMs, DCOs, and other counterparties to a swap transaction (*i.e.*, end-user, non-SD/non-MSP counterparties).

Estimated number of respondents: 1,732.

Estimated average burden hours per respondent: 839 hours (rounded).

Estimated total annual burden hours on respondents: 1,452,730 hours.

Frequency of collection: Ongoing.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: June 11, 2026.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2026–12041 Filed 6–15–26; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–SCC–1190]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Prison Education Program Application

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before July 16, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. Reginfo.gov provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, (202) 453–5967.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Prison Education Program Application.

¹ Final Rule, Swap Data Recordkeeping and Reporting Requirements, 85 FR 75503 (Nov. 25, 2020).

OMB Control Number: 1845–0171.
Type of Review: Extension without change of a currently approved ICR.
Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 800.

Total Estimated Number of Annual Burden Hours: 800.

Abstract: Prison Education Programs (PEP) is authorized under section 484(t) of the Higher Education Act of 1965, as amended (HEA) with the requirements for participation outlined in 34 CFR 668, Subpart P. These are the regulatory requirements for a school to offer a PEP to confined or incarcerated students.

This is a request for an extension without change for the application form from institutions that wish to participate in PEP under the regulations in 668, Subpart P. There have been no changes to the regulations.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–12096 Filed 6–15–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–SCC–0694]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Assistance General Provisions—Satisfactory Academic Progress Policy

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before July 16, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents

related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, (202) 453–5967.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Satisfactory Academic Progress Policy.

OMB Control Number: 1845–0108.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector; Individuals and Households; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 31,575,067.

Total Estimated Number of Annual Burden Hours: 1,383,595.

Abstract: The Department of Education (the Department) is requesting an extension of the current approval of the policies and procedures for determining satisfactory academic progress (SAP) as required in Section 484 of the Higher Education Act of 1965, as amended (HEA). A link to the Satisfactory Academic Progress regulations is provided at 34 CFR 668.34 and 34 CFR 600.55.

These regulations identify the policies and procedures to track if students are making satisfactory academic progress in their program at a pace and a level to receive or continue to receive Title IV, HEA program funds. If there is lapse in progress, the policy must identify how the student will be notified and what steps are available to a student not making satisfactory academic progress toward the completion of their program, and under what conditions a student who is not making satisfactory academic

progress may continue to receive Title IV, HEA program funds. There have been no changes to this collection.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–12097 Filed 6–15–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–SCC–1288]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for Approval To Participate in Federal Student Aid Programs

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before July 16, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, (202) 453–5967.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance

the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Approval to Participate in Federal Student Aid Programs.

OMB Control Number: 1845–0012.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 4,248.

Total Estimated Number of Annual Burden Hours: 16,097.

Abstract: Section 487(c) of the Higher Education Act (HEA) of 1965, as amended, requires that the Secretary of Education prescribe regulations to ensure that any funds postsecondary institutions receive under the HEA are used solely for the purposes specified in and in accordance with the provision of the applicable programs.

The One Big Beautiful Bill Act (OBBBA), signed into law on July 4, 2025, made statutory changes to Federal Pell Grants that impact regulatory requirements proposed in this information collection. Section 83002(b) of the OBBBA established a new academic program in which eligible students can receive Pell Grants. Programs must meet several criteria to become eligible workforce programs which the Department must obtain, review and maintain as outlined in the law and regulations.

This is a request for a revision of 1845–0012 to add Eligible Workforce Programs to the Application. There have been no other changes to the collection since the last ICR approved by OMB on 03/31/2026. All additional burden currently assessed to this collection remain the same.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–12110 Filed 6–15–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

National Coal Council

AGENCY: Hydrocarbons and Geothermal Energy Office (HGEO), Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the National Coal Council. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, July 21, 2026; 8 a.m. to 12 noon (EDT).

ADDRESSES: The Willard Hotel, 1401 Pennsylvania Ave NW, Washington, DC 20004. The meeting will be held in the Willard Room. In-person meeting. Information to access a live stream of the meeting proceedings will be available at: <https://nationalcoalcouncil.energy.gov/ncc/future-meetings>.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Giove, U.S. Department of Energy, telephone: (301) 903–4130 or email: joseph.giove@doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to coal and the coal industry.

Purpose of the Meeting: The National Coal Council will hold a meeting on July 21, 2026, to present, discuss and possibly finalize two subcommittee reports, and to discuss 1–2 new reports to be conducted in the future.

Tentative Agenda:

- Welcome from the Acting Assistant Secretary (HGEO) and Meeting Room Logistics;
- Welcome and Congratulatory Remarks from the Secretary of Energy; Secretary of Interior, and Secretary of Labor.
- Presentation/Discussion/Vote on two NCC subcommittee studies.
- Announcement of 1–2 new NCC studies.
- Public Statements, if any; and
- Dismissal.

Public Participation: The meeting will be accessible to the public via live stream, and will be conducted by the Council Chair to ensure an orderly flow of business. To make an oral statement on any agenda item, please contact Mr. Joseph Giove (using the contact details listed above) at least seven days prior to the meeting. Approximately 10 minutes will be reserved for public comments; individual speaking times will depend on the number of requests received but will not exceed three minutes per speaker. If you wish to attend the meeting in person, you must register seven days in advance, as space is limited, so please contact Mr. Giove to reserve a space. Written comments are also welcome either before or after the meeting and may be submitted directly to Mr. Giove for distribution to the committee.

Minutes: The minutes of the meeting will be available at <https://nationalcoalcouncil.energy.gov/ncc/past-meetings-and-events> or by contacting Mr. Giove. He may be reached at the email address or telephone number listed previously.

Signing Authority

This document of the Department of Energy was signed on June 11, 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC on June 12, 2026.

Treena V. Garrett,

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

[FR Doc. 2026–12061 Filed 6–15–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–488–A]

Application for Renewal of Authorization To Export Electric Energy; Mercuria Commodities Canada Corporation

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Mercuria Commodities Canada Corporation (the Applicant or MCCC) has applied for renewal of authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before July 16, 2026.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to Electricity.Exports@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Marina Fennel, (240) 702–6156, Electricity.Exports@hq.doe.gov.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from

the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export (16 U.S.C. 824a(e)). On January 8, 2026, the authority to issue such orders was delegated to the DOE's Assistant Secretary for Electricity by Redelegation Order No. S3-DEL-OE1-2026.

On February 25, 2026, MCCC filed an application with DOE (Application or App.) for renewal of export authority to transmit electric energy from the United States to Canada for an additional five-year term. App. at 1.

According to the Application, MCCC is an energy marketing and trading company authorized by the Federal Energy Regulatory Commission (FERC) "to make wholesale sales of electricity" pursuant to its market-based rate authority, granted by FERC in April of 2018. *Id.* at 2. MCCC states that its principal place of business is in Calgary, Alberta, Canada. *Id.* at 1. MCCC further represents that it "is subsidiary of the ultimate parent company Mercuria Energy Group Holding Ltd," which is a Cayman Islands holding company. *Id.* at 1-2.

In its Application, MCCC states that it will export wholesale electricity to Canada from "existing transmission interconnections between the United States and Canada." *Id.* at 3. MCCC notes that it "does not currently own, operate or control electric transmission or distribution facilities in the United States over which the export of wholesale electricity could have a reliability, fuel use, or system stability impact, nor is it affiliated with any entity that owns, operates, or controls electric transmission or distribution facilities in the United States over which the export of wholesale electricity could have a reliability, fuel use, or system stability impact." *Id.* Further, "MCCC does not own, or operate generation anywhere in the United States, nor is it affiliated with any entity that owns, operates or controls generation anywhere in the United States, and therefore, the wholesale electricity that MCCC will export using firm or interruptible transmission service will be purchased from other suppliers (*i.e.*, generators,

electric utilities and other power marketers) voluntarily, and therefore will be surplus to the needs of the selling entities." *Id.* MCCC asserts that exports of electricity under such circumstances would not impair or tend to impede the sufficiency of electric supply within the U.S. *Id.* at 4. MCCC states that it will conduct all electricity exports "in compliance with all applicable rules and regulations, including the standards and guidelines of the [North American Electric Reliability Corporation ('NERC')], Regional Reliability Councils, control area operators and the protocols, tariffs and manuals for all applicable regional transmission organizations or independent system operators." *Id.*

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at Electricity.Exports@hq.doe.gov. Protests should be filed in accordance with Rule 211 of FERC's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at Electricity.Exports@hq.doe.gov in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning MCCC's Application should be clearly marked with OE Docket No. EA-488-A. Additional copies are to be provided directly to Jay Michals, 20 E Greenway Plaza, Suite 650, Houston, TX 77046, jmichals@mercuria.com and Greg Johnston, Suite 600, 326-11th Avenue SW, Calgary, Alberta T2R0C5 Canada, gjohnston@mercuria.com.

A final decision will be made on the requested authorization after DOE evaluates environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (June 2025), including 10 CFR part 1021, and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at www.energy.gov/oe/pending-applications or by emailing Electricity.Exports@hq.doe.gov.

Signing Authority

This document of the Department of Energy was signed on June 12, 2026, by Victoria Tran, Acting Deputy Assistant Secretary, Office of Electricity, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 12, 2026.

Treena V. Garrett,

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

[FR Doc. 2026-12093 Filed 6-15-26; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. No. 94-409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: June 18, 2026, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426. Open to the public.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* *Note*—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Debbie-Anne A. Reese, Secretary, Telephone (202) 502-8400.

For a recorded message listing items stricken from or added to the meeting, call (202) 502-8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed online at the Commission's website at <https://elibrary.ferc.gov/eLibrary/search> using the eLibrary link.

1137TH—MEETING

[Open; June 18, 2026, 10:00 a.m.]

Item No.	Docket No.	Company
Administrative		
A-1	AD26-1-000	Agency Administrative Matters.
A-2	AD26-2-000	Customer Matters, Reliability, Security and Market Operations.
Electric		
E-1	RM26-4-000	Interconnection of Large Loads to the Interstate Transmission System.
E-2	EL25-49-002	PJM Interconnection, L.L.C.
	EL25-49-000	Allegheny Electric Cooperative, Inc., American Transmission Systems, Incorporated, Atlantic City Electric Company, Baltimore Gas and Electric Company, Delmarva Power & Light Company, Duke Energy Ohio, Inc., Duke Energy Kentucky, Inc., East Kentucky Power Cooperative, Inc., Essential Power Rock Springs, LLC, Hudson Transmission Partners, LLC, Jersey Central Power & Light Company, Mid-Atlantic Interstate Transmission, LLC, Neptune Regional Transmission System, LLC, Old Dominion Electric Cooperative, PECO Energy Company, PPL Electric Utilities Corporation, Potomac Electric Power Company, Public Service Electric and Gas Company, Rockland Electric Company, Trans-Allegheny Interstate Line Company, Transource West Virginia, LLC, UGI Utilities, Inc., Monongahela Power Company, The Potomac Edison Company, Commonwealth Edison Company, Commonwealth Edison Company of Indiana, Inc., The Dayton Power and Light Company, AEP Appalachian Transmission Company, Inc., AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Ohio Transmission Company, Inc., AEP West Virginia Transmission Company, Inc., Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, Duquesne Light Company, Virginia Electric and Power Company, Linden VFT, LLC, City of Cleveland, Department of Public Utilities, Division of Cleveland Public Power, City of Hamilton, OH, Southern Maryland Electric Cooperative, Inc., Ohio Valley Electric Corporation, AMP Transmission, LLC, Silver Run Electric, LLC, NextEra Energy Transmission MidAtlantic Indiana, Inc., Wabash Valley Power Association, Inc. and Keystone Appalachian Transmission Company.
	AD24-11-001	Large Loads Co-Located at Generating Facilities.
	EL25-20-001 (consolidated)	Constellation Energy Generation, LLC v. PJM Interconnection, L.L.C.
	ER26-1479-000	PJM Interconnection, L.L.C.
E-3	ER23-313-000	Public Service Company of New Mexico.
E-4	ER23-340-000	El Paso Electric Company.
E-5	ER23-312-000	Townsite Solar, LLC.
E-6	ER25-1886-000	Midcontinent Independent System Operator, Inc.
	ER25-1886-001.	
Miscellaneous		
M-1	RM26-12-000	Revisions to Financial Forms Reporting and Filing Requirements.
Hydro		
H-1	P-15402-000	Kinetic Energy Storage LLC.
Certificates		
C-1	CP25-10-001	Transcontinental Gas Pipe Line Company, LLC.
C-2	CP25-528-000	Eastern Gas Transmission and Storage, Inc.
C-3	CP26-52-000	Cheniere Creole Trail Pipeline, L.P.

A free webcast of this event is available through the Commission's website. Anyone with internet access who desires to view this event can do so by navigating to www.ferc.gov's Calendar of Events and locating this event in the Calendar. The Federal Energy Regulatory Commission provides technical support for the free webcasts.

Please call (202) 502-8680 or email customer@ferc.gov if you have any questions.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is

intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters but will not be telecast.

Issued: June 11, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–12079 Filed 6–12–26; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC26–28–000]

Commission Information Collection Activities (FERC–1005); Comment Request; Extension

AGENCY: Federal Energy Regulatory
Commission.

ACTION: Notice of information collection
and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collection FERC–1005: Credit Related Information Sharing Between RTOs/ISOs to the Office of Management and Budget (OMB) for review of the information collection requirements. There are no proposed changes to the information sharing requirement, but the Commission is removing a one-time information collection that has been completed. There were no comments on the 60-day **Federal Register** Notice.

DATES: Comments on the collections of information are due July 16, 2026.

ADDRESSES: Send written comments on FERC–1005 to OMB through https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202604-1902-004. You can also visit <https://www.reginfo.gov/public/do/PRAMain> and use the drop-down under “Currently under Review” to select the

“Federal Energy Regulatory Commission” where you can see the open opportunities to provide comments. Comments should be sent within 30 days of publication of this notice.

- Please submit a copy of your comments to the Commission via email to DataClearance@FERC.gov. You must specify the Docket No. (IC26–28–000) and the FERC Information Collection number (FERC–1005) in your email. If you are unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service Only:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *All other delivery methods:* Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Docket: To view comments and issuances in this docket, please visit <https://elibrary.ferc.gov/eLibrary/search>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov, or by telephone at (202) 502–6468.

SUPPLEMENTARY INFORMATION:

Title: Credit Related Information Sharing Between RTOs/ISOs.

OMB Control No.: 1902–0325.

Type of Request: Three-year extension of the FERC–1005 information collection requirements with no changes to the on-going reporting requirements.

Abstract: In 2023, FERC issued the Final Rule in Docket No. RM22–13–000 for RTOs/ISOs to share credit-related information with each other to improve their ability to accurately assess market participants’ credit exposure and risks related to their activities across organized wholesale electric markets. The ability to share such information also enables RTOs/ISOs to respond to credit events more quickly and

effectively, minimizing the overall credit-related risks of unexpected defaults by market participants in organized wholesale electric markets. Examples of the types of information RTOs/ISOs are allowed include: (1) lists of market participants with positions in that market; (2) reports and metrics around risk and credit exposures; (3) disclosure that a market participant or affiliate has defaulted on any of its financial or contractual obligations, failed to pay invoices on a timely basis, or failed to meet a collateral call; (4) information regarding a market participant’s or its affiliate’s unresolved credit/collateral issues; (5) information indicating that a market participant or its affiliate has an increased risk of default, such as instances where a market participant or its affiliate has experienced a material adverse condition or material adverse change under an RTO/ISO OATT or related agreement; and (6) any other information on a market participant or its affiliate that indicates a possible material adverse change in creditworthiness or financial status or an unreasonable credit risk.

The rule did not create an information collection that is submitted to FERC, rather it permits RTOs/ISOs to share information and directed RTOs/ISOs to update their tariff provisions to include processes and procedures to do so. This process has been completed, which is why the Commission is removing the burden related to this action. The remaining burden is associated with facilitating the information sharing between entities in accordance with each RTO’s/ISO’s processes and procedures.

Type of Respondents: RTOs/ISOs.

*Estimate of Annual Burden:*¹ The Commission estimates the annual public reporting burden for the information collection as:

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ²	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Credit Related Information Sharing (ongoing).	6	2	12	4 hrs.; \$408	48 hrs.; \$4,896	\$916.

¹ The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or

provide information to or for a Federal agency. For further explanation of what is included in the

information collection burden, reference 5 Code of Federal Regulations 1320.3.

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ²	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Information Collection Activities to be removed						
Tariff Provisions Compliance Filing (one-time).	6	1	6	25 hrs.; \$2,550	150 hrs.; \$15,300	25 hrs.; \$2,550.
Total			12		48 hrs.; \$4,896.	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: June 10, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-12017 Filed 6-15-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2242-159]

Eugene Water & Electric Board; Notice of Availability of Environmental Assessment

The final EA contains Commission staff's analysis of the potential environmental effects of the proposed load bank station alternative, alternatives to the proposed action, and concludes that the proposed load bank with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The final EA may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link.

² The Commission staff estimates that industry is similarly situated in terms of hourly cost (for wages plus benefits). Based on the Commission's FY (Fiscal Year) 2026 average cost (for wages plus benefits), \$102/hour is used.

Enter the docket number (P-2242) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed by 5:00 p.m. Eastern Time on July 13, 2026.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-2242-159.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

For further information, contact Erich Gaedeke at 503-552-2716 or erich.gaedeke@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: June 11, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-12078 Filed 6-15-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD26-8-000]

Reliability Technical Conference; Notice of Reliability Technical Conference

The Federal Energy Regulatory Commission (Commission) will convene its annual Commissioner-led Reliability Technical Conference, in the above-referenced proceeding, on Wednesday, October 21, 2026, to discuss policy issues related to the reliability and security of the Bulk-Power System. The conference will be held in-person at the Commission's headquarters at 888 First Street NE, Washington, DC 20426 in the Kevin J. McIntyre Commission Meeting Room.

The conference will be open for the public to attend, and there is no fee for attendance. Supplemental notices will be issued prior to the conference with further details regarding the agenda. Information on this technical conference will also be posted on the Calendar of Events on the Commission's website, www.ferc.gov, prior to the event. The Commission provides technical support for the free webcasts. Please call 202-502-8680 or email customer@ferc.gov if you have any questions.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov or call toll free 1-866-208-3372 (voice) or 202-208-8659 (TTY) or send a fax to 202-208-2106 with the required accommodations.

For more information about this conference, please contact Lodie White

at Lodie.White@ferc.gov or (202) 502–8453 or Michael Gildea at Michael.Gildea@ferc.gov or (202) 502–8420.

Dated: June 11, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026–12085 Filed 6–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2742–040]

Copper Valley Electric Association; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2742–040.

c. *Date Filed:* May 27, 2026.

d. *Applicant:* Copper Valley Electric Association, Inc. (CVEA).

e. *Name of Project:* Solomon Gulch Hydroelectric Project.

f. *Location:* On Solomon Lake and Solomon Gulch Creek, in the Chugach Census Area, in Valdez, Alaska. The project occupies 440 acres under the jurisdiction of the U.S. Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Coreen Palacios, Regulatory and Compliance Specialist CVEA; P.O. Box 45, Mile 187 Glenn Highway, Glenallen, AK 99588; telephone at (907) 822–8301; email at CPalacios@cvea.org.

i. *FERC Contact:* Lauren Townson, Project Coordinator, Northwest Branch, Division of Hydropower Licensing; telephone at (202) 502–8572; email at Lauren.Townson@ferc.gov.

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental

document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* on or before 5:00 p.m. Eastern Time on July 27, 2026.¹

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. For assistance, please contact FERC Online Support at FEROnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy via U.S. Postal Service to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Solomon Gulch Hydroelectric Project (P–2742–040).

m. The application is not ready for environmental analysis at this time.

n. *The Solomon Gulch Project includes:* (1) a reservoir with a total drainage area of approximately 19.7 square miles with a maximum elevation of 693.5 feet mean sea level, a surface area of 660 acres, and a maximum storage volume at normal maximum pool elevation of 31,560 acre-feet; (2) a 400-foot-long and 115-foot-high rockfill

dam with asphaltic concrete face; (3) a 365-foot-long saddle dike, or auxiliary dam, with a maximum height of approximately 65 feet, and a 450-foot concrete spillway with a nominal crest elevation of 685 feet mean sea level; (4) two 48-inch diameter intake pipes with slide gate facilities and a trash rack; (5) two 48-inch diameter, concrete-encased steel penstocks; (6) a 70-foot-long by 60-foot-wide powerhouse containing two Francis-type turbine/generator units with a total rated capacity of 12 megawatts (MW); (7) a substation located on the powerhouse, connecting to a 110-mile-long transmission line that runs from the project the substation adjacent to Pump Station 11 near Glennallen; (8) a tailrace; (9) two 300-foot-long pipes that supply water to the nearby Solomon Gulch Hatchery, owned and operated by the Valdez Fisheries Development Association (VFDA); and (10) appurtenant facilities. The project is a conventional hydroelectric facility that generates electricity using stored water from Solomon Lake through two Francis turbine-generator units, with a total installed capacity of 12 MW.

The project uses stored water from Solomon Lake and is operated to supply energy to CVEA's electrical system serving Valdez and other communities in the Copper River Basin. The reservoir is maintained between elevations 615 feet and 685 feet and the project is required to maintain continuous minimum flows of 2 cubic feet per second (cfs) at the head of the project tailrace and 2 cfs at the base of the lower falls of Solomon Gulch Creek for the protection of fish resources. Power generation generally follows seasonal hydrology, with increased generation during periods of higher inflow and reduced generation during low inflow periods. CVEA proposes to continue to operate the project as it does currently. Additionally, CVEA proposes to remove approximately 443 acres from the existing project boundary, including approximately 355 acres of federal lands managed by the BLM (located at the southern end of Solomon Lake), and approximately 91 acres of state-managed lands. Approximately 2 acres of private land would be added to the proposed project boundary to reflect the full extent of the existing 100-foot-wide primary transmission line right of way to the Petro Star Switch Building. Therefore, the proposed project boundary would total approximately 760 acres, consisting of approximately 671 acres of state-managed lands, 85 acres of BLM-managed federal lands, and 3 acres of private lands.

o. In addition to publishing the full text of this notice in the **Federal**

¹ The Commission's Rules of Practice and Procedure provide that if a filing deadline falls on a Saturday, Sunday, holiday, or other day when the Commission is closed for business, the filing deadline does not end until the close of business on the next business day. 18 CFR 385.2007(a)(2) (2025). Because the 60-day filing deadline falls on a Sunday (i.e., July 26, 2026), the filing deadline is extended until the close of business on Monday, July 27, 2026.

Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (e.g., license application) via the internet through the Commission's Home Page (<http://www.ferc.gov>) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document (P-8632). For assistance, contact FERC at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/ferconline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

q. **Procedural Schedule and Final Amendments:** The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter and Request Additional Information.	July 2026.
Issue Notice of Application Accepted for Filing.	November 2026.
Issue Scoping Notice	November 2026.
Scoping Comments Due	December 2026.
Issue Notice of Ready for Environmental Analysis.	February 2027.

r. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

(Authority: 18 CFR 2.1)

Dated: June 10, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-12014 Filed 6-15-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP26-926-000.

Applicants: Ruby Pipeline, L.L.C.
Description: § 4(d) Rate Filing: RP 2026-06-10 Non-Conforming Agreement Amendment to be effective 6/10/2026.

Filed Date: 6/10/26.

Accession Number: 20260610-5166.

Comment Date: 5 p.m. ET 6/22/26.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

Dated: June 11, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026-12084 Filed 6-15-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC26-34-000]

Commission Information Collection Activities (Ferc-606 and Ferc-607); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection renewal and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collections, FERC-606, (Notification of

Request for Federal Authorization and Requests for Further Information), and FERC-607, (Report on Decision or Action on Request for Federal Authorization). There are no proposed changes to the reporting requirements.

DATES: Comments on the collection of information are due August 17, 2026.

Please submit comments via email to DataClearance@FERC.gov. You must specify the Docket No. (IC26-34-000) and the FERC Information Collection number (FERC-606 and 607) in your email. If you are unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

☐ *Mail via U.S. Postal Service only, addressed to:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

☐ *Hand (including courier) delivery to:* Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Docket: To view comments and issuances in this docket, please visit <https://elibrary.ferc.gov/eLibrary/search>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov, or by telephone at (202) 502-6468.

SUPPLEMENTARY INFORMATION: *Title:* FERC-606, Notification of Request for Federal Authorization and Requests for Further Information; FERC-607, Report on Decision or Action on Request for Federal Authorization.

OMB Control No.: 1902-0241.

Type of Request: Three-year extension of these information collection requirements for all collections described below with no changes to the current reporting requirements.

Abstract: FERC-606 requires federal and state agencies and officials responsible for issuing, conditioning, or denying requests for federal authorizations necessary for a proposed natural gas project to report to the Commission regarding the status of an authorization request. This reporting requirement is intended to allow agencies to assist the Commission to make better informed decisions in establishing due dates for agencies' decisions.

FERC-607 requires federal and state agencies or officials to submit to the Commission a copy of a decision or action on a request for federal authorization and an accompanying index to the documents and materials relied on in reaching a conclusion.

These information collections can neither be discontinued nor collected

less frequently because of statutory ¹ and regulatory ² requirements. The consequences of not collecting this information are that the Commission would be unable to fulfill its statutory mandate under the Energy Policy Act of 2005 to:

- Establish a schedule for agencies to review requests for federal

authorizations required for a project, and

- Compile a record of each agency's decision, together with the record of the Commission's decision, to serve as a consolidated record for the purpose of appeal or review, including judicial review.

Type of Respondent: Agencies with federal authorization responsibilities.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden ³ and cost ⁴ (rounded) for the information collection as follows:

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC-606—Notification of Request for Federal Authorization and Requests for Further Information.	1	1	1	4 hrs.; \$408	4 hrs.; \$408	\$408
FERC-607—Report on Decision or Action on Request for Federal Authorization.	1	1	1	1 hr.; 102	1 hr.; 102	102
Total	2		2		5 hrs.; \$510	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: June 11, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026-12087 Filed 6-15-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP26-537-000; CP17-117-000]

Louisiana LNG Infrastructure LLC; Driftwood Pipeline LLC; Notice of Amendment Application and Motion To Vacate in Part Certificate Authorization and Establishing Intervention Deadline

Take notice that on June 1, 2026, Louisiana LNG Infrastructure LLC (Louisiana LNG), 1500 Post Oak, Houston, Texas 77056, filed an application under Section 3 of the Natural Gas Act (NGA) and Part 153 of the Commission's regulations to amend its Louisiana LNG Project (Project) issued in Docket No. CP17-117-000.¹ Specifically, Louisiana LNG requests Commission approval to amend the authorization granted in the 2019 Order to incorporate the Kinder Morgan Louisiana Pipeline LLC (KMLP) Interconnect into the Louisiana LNG facility authorized under Section 3(a) of the NGA rather than as part of the Driftwood Pipeline project as originally authorized. The amended authorization will allow the Project to connect directly to the KMLP pipeline, which will serve as a significant source of

supply for the Project, and to do so in a way that will permit natural gas to be delivered sooner than it is likely to be available from other supply sources. Concurrently, on June 1, 2026, Driftwood Pipeline LLC 2800 Post Oak Boulevard, Houston, Texas 77056 filed a motion to vacate, in part, its certificate authorization for the KMLP interconnect which it will no longer need as part of the Driftwood Pipeline Project, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from

Pipeline) to construct the Driftwood Pipeline Project to deliver natural gas to the Louisiana LNG Project. An interconnect and receipt meter station that would interconnect with the KMLP pipeline system and would receive gas for redelivery to the Louisiana LNG Project (KMLP Interconnect) was granted as part of the Driftwood Pipeline project.

¹ Section 313 of the Energy Policy Act of 2005.

² 18 CFR 385.2013.

³ Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

⁴ FERC estimates that industry hourly costs are similar to the Commission FY 2026 average salary plus benefits of \$213,003 per year (or \$102/hour).

¹ *Driftwood LNG LLC and Driftwood Pipeline LLC*, 167 FERC ¶ 61,054 (2019 Order). The 2019 Order authorized Driftwood LNG LLC (now Louisiana LNG), to construct the Louisiana LNG Project, and authorized Driftwood Pipeline LLC (Driftwood

FERC Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

Any questions regarding the proposed projects should be directed to James F. Bowe, Jr., King & Spalding LLP, 1700 Pennsylvania Avenue, Suite 900, Washington, DC 20006, by phone at (202) 626-9601, or by email at jbowe@kslaw.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,² within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on July 1, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation (OPP) at (202) 502-6595 or OPP@ferc.gov.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more

specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)³ and 385.211⁴ of the Commission's regulations under the NGA, any person⁵ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁶ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on July 1, 2026.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket numbers CP26-537-000 and CP17-117-000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket numbers (CP26-537-000 and CP17-117-000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

³ 18 CFR 157.10(a)(4).

⁴ 18 CFR 385.211.

⁵ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁶ 18 CFR 385.2001.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁷ has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁸ and the regulations under the NGA⁹ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on July 1, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket numbers CP26-537-000 and CP17-117-000 in your submission.

(1) You may file your motion to intervene by using the Commission's

⁷ 18 CFR 385.102(d).

⁸ 18 CFR 385.214.

⁹ 18 CFR 157.10.

² 18 CFR 157.9.

eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket numbers CP26–537–000 and CP17–117–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: James F. Bowe, Jr., King & Spalding LLP, 1700 Pennsylvania Avenue, Suite 900, Washington, DC 20006, or by email (with a link to the document) at jbowe@kslaw.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed¹⁰ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹¹ Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.¹² A person obtaining party status will be placed on the service list maintained by

the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Intervention Deadline: 5:00 p.m. Eastern Time on July 1, 2026.

(Authority: 18 CFR 2.1)

Dated: June 11, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–12086 Filed 6–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Accounting Request filings:

Docket Numbers: AC26–84–000.

Applicants: Consumers Energy Company.

Description: Consumers Energy Company submits proposed journal entries re sale of certain gas storage field assets on 12/15/2025 to VCP Michigan, LLC.

Filed Date: 6/10/26.

Accession Number: 20260610–5189.

Comment Date: 5 p.m. ET 7/1/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–1818–031.

Applicants: Boston Energy Trading and Marketing LLC.

Description: Updated Triennial Market Power Analysis for Northeast Region of Boston Energy Trading and Marketing LLC.

Filed Date: 6/10/26.

Accession Number: 20260610–5198.

Comment Date: 5 p.m. ET 8/10/26.

Docket Numbers: ER26–1915–001.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: Tariff Amendment:

2026–06–11 Amendment to Interconnection Limit Constraint to be effective 12/31/9998.

Filed Date: 6/11/26.

Accession Number: 20260611–5032.

Comment Date: 5 p.m. ET 6/22/26.

Docket Numbers: ER26–2777–000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: § 205(d) Rate Filing:

2026–06–10 SA 2677 GRE–NSP 4th Rev GIA (J278) to be effective 5/11/2026.

Filed Date: 6/10/26.

Accession Number: 20260610–5160.

Comment Date: 5 p.m. ET 7/1/26.

Docket Numbers: ER26–2778–000.

Applicants: Ringer Solar Energy LLC.

Description: Request for Prospective Waiver, et al. of Ringer Solar Energy LLC.

Filed Date: 6/10/26.

Accession Number: 20260610–5180.

Comment Date: 5 p.m. ET 7/1/26.

Docket Numbers: ER26–2779–000.

Applicants: Silver Star Solar I, LLC.

Description: Petition for Limited

Waiver and Expedited Action of Silver Star Solar I, LLC.

Filed Date: 6/4/26.

Accession Number: 20260604–5190.

Comment Date: 5 p.m. ET 6/18/26.

Docket Numbers: ER26–2780–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing:

3215R19 People's Electric Cooperative NITSA NOA to be effective 6/1/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5016.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2781–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing:

4193R3 City of Paris NITSA NOA to be effective 9/1/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5020.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2782–000.

Applicants: Viridon Path 15 LLC.

Description: Application for

Authorization for Abandoned Plant Incentive Rate Treatment of Viridon Path 15 LLC.

Filed Date: 6/5/26.

Accession Number: 20260605–5187.

Comment Date: 5 p.m. ET 6/26/26.

Docket Numbers: ER26–2783–000.

Applicants: Jersey Central Power & Light Company.

¹⁰ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹¹ 18 CFR 385.214(c)(1).

¹² 18 CFR 385.214(b)(3) and (d).

Description: Expedited Petition of Jersey Central Power & Light Company for Limited Waiver of Formula Rate Implementation Protocols and Waiver of Answering Period.

Filed Date: 6/9/26.

Accession Number: 20260609–5184.

Comment Date: 5 p.m. ET 6/30/26.

Docket Numbers: ER26–2784–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1266R21 Kansas Municipal Energy Agency NITSA and NOA to be effective 6/1/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5028.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2786–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of NSA, Service Agreement No. 7476; Queue No. AA1–145 to be effective 8/11/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5035.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2787–000.

Applicants: Brookhaven Energy Center, LLC.

Description: Compliance filing: Notice of Succession to Market-Based Rate Tariff to be effective 6/12/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5050.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2788–000.

Applicants: Alpha Generation Brandywine, LLC.

Description: Compliance filing: Notice of Succession, Notice of Change in Status, and Tariff Revisions to be effective 6/12/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5082.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2789–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2026–06–11 Startup Funding for the Regional Org. for Western Energy Tariff Amdt to be effective 1/1/2028.

Filed Date: 6/11/26.

Accession Number: 20260611–5084.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2790–000.

Applicants: Alpha Generation Brandywine, LLC.

Description: Compliance filing: Notice of Succession and Revised Reactive Rate Schedule to be effective 6/12/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5088.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2791–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Tariff Amendment: Notice of Cancellation of Rate Schedule FERC No. 320 to be effective 8/11/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5096.

Comment Date: 5 p.m. ET 7/2/26.

Docket Numbers: ER26–2792–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Tariff Amendment: Notice of Cancellation of Service Agreement FERC No. 906 to be effective 8/11/2026.

Filed Date: 6/11/26.

Accession Number: 20260611–5121.

Comment Date: 5 p.m. ET 7/2/26.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF26–1150–000.

Applicants: NuPower Bridgeport FC LLC.

Description: Form 556 of NuPower Bridgeport FC LLC.

Filed Date: 6/10/26.

Accession Number: 20260610–5212.

Comment Date: 5 p.m. ET 7/1/26.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date.

Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: June 11, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–12088 Filed 6–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2548–056]

Northbrook Lyons Falls, LLC; Notice of Revised Procedural Schedule

This notice revises the Federal Energy Regulatory Commission's (Commission) schedule for processing the relicense application for the Lyons Falls Hydroelectric Project No. 2548, which was filed by Northbrook Lyons Falls, LLC (Northbrook) on May 31, 2024. On June 14, 2024, Commission staff issued a notice of application tendered for filing, which included an initial processing schedule.

On August 29, 2024, Commission staff requested that Northbrook resolve deficiencies and provide additional information on the application. On June 10, 2026, Commission staff granted Northbrook's requested extension of time to file study reports for a Bypassed Reach Flow Evaluation Study and Visual Resources Study by July 27, 2026. Also, on June 10, 2026, staff requested additional information on the relicense application by September 8, 2026.

By this notice, Commission staff is updating the procedural schedule. The revised schedule is shown below. Further revisions to the schedule may be made as appropriate.

Milestone	Target date
File Study Reports	July 2026.
File Additional Information	September 2026.
Issue Acceptance Notice and Letter.	October 2026.
Issue Scoping Notice	October 2026.
Issue Notice of Ready for Environmental Analysis.	January 2027.

Any questions regarding this notice may be directed to Joshua Dub by email at Joshua.Dub@FERC.gov or by telephone at (202) 502–8138.

(Authority: 18 CFR 2.1)

Dated: June 10, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–12015 Filed 6–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Project No. 137–227]****Pacific Gas & Electric Company;
Notice of Availability of Environmental
Assessment**

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380, Commission staff reviewed Pacific Gas & Electric Company's application for non-capacity amendment of the Mokelumne Hydroelectric Project No. 137 and have prepared an Environmental Assessment (EA) for the project.¹ To mitigate seepage along the downstream embankment of Lower Blue Lake dam, the licensee proposes to install a filter and buttress. To minimize potential effects of seismic activity, the licensee proposes to increase the height of the dam by 2 feet. The licensee does not propose any changes to the operating elevation of the reservoir. The licensee also proposes to repair a monitoring weir downstream of the dam and incorporate the weir into the project boundary. Lower Blue Lake is a storage development of the Mokelumne Project located on Middle Creek, a tributary of Blue Creek, in Alpine County, California. The Mokelumne Project partially is located on lands administered by the U.S. Forest Service.

The EA contains Commission staff's analysis of the potential environmental effects of the proposed amendment, alternatives to the proposed action, and concludes that the proposed amendment, with the licensee's proposed environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The EA may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number (P–137–227) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances

related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed by July 10, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–137–227.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

For further information, contact Elizabeth Moats at 202–502–6632 or Elizabeth.Moats@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: June 10, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–12016 Filed 6–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Western Area Power Administration****Boulder Canyon Project**

AGENCY: Western Area Power Administration, Department of Energy (DOE).

ACTION: Notice of proposed fiscal year 2027 Boulder Canyon Project base charge and rates for electric service.

SUMMARY: The Desert Southwest region (DSW) of the Western Area Power Administration (WAPA) proposes the fiscal year (FY) 2027 base charge and rates for Boulder Canyon Project (BCP) electric service under Rate Schedule BCP–F11 to remain at \$76.2 million, unchanged from FY 2026. The proposed base charge and rates would go into

effect on October 1, 2026, and remain in effect through September 30, 2027. Publication of this **Federal Register** notice will initiate the public process.

DATES: A consultation and comment period begins June 16, 2026 and will end on September 14, 2026. DSW will present a detailed explanation of the proposed FY 2027 base charge and rates at a public information forum on July 16, 2026, from 10 a.m. Mountain Standard Time to no later than 12 p.m. Mountain Standard Time. DSW will also host a public comment forum on August 17, 2026, from 10 a.m. Mountain Standard Time to no later than 12 p.m. Mountain Standard Time, or until the last comment is received. The public information and public comment forums will be held virtually and in person at WAPA's Desert Southwest Regional Office located at 615 South 43rd Avenue, Phoenix, Arizona 85009. Instructions for participating in the forums will be posted on DSW's BCP Rates website at least 14 days prior to the public information and comment forums at www.wapa.gov/about-wapa/regions/dsw/rates/boulder-canyon-project-rates. DSW will accept written comments at any time during the consultation and comment period.

Individuals attending the public forums in person who are U.S. citizens must present an official form of government-issued photo identification (ID) at the time of the meeting. Acceptable forms of ID include a REAL ID-compliant driver's license, U.S. passport, U.S. Government ID, or U.S. Military ID. REAL ID-compliant driver's licenses are marked with a star in the upper corner; attendees should verify compliance in advance. Foreign nationals should contact Tina Ramsey, Rates Manager, Desert Southwest Region, Western Area Power Administration, (602)812–2355, or dswpwrmrk@wapa.gov in advance of a forum to obtain the necessary form for admittance to the Desert Southwest Regional Office.

ADDRESSES: Written comments and requests to be informed of Federal Energy Regulatory Commission (FERC) actions concerning the proposed base charge and rates should be sent to: Scott R. Lund, Regional Manager, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457, or dswpwrmrk@wapa.gov. DSW will post information concerning the rate process and written comments received to its BCP Rates website at www.wapa.gov/about-wapa/regions/dsw/rates/boulder-canyon-project-rates.

¹ The unique identification number for documents relating to this environmental review is EAXX–019–20–000–1759504341.

FOR FURTHER INFORMATION CONTACT: Tina Ramsey, Rates Manager, Desert Southwest Region, Western Area Power Administration, (602) 812-2355, or dswpwrmrk@wapa.gov.

SUPPLEMENTARY INFORMATION: Hoover Dam,¹ authorized by the Boulder Canyon Project Act of 1928, as amended (43 U.S.C. 617, *et seq.*), sits on the Colorado River along the Arizona-Nevada border. The Hoover Dam power plant has 19 generating units (including two for plant use) with an installed capacity of 2,078.8 megawatts (4,800 kilowatts for plant use). In collaboration with Reclamation, WAPA markets and delivers hydropower from the Hoover Dam power plant through high-voltage

transmission lines and substations to customers in Arizona, Southern California, and Southern Nevada.

The rate-setting methodology for BCP calculates an annual base charge rather than a unit rate for Hoover Dam hydropower. Under the Implementation Agreement, Section 8.5.5, Reclamation determines the amount of project costs to be included in the annual base charge. The base charge recovers an annual revenue requirement that includes projected costs for investment repayment, interest, operations, maintenance, replacements, payments to states, and Hoover Dam visitor services. Non-power revenue projections, such as water sales, Hoover Dam visitor revenue, ancillary services,

and late fees help offset these projected costs. Hoover power customers are billed a percentage of the base charge in proportion to their power allocation. Unit rates are calculated for comparative purposes but are not used to determine the charges for service.

On March 31, 2023, FERC approved and confirmed Rate Schedule BCP-F11, under Rate Order No. WAPA-204, on a final basis through September 30, 2027.² Rate Schedule BCP-F11 and the BCP Electric Service Contract require WAPA to determine the annual base charge and rates for the next fiscal year before October 1 of each year. The FY 2026 BCP base charge and rates expire on September 30, 2026.

COMPARISON OF BASE CHARGE AND RATES³

	FY 2026	FY 2027	Amount change	Percent change
Base Charge (\$ in thousands)	76,175	76,175	0.00	0.0
Composite Rate (mills/kWh)	25.89	25.89	0.00	0.0
Energy Rate (mills/kWh)	12.95	12.95	0.00	0.0
Capacity Rate (\$/kW-Mo)	2.27	2.27	0.00	0.0

The proposed FY 2027 base charge for BCP electric service is projected to remain at \$76.2 million, unchanged from FY 2026.

COMPARISON OF BASE CHARGE INPUTS (In thousands of dollars)

	FY 2026	FY 2027 TYOP	FY 2027 Proposed	Change (FY 2026 to FY 2027 Proposed)	Percent change
Reclamation Budget	86,339	89,846	89,096	2,757	3.2
WAPA Budget	9,091	9,827	8,594	(497)	(5.5)
Non-Power Revenue	18,826	18,773	18,773	(53)	(0.3)
Carryover	429		2,742	2,313	538.5
Base Charge ⁴	76,175		76,175		0.0

Reclamation and WAPA's FY 2027 budgets are established within the Final FY 2027 Ten-Year Operating Plan (TYOP), which was reviewed and coordinated with Hoover power customers. Following publication of the Final FY 2027 TYOP, Reclamation and WAPA management conducted a comprehensive review of recent expenditures, execution trends and replacement project priorities.

As part of this review, Reclamation reduced its FY 2026 budget, increasing projected carryover into FY 2027, and further reduced its FY 2027 operations

and maintenance (O&M) and replacement budgets by adjusting project schedules and deferring planned replacement activities, resulting in a combined reduction of \$2.6 million.

Reclamation's FY 2027 budget, after these reductions, is increasing by \$2.8 million, from \$86.3 million to \$89.1 million, a 3.2 percent increase over FY 2026. This increase includes a \$1.7 million increase in O&M, primarily driven by higher projected costs for salaries, benefits, overhead, and overtime. Additionally, costs for services, materials, and supplies have

increased due to greater purchasing needs and inflation. Although several large projects have been deferred, thus reducing replacement costs by \$478,000, work continues on many projects, including the Unit Control Modernization Lifecycle Replacement; Heating, Ventilation and Air Conditioning replacement and renovations of the 7th and 8th floors; and the cylinder gate stem replacement. Visitor services expenses are increasing \$1.5 million, primarily due to higher projected labor and support costs.

¹ Hoover Dam was known as Boulder Dam from 1933 to 1947, but was renamed Hoover Dam by an April 30, 1947, joint resolution of Congress. *See Act of April 30, 1947, H.J. Res. 140, ch. 46, 61 Stat. 56-57.*

² *Order Confirming and Approving Rate Schedule on a Final Basis*, FERC Docket No. EF22-4-000.

³ Unit rate calculations use forecasted energy and capacity values from FY 2026, which will be

updated based on recent hydrological conditions when determining the final base charge and rates.

⁴ Base Charge = Reclamation Budget + WAPA Budget - Non-Power Revenue - Carryover.

Similarly, WAPA reduced its FY 2026 budget, increasing projected carryover into FY 2027, and reduced its FY 2027 O&M and replacement budgets by deferring the Mead 69-kilovolt breaker and relay replacement project to 2028 or later, resulting in a total reduction of \$2.2 million.

WAPA's FY 2027 budget has been refined, decreasing \$497,000 from \$9.1 million to \$8.6 million, a 5.5 percent decrease from FY 2026. This refinement reflects the consistent pattern over the past three fiscal years, in which actual charges have been lower than prior projections.

Non-power revenue projections for Reclamation and WAPA are forecasted to be \$52,000 lower in FY 2027, due to reduced estimated revenues from ancillary services. Carryover from FY 2026 to FY 2027 is projected to be \$2.7 million, which is \$2.3 million more than the projected carryover of \$429,000 from FY 2025 into FY 2026. This increase is primarily due to the previously mentioned reductions to the FY 2026 budget.

The composite, energy, and capacity rates remain unchanged from FY 2026. These unit rate calculations use forecasted energy and capacity values from FY 2026, which will be updated based on recent hydrological conditions when determining the final base charge and rates.

WAPA's proposed base charge and rates for FY 2027, which would be effective October 1, 2026, are preliminary and subject to change based on modifications to forecasts before publication of the final base charge and rates.

Legal Authority

WAPA is establishing rates for BCP electric service in accordance with section 302 of the DOE Organization Act (42 U.S.C. 7152). This provision transferred to, and vested in, the Secretary of Energy certain functions of the Secretary of the Interior, along with the power marketing functions of Reclamation. Those functions include actions that specifically apply to the BCP.

WAPA's proposal to calculate the base charge and rates for FY 2027 constitutes a major rate adjustment, as defined by 10 CFR 903.2(d). In accordance with 10 CFR 903.15, 10 CFR 903.16, and 10 CFR 904.7(e), DSW will hold public information and public comment forums for this rate adjustment. DSW will review and consider all timely public comments at the conclusion of the consultation and comment period and adjust the proposal as appropriate.

DOE regulations governing charges for the sale of BCP power, 10 CFR 904.7(e), requires an annual review of the BCP base charge and an "adjust[ment] either upward or downward, when necessary and administratively feasible, to assure sufficient revenues to effect payment of all costs and financial obligations associated with the [p]roject." This proposal is issued pursuant to Delegation Order No. S1-DEL-RATES-2016, effective November 19, 2016, in which the Secretary of Energy delegated the authority to develop power and transmission rates to WAPA's Administrator. The BCP Electric Service Contract states that for years other than the first year, and each fifth year thereafter, when the rate schedule is approved by the Deputy Secretary of Energy on a provisional basis, and by FERC on a final basis, adjustments to the base charge "shall become effective upon approval by the Deputy Secretary of Energy." Accordingly, the Deputy Secretary of Energy would approve the final FY 2027 base charge and rates for BCP electric service, as authorized by the BCP Electric Service Contract and DOE's procedures for public participation in rate adjustments set forth at 10 CFR parts 903 and 904.⁵ The FY 2027 base charge will also be filed at FERC for informational purposes only.

Availability of Information

All brochures, studies, comments, letters, memorandums, or other documents that DSW initiates or uses to develop the proposed formula rates for electric service and the base charge and rates are available for inspection and copying at the Desert Southwest Regional Office, located at 615 South 43rd Avenue, Phoenix, Arizona 85009. Many of these documents and supporting information are also available on DSW's BCP Rates website at www.wapa.gov/about-wapa/regions/dsw/rates/boulder-canyon-project-rates.

Ratemaking Procedure Requirements Environmental Compliance

WAPA is in the process of determining whether an environmental assessment or an environmental impact statement should be prepared or if this action can be categorically excluded from those requirements.⁶

⁵ 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

⁶ In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321-4347, DOE NEPA regulations at 10 CFR part 1021, and DOE's NEPA implementing procedures outside the Code of Federal Regulations available at energy.gov/nepa.

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on June 11, 2026, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 12, 2026.

Jennifer Hartzell,

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

[FR Doc. 2026-12068 Filed 6-15-26; 8:45 am]

BILLING CODE 6450-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0462; FRL-13443-01-OCSP]

4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA) Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of and seeking public comment on the draft risk evaluation under the Toxic Substances Control Act (TSCA) for 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA). The purpose of risk evaluations under TSCA are to determine whether a chemical substance presents an unreasonable risk of injury to human health or the environment under the conditions of use (COUs), including unreasonable risk to potentially exposed or susceptible

subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors. EPA is seeking comment on the draft risk evaluation for TBBPA.

DATES: Comments must be received on or before August 17, 2026.

ADDRESSES: To submit comments on the TBBPA draft risk evaluation, submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0462, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information on TBBPA: John Allran, Existing Chemical Risk Assessment Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-7656; email address: TBBPA.TSCA@epa.gov.

For general information: The TSCA Assistance Information Service Hotline, Goodwill Vision Enterprises, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471-7127 or (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution, use, and disposal of TBBPA, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, State and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the relevant technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

The Agency is conducting this risk evaluation under TSCA section 6, (15 U.S.C. 2605) which requires that EPA conduct risk evaluations on chemical substances and identifies the minimum components EPA must include in the risk evaluations. Each risk evaluation must be conducted consistent with the best available science, be based on the weight of the scientific evidence, and consider reasonably available information, and not consider costs or non-risk factors (15 U.S.C. 2625(h), (i), and (k)). See also the implementing procedural regulations at 40 CFR part 702.

C. What action is the Agency taking?

EPA is announcing the availability of and seeking public comment on the draft risk evaluation under TSCA for TBBPA. EPA used the best available science to prepare the draft risk evaluation and preliminarily determined, based on the weight of scientific evidence, that TBBPA poses unreasonable risk to human health and the environment driven primarily by certain COUs analyzed in the draft risk evaluation.

D. What should I consider as I submit my comments to EPA?

1. Submitting CBI.

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

2. Tips for preparing comments.

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

A. What is TBBPA?

TBBPA is a crystalline solid used as an additive and reactive flame retardant. As an additive flame retardant, TBBPA is incorporated into polymers and used in electronic enclosures and electronic consumer products with an outer plastic casing. As a reactive flame retardant, TBBPA is primarily used in epoxy resin printed circuit boards. TBBPA is used in fabric, textile, leather products, and construction materials. Workers may be exposed to TBBPA through inhalation of dust or dermal contact during the

manufacturing, processing, use, or disposal of TBBPA. Consumers may be exposed to TBBPA through dermal or oral exposure to products, as well as inhalation of dust. TBBPA is primarily released to the environment through land disposal. Environmental TBBPA release can also occur through air and water releases. TBBPA has been found in drinking water, ground water, ambient air, indoor air, fish, human breast milk, and dust and soil.

B. The Risk Evaluation of TBBPA

In December 2019, EPA announced its designation of TBBPA (Docket ID EPA-HQ-OPPT-2018-0462) as a high priority substance for risk evaluation under TSCA (84 FR 71924) (FRL-10003-15). In April 2020, EPA published and sought public comment on the draft scope of the TBBPA risk evaluation (85 FR 19941) (FRL-10007-11-OCSPP) and, after considering public comments, issued the final scope on September 4, 2020 (85 FR 55281) (FRL-10013-90-OCSPP).

III. Request for Comment

EPA seeks feedback on the assessment of risk presented in the draft risk evaluation for TBBPA, a copy of which is available in the docket, and encourages all potentially interested parties, including individuals, governmental and non-governmental organizations, non-profit organizations, academic institutions, research institutions, and private sector entities to comment on the draft risk evaluation. To the extent possible, the Agency asks commenters to please cite any public data related to or that support comments provided, and to the extent permissible, describe any supporting data that are not publicly available.

EPA welcomes specific input on each section of the draft risk evaluation, particularly input on the following:

- Non-cancer human health hazard conclusions (e.g., selection of intermediate and chronic endpoints);
- Cancer human health hazard conclusions (e.g., conclusion of non-genotoxic mode of action and preliminary cancer classification);
- Exposure assumptions for occupational exposure scenarios (e.g., how exposure controls and personal protective equipment are used, the frequency of occupational task(s) per shift, use of respirators with an Assigned Protection Factor higher than 10 during higher exposure tasks);
- Modeling assumptions for conditions of use without Toxics Release Inventory data (e.g., use as a laboratory chemical);

- Domestic manufacturing as a reasonably foreseen use and any information regarding domestic manufacturing being reestablished in the United States;
- Information that may inform assessment of water releases and environmental impacts (e.g., percent of TBBPA in waste disposal streams); and
- Relevant studies or other data sources not identified by EPA.

IV. Next Steps

After consideration of comments received from the public on the draft risk evaluation and input from the SACC peer review, EPA will issue a final risk evaluation for TBBPA. Under TSCA section 6, EPA must determine in the final risk evaluation, based on the weight of scientific evidence, whether or not the chemical presents an unreasonable risk to human health or the environment under the chemical's COUs. This includes consideration of risks to potentially exposed susceptible subpopulations who may be at greater risks than the general population, such as children and workers. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: June 11, 2026.

Douglas M. Troutman,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2026-12012 Filed 6-15-26; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2024-0154; FRL-OCSPP-13447-01]

United States Department of Justice and Parties to Certain Litigation; Transfer of Information Potentially Containing Confidential Business Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces that pesticide-related information submitted to the Environmental Protection Agency (EPA or Agency) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including

information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred to the U.S. Department of Justice (DOJ) and parties to certain litigation. This transfer of data is in accordance with the CBI regulations governing the disclosure of potential CBI in litigation.

DATES: Access to this information by DOJ and the parties to certain litigation is ongoing and expected to continue during the litigation as discussed in this document.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566-1030; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION: This document is being provided pursuant to 40 CFR 2.209(d) to inform affected businesses that EPA, via DOJ, will provide certain information to the parties and the Court in the consolidated matters of *American Soybean Association v. U.S. Environmental Protection Agency, et al.*, Case No. 26-1326 (8th Cir.) and *National Family Farm Coalition, et al. v. U.S. Environmental Protection Agency, et al.*, Case No. 26-1556 (8th Cir.). The information is contained in documents that have been submitted to EPA pursuant to FIFRA and FFDCA, including information that has been claimed to be, or determined to potentially contain, CBI. In the pending litigation, the petitioners seek judicial review of EPA's registrations of three dicamba products for use on dicamba-tolerant cotton and soybeans, issued under FIFRA, 7 U.S.C. 136 *et seq.*

The documents are being produced as part of the Administrative Record of the decisions at issue and include documents that registrants or other data-submitters may have submitted to EPA regarding the pesticide dicamba, and that may be subject to various release restrictions under federal law. The information includes documents submitted with pesticide registration applications and may include CBI as well as scientific studies subject to the disclosure restrictions of section 10(g) of FIFRA, 7 U.S.C. 136h(d).

All documents that may be subject to release restrictions under federal law will be designated as "Protected Information" in the certified list of record materials that EPA will file in these consolidated cases. Further, EPA intends to seek a Protective Order that would preclude public disclosure of any

such documents by the parties in these actions who have received the information from EPA and limit the use of such documents to litigation purposes only, unless a party successfully obtains a de-designation as Protected Information of any portion of the Administrative Record via a procedure that would be described in the Protective Order. If such documents are filed with the Court, the anticipated Protective Order would require that such documents be filed under seal and not be available for public review, unless the information contained in the document has been determined to not be subject to section 10(g) of FIFRA and all CBI has been redacted.

At the conclusion of the litigation, the anticipated Protective Order would require that record material EPA designates as "Protected Information" be destroyed or returned to EPA.

Authority: 7 U.S.C. 136 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: June 11, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2026-12055 Filed 6-15-26; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0745; FR ID 351348]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated

collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before August 17, 2026. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0745.

Title: Implementation of the Local Exchange Carrier Tariff Streamlining Provisions in the Telecommunications Act of 1996, CC Docket No. 96–187.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 50 respondents; 1,520 responses.

Estimated Time per Response: 0.25–5 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement, and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1, 4(i), and 204(a)(3) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), and 204(a)(3).

Total Annual Burden: 4,006 hours.

Total Annual Cost: \$471,000.

Needs and Uses: This collection will be submitted as an extension to the Office of Management and Budget (OMB) in order to obtain the full three-year clearance.

In CC Docket 96–187, the Commission adopted measures to streamline tariff filing requirements for local exchange carriers (LECs) pursuant to the

Telecommunications Act of 1996. In order to achieve a streamlined and deregulatory environment for LEC tariff filings, LECs are required to file tariffs electronically. The information collected under the electronic filing program will facilitate access to tariffs and associated documents by the public, as well as by state and federal regulators. Ready electronic access to carrier tariffs will also facilitate the compilation of aggregate data for industry analysis purposes without imposing new reporting requirements on carriers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2026–12114 Filed 6–15–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 350890]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before August 17, 2026. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should

advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Protecting our Communications Networks by Promoting Transparency Regarding Foreign Adversary Control, Report and Order, (GN Docket No. 25–166, FCC 26–2).

Form Number: FCC Form 5655.

Type of Review: New information collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions.

Number of Respondents and Responses: 18,000 respondents; 18,000 responses.

Estimated Time per Response: 2 hours (average).

Frequency of Response: One-time reporting and on occasion reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for collecting information is set out in 47 U.S.C. 34–39, 151, 152, 153, 154(i), 154(n), 155, 201–205, 211–220, 222, 225, 227b–1, 251(e), 254, 301, 302a, 303, 304, 307–310, 312, 316, 317, 319, 325, 332, 335, 336, 337, 338(i), 403, 409(e), 412, 503, 521, 551, 573, 761, 1302, 1401–1473.

Total Annual Burden: 36,000 hours.

Total Annual Cost: No Cost.

Needs and Uses: In January 2026, the Federal Communications Commission adopted the *Foreign Adversary Control Report & Order* which established new attestation and disclosure requirements for Commission regulated entities to report whether and the extent to which they are owned, controlled, or subject to the jurisdiction of a foreign adversary. The Order categorized each Commission assigned license, authorization, and other approval into different schedules with different levels of attestation and disclosure requirements based on their importance to national security. Respondents who indicate they are subject to control by a foreign adversary must report additional information on the nature of that control. The Order additionally establishes ongoing reporting triggers and a streamlined enforcement and revocation process for non-compliance when necessary. Finally, the Order directed the Commission to establish a new system and procedures for collecting the information from regulated entities.

The information collected in the Foreign Adversary Risk Report will fill critical information gaps in the existing understanding of the threat that adversaries pose to U.S. networks. As such, the information from the collection will improve the Commission’s situational awareness of the threat that foreign adversaries currently pose. The Commission will use this information in support of various rulemakings and proceedings as they relate to national security and in developing appropriate actions to mitigate and eliminate threats from

adversarial control or influence. Additionally, certain information from the attestation and the additional disclosures will be made available to the public for inspection, subject to privacy and confidentiality considerations, to improve transparency into U.S. communications network and enable outside parties to raise concerns where appropriate.

Federal Communications Commission.
Marlene Dortch,
Secretary, Office of the Secretary.
[FR Doc. 2026–12089 Filed 6–15–26; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate Receiverships

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for the institutions listed below, intends to terminate its receivership for said institutions.

NOTICE OF INTENT TO TERMINATE RECEIVERSHIPS

Fund	Receivership name	City	State	Date of appointment of receiver
10008	First National Bank of Nevada	Reno	NV	07/25/2008
10275	The Cowlitz Bank	Longview	WA	07/30/2010
10526	First NBC Bank	New Orleans	LA	04/28/2017
10545	Citizens Bank	Sac City	IA	11/03/2023

The liquidation of the assets for each receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors. Based upon the foregoing, the Receiver has determined that the continued existence of the receiverships will serve no useful purpose. Consequently, notice is given that the receiverships shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of any of the receiverships, such comment must be made in writing, identify the receivership to which the comment pertains, and be sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Section, 600 North Pearl, Suite 700, Dallas, TX 75201. No comments concerning the termination of the above-mentioned receiverships will be considered which are not sent within this timeframe.

(Authority: 12 U.S.C. 1819)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on June 10, 2026.

Jennifer M. Jones,
Deputy Executive Secretary.

[FR Doc. 2026–12010 Filed 6–15–26; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1879]

Announcement of Financial Sector Liabilities

The Board’s Regulation XX prohibits a merger or acquisition that would result in a financial company that controls more than 10 percent of the aggregate consolidated liabilities of all financial companies (“aggregate financial sector liabilities”).¹ Specifically, an insured depository institution, a bank holding company, a savings and loan holding company, a foreign banking organization, any other company that controls an insured depository institution, and a nonbank financial company designated by the Financial Stability Oversight Council (each, a “financial company”) is prohibited from merging or consolidating with, acquiring all or substantially all of the assets of, or acquiring control of, another company if the resulting company’s consolidated liabilities would exceed 10 percent of the aggregate financial sector liabilities.²

Under Regulation XX, the Federal Reserve will publish the aggregate financial sector liabilities by July 1 of each year. Aggregate financial sector liabilities are equal to the average of the year-end financial sector liabilities

¹ Regulation XX implements section 622 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. See 12 U.S.C. 1852.

² 12 U.S.C. 1852(a)(2), (b); 12 CFR 251.3.

figure (as of December 31) for each of the preceding two calendar years.

FOR FURTHER INFORMATION CONTACT: Lesley Chao, Lead Financial Institution Policy Analyst, (202) 617–5825; Shooka Saket, Financial Institution Policy Analyst III, (202) 951–0747; Laura Bain, Special Counsel, (202) 736–5546; for users of telephone systems via text telephone (TTY) or any TTY-based Telecommunications Relay Services (TRS), please call 711 from any telephone, anywhere in the United States; Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

Aggregate Financial Sector Liabilities

“Aggregate financial sector liabilities” is equal to \$23,847,731,488,000.³ This measure is in effect from July 1, 2026 through June 30, 2027.

Calculation Methodology

The aggregate financial sector liabilities measure equals the average of the year-end financial sector liabilities figure (as of December 31) for each of the preceding two calendar years. The year-end financial sector liabilities figure equals the sum of the total consolidated liabilities of all top-tier U.S. financial companies and the U.S. liabilities of all top-tier foreign financial companies, calculated using the applicable methodology for each

³ This number reflects the average of the financial sector liabilities figure for the years ending December 31, 2024 (\$23,090,802,562,000) and December 31, 2025 (\$24,604,660,414,000).

financial company, as set forth in Regulation XX and summarized below.

Consolidated liabilities of a U.S. financial company that was subject to consolidated risk-based capital rules as of December 31 of the year being measured equal the difference between the U.S. financial company's risk-weighted assets (as adjusted upward to reflect amounts that are deducted from regulatory capital elements pursuant to the Federal banking agencies' risk-based capital rules) and total regulatory capital, as calculated under the applicable risk-based capital rules. Companies in this category include (with certain exceptions listed below) bank holding companies, savings and loan holding companies, and insured depository institutions. The Federal Reserve used information collected on the Consolidated Financial Statements for Holding Companies ("FR Y-9C") and the Bank Consolidated Reports of Condition and Income ("Call Report") to calculate liabilities of these institutions.

Consolidated liabilities of a U.S. financial company not subject to consolidated risk-based capital rules as of December 31 of the year being measured equal liabilities calculated in accordance with applicable accounting standards. Companies in this category include bank holding companies and savings and loan holding companies subject to the Federal Reserve's Small Bank Holding Company Policy Statement, savings and loan holding companies substantially engaged in insurance underwriting or commercial activities, and U.S. companies that control insured depository institutions but are not bank holding companies or savings and loan holding companies. "Applicable accounting standards" is defined as Generally Accepted Accounting Principles ("GAAP"), or such other accounting standard or method of estimation that the Board determines is appropriate.⁴ The Federal

Reserve used information collected on the FR Y-9C, the Parent Company Only Financial Statements for Small Holding Companies ("FR Y-9SP"), and the Financial Company Report of Consolidated Liabilities ("FR XX-1") to calculate liabilities of these institutions.

Under Regulation XX, liabilities of a foreign banking organization's U.S. operations are calculated using the risk-weighted asset methodology for subsidiaries subject to the risk-based capital rule, plus the assets of all branches, agencies, and nonbank subsidiaries, calculated in accordance with applicable accounting standards. Liabilities attributable to the U.S. operations of a foreign financial company that is not a foreign banking organization are calculated in a similar manner to the method described for foreign banking organizations, and liabilities of a U.S. subsidiary not subject to the risk-based capital rule are calculated based on the U.S. subsidiary's liabilities under applicable accounting standards. The Federal Reserve used information collected on the Capital and Asset Report for Foreign Banking Organizations ("FR Y-7Q"), the FR Y-9C, and the FR XX-1 to calculate liabilities of these institutions.

By order of the Board of Governors of the Federal Reserve System, acting through the Director of Supervision and Regulation under delegated authority.

Benjamin W. McDonough,
Secretary of the Board.

[FR Doc. 2026-12083 Filed 6-15-26; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by

continue to be subject to Regulation XX continue to use the previously approved methods. The Board did not receive any new requests this year.

contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than July 1, 2026.

A. Federal Reserve Bank of Chicago (Christopher Koopmans, Senior Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414.

Comments can also be sent electronically to Comments.applications@chi.frb.org:

1. *Jean A. Triplett and Mary S. Thomson, both of Primghar, Iowa; Steven J. Leng, Arnolds Park, Iowa; and Jan M. L. Westergard, Omaha, Nebraska;* to join the Leng Family Control Group, a group acting in concert, to retain voting shares of Capital Bancshares, Inc., and thereby indirectly retain voting shares of Savings Bank, both of Primghar, Iowa.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,
Associate Secretary of the Board.

[FR Doc. 2026-12064 Filed 6-15-26; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-XXXX; Docket No. 2026-0265; Sequence No. 1]

Information Collection; System for Award Management Quarterly Certification of Compliance With Executive Order 14400, Urgent National Action To Save College Sports

AGENCY: Integrated Award Environment, General Services Administration (GSA).

ACTION: Notice and request for comments.

⁴ A financial company may request to use an accounting standard or method of estimation other than GAAP if it does not calculate its total consolidated assets or liabilities under GAAP for any regulatory purpose (including compliance with applicable securities laws). 12 CFR 251.3(e). In previous years, the Board received and approved requests from eleven financial companies to use an accounting standard or method of estimation other than GAAP to calculate liabilities. Ten of the companies were insurance companies that reported financial information under Statutory Accounting Principles ("SAP"), and one was a foreign company that controlled a U.S. industrial loan company that reported financial information under International Financial Reporting Standards ("IFRS"). For the insurance companies, the Board approved a method of estimation that was based on line items from SAP-based reports, with adjustments to reflect certain differences in accounting treatment between GAAP and SAP. For the foreign company, the Board approved the use of IFRS. Such companies that

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement regarding a new collection of quarterly certification of compliance with the rules of Executive Order 14400 from registered Higher Education Institutions in the System for Award Management (*SAM.gov*).

DATES: Submit comments on or before August 17, 2026.

ADDRESSES: Submit comments identified by Information Collection 3090–XXXX; System for Award Management Quarterly Certification of Compliance with Executive Order 14400, Urgent National Action to Save College Sports to <https://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by searching for “Information Collection 3090–XXXX; System for Award Management Quarterly Certification of Compliance with Executive Order 14400, Urgent National Action to Save College Sports”. Select the link “Submit a Comment” that corresponds with “Information Collection 3090–XXXX; System for Award Management Quarterly Certification of Compliance with Executive Order 14400, Urgent National Action to Save College Sports”. Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “Information Collection 3090–XXXX; System for Award Management Quarterly Certification of Compliance with Executive Order 14400, Urgent National Action to Save College Sports” on your attached document. If your comment cannot be submitted using [regulations.gov](https://www.regulations.gov), call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090–XXXX; System for Award Management Quarterly Certification of Compliance with Executive Order 14400, Urgent National Action to Save College Sports, in all correspondence related to this collection. Comments received generally will be posted without change to [regulations.gov](https://www.regulations.gov), including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [regulations.gov](https://www.regulations.gov), approximately two-to-three business days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: IAE Program Office at IAE_Admin@gsa.gov for clarification of content.

SUPPLEMENTARY INFORMATION:

A. Purpose

Executive Order 14400, Urgent National Action to Save College Sports, directs the Administrator of General Services to propose a regular collection of information to evaluate compliance with the rules covered in the E.O. to aid contract and grantmaking agencies’ compliance with the E.O. starting August 1, 2026.

The System for Award Management (SAM or *SAM.gov*) serves as the primary registration and award management database for the U.S. Federal Government. SAM currently collects, validates, stores, and disseminates data in support of agency acquisition and financial assistance missions. SAM validates entity registration information and electronically shares the secure and encrypted data with Federal agency personnel to facilitate their award making and payments. Additionally, SAM shares its data with Federal Government procurement, financial assistance, and electronic business systems.

Both current and potential Colleges and Universities are required to register in SAM pursuant to Title 2 of the Code of Federal Regulations (CFR) and the Federal Acquisition Regulation (FAR) to receive specified Federal awards. Entities complete a registration process to provide basic information relevant to procurement and Federal financial assistance transactions. These entities may also report various information applicable to the federal award process in *SAM.gov*.

Registered entities identified as Higher Education Institutions during the SAM entity registration and meeting the \$20M (adjusted for inflation) threshold for intercollegiate athletics activities revenue will certify their compliance quarterly with the terms within E.O. 14400. This certification information will be available for Federal officials for contract and grantmaking activities and compliance verification.

B. Annual Reporting Burden

Respondents: 11,720.

Responses per Respondent: 1–5 (1 for screening responses and 4 for certification responses).

Total Annual Responses: 14,620 (11,720 screening responses and 2,900 certification responses).

Hours per Response: 0.25 for screening response and 0.5 for certification response.

Total Burden Hours: \$241,557 (\$161,589.50 for screening response and \$79,967.50 for certification response).

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a watermarked “DRAFT” copy of the supporting statement via the Federal eRulemaking portal at [regulations.gov](https://www.regulations.gov) and searching for Docket ID “GSA–GSA–2026–0265.” Select the document titled “Supporting Statement: 3090–XXXX—System for Award Management Quarterly Certification of Compliance with Executive Order 14400, Urgent National Action to Save College Sports—DRAFT” located under Supporting and Related Material.

Richard Speidel,

Deputy Chief Data Officer, General Services Administration.

[FR Doc. 2026–12018 Filed 6–15–26; 8:45 am]

BILLING CODE 6820–WY–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–43 and CMS–10791]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by July 16, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is

publishing this notice that summarizes the following proposed collection(s) of information for public comment.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* Portable X-ray services are basic radiology studies (predominately chest and extremity X-rays) that are performed on residents in Skilled Nursing Facilities (SNFs) or Long-term Care Facilities (LTCs) or those who are homebound and unable to travel to an outpatient radiology facility. Portable X-ray suppliers must comply with health and safety requirements under Title 42 Code of Regulations (CFR) Section 486, Subpart C in order to receive payment for services from the Medicare and Medicaid programs. The Centers for Medicare and Medicaid Services (CMS) use the ICs to ensure suppliers are in compliance. *Form Number:* CMS-R-43 (OMB Control number: 0938-0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 540; *Total Annual Responses:* 1,080; *Total Annual Hours:* 340. (For policy questions regarding this collection contact Claudia Molinar at 410-786-8445.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Requirements Related to Surprise Billing; Part II; *Use:* The collection of information is associated with the October 7, 2021 (86 FR 55980) interim final rules. The collection has two components:

A. *Good Faith Estimates.* Providers and facilities must inform uninsured (or self-pay) individuals of their right to receive a good faith estimate (GFE) of expected charges for items and services. They must also furnish a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request, which provides uninsured (or self-pay) individuals information about health care pricing before receiving care. This information would allow uninsured (or self-pay) individuals to evaluate options for receiving health care and make cost-conscious health care purchasing decisions and reduces surprises regarding individuals' health care costs for items and services. Additionally, uninsured (or self-pay) individuals need a good faith estimate

to initiate the patient-provider dispute resolution process.

B. *Certification and Recertification of SDR Entities.* HHS requests information from entities seeking to be certified or recertified as an SDR entity. This information is used to assess whether or not the entity satisfies the requirements for certification. Entities must submit information on their organizational structure, policies and procedures, staff qualifications, conflict-of-interest safeguards, and operational capacity, along with attestations of compliance with applicable standards. This information allows HHS to determine the entity's eligibility and capability to perform SDR functions effectively and impartially. *Form Number:* CMS-10791 (OMB control number: 0938-1433); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 511,749; *Total Annual Responses:* 5,248,414; *Total Annual Hours:* 3,498,944. (For policy questions regarding this collection contact Daniel Kidane at daniel.kidane@cms.hhs.gov.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026-12105 Filed 6-15-26; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-1224]

Masuu Global Solutions LLC, U.S. Agent for Extrovis AG, et al.; Withdrawal of Approval of 11 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on February 20, 2026. The document announced the withdrawal of approval of 11 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of March 23, 2026. The document indicated that FDA was withdrawing approval of ANDAs 078022 for propranolol hydrochloride (HCl), extended-release capsule, 60 milligrams (mg), 80 mg, 120 mg, and 160 mg, and 090665 for lidocaine HCl, injectable, 2%, held by Masuu Global Solutions LLC, U.S. Agent for Extrovis

AG, 2255 Glades Rd., Suite 324A, Boca Raton, FL 33431. Before FDA withdrew the approval of these ANDAs, Masuu Global Solutions LLC, U.S. Agent for Extrovis AG, informed FDA that they did not want the approval of the ANDAs withdrawn. Because Masuu Global Solutions LLC, U.S. Agent for Extrovis AG, timely requested that approval of their ANDAs not be withdrawn, the approvals are still in effect. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, February 20, 2026 (91 FR 8242), appearing on page 8242 in FR Doc. 2026–03411, the following correction is made:

On page 8243, in the table, the entries for ANDA 078022 and ANDA 090665 are removed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12044 Filed 6–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Resources and Services Administration Uniform Data System

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 16, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–3983.

SUPPLEMENTARY INFORMATION: *Information Collection Request Title:* Health Resources and Services Administration Uniform Data System, OMB No. 0915–0193—Revision.

Abstract: The Health Center Program, administered by HRSA, is authorized under section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b). Health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients on a sliding fee based on income and family size. Nearly 1,400 health centers operate more than 16,200 service delivery sites that provide primary health care to over 32 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

HRSA uses the Uniform Data System (UDS) for required annual reporting of program-specific data by Health Center Program awardees (those funded under section 330 of the PHS Act), Health Center Program look-alikes (entities meeting requirements of, but not funded under, section 330 of the PHS Act), and Nurse Education, Practice, Quality and Retention (NEPQR) and Advanced Nursing Education (ANE) Program awardees (specifically those funded under the practice priority areas of sections 831(b) and 811 of the PHS Act).

Some NEPQR and ANE Program awardees establish and expand nursing practice arrangements in non-institutional settings to demonstrate methods to improve access to primary health care in medically underserved communities. Nursing grantees implementing nursing practice arrangements have historically used the same data collection system as the Health Center Program.

A 60-day notice published in the **Federal Register** on December 10, 2025, vol. 90, No. 235; pp. 57205–57208. There were 16 public comments. Below

is a summary of key themes raised in the comments and HRSA's responses:

- *Maintain COVID-related measures (Two comments):*

- Stakeholders recommended reconsideration of the proposed removal of several COVID-related measures in *Table 6A: Selected Diagnoses and Services Rendered*, including *Respiratory conditions related to COVID–19*, *Long COVID*, *Novel coronavirus (SARS-CoV–2) disease*, *Novel coronavirus (SARS-CoV–2) diagnostic test*, and *Novel coronavirus (SARS-CoV–2) antibody test*, emphasizing the importance of continued tracking for surveillance, resource allocation, and monitoring impacts on special medically underserved populations. Of the five COVID-related measures currently included in the 2025 UDS, HRSA will retain two measures in response to stakeholder feedback, while three measures will be removed as part of broader streamlining efforts.

- *Recognize Psychiatric Mental Health Nurse Practitioners (PMHNP) distinctly (One comment):*

- One stakeholder requested to specify PMHNPs separately in *Table 5: Staffing and Utilization* due to their significant role in delivering mental health services and managing high patient volume. In response to this feedback, PMHNPs will be added to *Table 5*, line 20b, under *Other Licensed Mental Health Providers*.

- *Include additional case management codes (Two comments):*

- Commenters also requested enhancements to the Case Management codes under *Table 6A: Patient Support Services* to include Advance Primary Care Management codes (G0556, G0557, G0558) and T1016, to capture broader case management services beyond Medicare. Based on stakeholder feedback, these codes will be added to *Table 6A*, line 35, *Case Management*.

- *Adjust Substance Use Disorder Initiation/Engagement electronic clinical quality measure (eCQM) for health center realities (Two comments):*

- Commenters recommended reconsideration of the substance use disorder (SUD) measure, *Initiation and Engagement of SUD Treatment*, which was introduced in the 2025 UDS instrument. Stakeholders noted that the current eCQM does not align with health center data capabilities, resulting in misclassification of ongoing SUD treatment and understated health center performance. Commenters specifically

noted the reporting challenges with the measure's definition of a "new SUD episode," which does not account for care received outside the health center and may inadvertently include patients in the denominator. Commenters also expressed that due to scope-of-practice limitations and operational challenges, there may be constraints in meeting the initiation and engagement timeframes outlined in the measure.

As 2025 was the first year of implementation for the SUD eCQM, HRSA recognizes that health centers may require time to fully operationalize workflows and reporting processes. HRSA will continue to provide technical assistance, monitor implementation, and assess the measure's ongoing relevance as additional data becomes available. Regarding proposed changes to the specifications for a measure, reporting specifications are set by the measure steward and cannot be modified. Measure stewards for each UDS clinical quality measure are listed in Appendix G of the forthcoming 2026 UDS Manual, which HRSA plans to release in summer 2026.

• *General objection to proposed changes (One comment):*

- One commenter expressed the need for transparency regarding the rationale for proposed measurement changes. HRSA maintains open communication channels (e.g., all-programs webcasts, newsletters, tailored technical assistance calls) and will continue to provide technical assistance on UDS reporting to ensure stakeholders understand the rationale and best practices for implementing UDS instrument changes.

• *Support for overall UDS streamlining/burden reduction (Six comments):*

- Commenters conveyed broad approval and support for HRSA's proposed measurement alignment, elimination, and simplification efforts, noting that these changes are expected to meaningfully reduce administrative reporting burden.

• *Consideration regarding mental health and substance use disorder tracking (Three comments):*

- In response to the proposed removal of Table 5: *Selected Services Detail Addendum*, stakeholders requested that the decision be reconsidered, noting potential underreporting of integrated mental health and substance use disorder services that are delivered by non-psychiatric and non-licensed professional counselor

providers. Additionally, stakeholders expressed that the removal of the *Selected Services Detail Addendum* would impair accurate performance assessment and collaborative care tracking. HRSA maintains that the measures in this section are not used to assess compliance with grant performance requirements, and related reporting in the main part of Table 5 would remain unchanged. Given areas of duplication, HRSA is exploring ways to capture unduplicated data on integrated care for a future iteration of the UDS instrument.

• *Patient support services and upstream drivers of health reporting implications: (Two comments):*

- Commenters applauded the transition of patient support services and upstream drivers of health measures from the appendices to Table 6A: *Selected Services and Diagnosis Rendered* but identified potential challenges of these additions if certified health information technology cannot automate extraction, leading to an increase in administrative and operational burden. As with any new reporting requirement, HRSA anticipates an initial transition period and will continue to provide technical assistance and guidance to support implementation. HRSA will monitor early reporting experience to assess burden and inform future refinements in 2027.

• *Lifestyle Medicine proposals (One comment):*

- One commenter recommended incorporating lifestyle measures into the UDS instrument to strengthen preventative care and whole-person health. The stakeholder specifically proposed a variety of related measures reflecting upstream risks and outcomes, standardized lifestyle medicine assessments, Type 2 diabetes remission, deprescribing outcomes, and community support. HRSA appreciates the thoughtful suggestion and will evaluate these recommendations for alignment with Administration and HRSA priorities for a future UDS instrument.

• *Financial and Service Reporting Transparency (Two comments):*

- Commenters requested reconsideration of the removal of grant-level reporting in Table 9E: Other Revenue and the consolidation of line items in Table 8A: Financial Costs. Commenters noted that maintaining grant-level reporting is necessary to promote transparency

and accountability by demonstrating how federal resources are used to support health centers. Further, it was noted that the proposed consolidation and removal of Table 8A line items will reduce visibility into critical health center services. HRSA notes that these removals reflect an effort to reduce reporting burden by modernizing and streamlining the instrument and eliminating redundancies where comparable data may be collected in other grant financial reporting forms, including Health Center Program Forms (OMB No. 0915-0285-Revision).

• *Desire to retain multiple Table 6A clinical measures (One comment):*

- One stakeholder expressed a desire to retain several Table 6A: *Selected Diagnoses and Services Rendered* measures, including abnormal breast cancer and cervical cancer findings, contact dermatitis and other eczema, mammograms, Pap tests, sealants, and oral surgery. HRSA is removing these measures from Table 6A due to redundancies where similar information is captured elsewhere in the UDS instrument. For example, the abnormal breast cancer findings measure is also similarly reflected in Table 6B's Breast Cancer Screening measure (CMS125v13).¹

• *Clarifications on Tables 8A/9D/9E (Three comments):*

- Commenters also expressed the need for additional reporting guidance clarification across multiple tables, including tables 8A, 9D, and 9E, particularly related to managed care dynamics, including treatment of insured patient copays in payer mix. HRSA will provide detailed reporting instructions for the relevant tables, consistent with standard practice, in the forthcoming 2026 UDS Manual release, which HRSA plans to release in summer 2026.

Need and Proposed Use of the Information: HRSA requires the collection of information through UDS to monitor and evaluate the performance of health centers under section 330 and select NEPQR and ANE recipients under sections 831(b) and 811 of the PHS Act. These data support program compliance, inform quality improvement initiatives, guide the delivery of technical assistance, and shape federal health program decisions. To keep this instrument relevant and

¹ eCQI Resource Center. (2025). *Breast cancer screening (CMS125v13)*. U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. <https://ecqi.healthit.gov/ecqm/ec/2025/cms0125v13>.

responsive to the Health Center Program's needs and Administration priorities, periodic updates are essential. This includes adjustments to the proposed measures made during the internal HRSA review and approval process used to finalize the proposed measures for submission to OMB. The purpose of these updates is to capture the breadth of integrated primary care services offered by health centers. Measures that were added during the internal HRSA review and approval process are signified by an asterisk (*) in the list below.

HRSA proposes to make the following updates for the performance year 2026 UDS data collection (note: measures to be removed refer to the line in the 2025 UDS):

Table 4: Selected Patient Characteristics

Removal

- *Managed Care Utilization*—UDS measures associated with managed care member months, *Capitated Member Months*, *Fee-for-Service Member Months*, and *Total Member Months* (Lines 13a—13c) will be removed to reduce the reporting burden, given the variations in payer structures and payment arrangements across health centers.

Table 5: Staffing and Utilization and Selected Service Detail Addendum *

Removal

- *Selected Service Detail Addendum*—Detailed reporting elements related to integrated mental health and substance use disorder service delivery (Lines 20a01—21h) will be removed to streamline reporting and reduce burden on health centers. Mental health and substance use disorder services will continue to be reported in the core part of Table 5.

Addition

- *Staffing and Utilization*—Specific mental health personnel types, including PMHNPs, will be added as drop-down options to Line 20b, *Other Licensed Mental Health Providers*. This addition will allow for more accurate classification of licensed mental health providers and better reflect the composition of the behavioral health workforce.

Table 6A: Selected Diagnoses and Services Rendered

Removals

- *Various Clinical Measures*—Clinical measures associated with various diagnoses and selected services rendered are being removed from Table

6A to streamline reporting, reduce burden, and eliminate potential redundancies where similar information is captured elsewhere in the UDS. The specific measures proposed for removal are indicated below:

- Respiratory conditions related to COVID-19 (Line 6a)
- Abnormal breast findings, female (Line 7)
- Abnormal cervical findings (Line 8)
- Contact dermatitis and other eczema (Line 12)
- Novel coronavirus (SARS-CoV-2) diagnostic test (Line 21c)
- Novel coronavirus (SARS-CoV-2) antibody test (Line 21d)
- Mammogram (Line 22)
- Pap test (Line 23)
- Sealants (Line 30)
- Oral surgery (extractions and other surgical procedures) (Line 33)
- Rehabilitative services (Endo, Perio, Prostho, Ortho) (Line 34)

As mentioned above, because of feedback received during the 60-day comment period, HRSA added “Novel coronavirus (SARS-CoV-2) disease (Line 4c)” and “Long COVID (Line 4d)” back into Table 6A.

Additions

- *Type 1 Diabetes*—A new measure is being added as line 9a to identify the number of patients with Type 1 Diabetes. This addition will help address key data gaps and improve HRSA's understanding of the distinct care and resource needs of patients with Type 1 Diabetes.

- *Intellectual and Developmental Disabilities*—A new measure is being added as line 20g to capture the number of patients with intellectual and developmental disabilities. Available data indicate that this population may experience lower rates of access to preventive and chronic care, including fewer screenings, lower utilization of dental care, and higher rates of undiagnosed or unmanaged conditions. Capturing this information will improve understanding of the prevalence of persons with intellectual and developmental disabilities in the Health Center Program and support efforts to enhance health care access and quality of care for individuals who require complex, coordinated services.

- *Autism Spectrum Disorder Screening*—A new measure is being added as line 26g to capture the number of patients screened for autism spectrum disorder. This measure will help assess the extent to which health centers are implementing recommended developmental screening practices and connecting children and families to needed support services.

- *Patient Support Services*—Four new measures are being added as lines 35–38 to capture the number of patients receiving case management, eligibility assistance, transportation, and language assistance services to better understand the range of non-clinical services that facilitate access to care and contribute to improved patient outcomes.

- *Upstream Drivers of Health*—Four new measures are being added as lines 39–42, transitioning from Appendix D to the UDS core tables, to identify the number of patients who are screened for, and who receive, services addressing upstream drivers of health. These or similar measures are now being elevated to the core reporting set to support standardized data collection. Integrating these measures within the core tables will enhance the ability to monitor how health centers identify and address patients' access to and utilization of services.

Table 6B: Quality of Care Measures *

Additions

- *Fall Risk Screenings*—One new measure is being added as line 24 to capture the number of patients 65 years of age and older who were screened for future fall risk, in alignment with eCQM CMS139v14.² Incorporating a fall risk screening measure aligns the UDS with national quality and preventive care efforts, including routine fall risk assessments conducted during Medicare Initial and Annual Wellness Visits.³ This alignment supports harmonization across federal programs, enables HRSA to better understand the needs and resources required to support the growing aging population served by the Health Center Program and inform technical assistance for health centers.

Table 6B: Quality of Care Measures and Table 7: Health Outcomes

Updates

- *Clinical Quality Measures*—Tables 6B and 7 collect UDS clinical quality measures, and where applicable, clinical quality measures will be updated in alignment with specifications of the issued performance year 2026 electronic clinical quality measures. These specifications were

² eCQI Resource Center. (2026). *Falls: Screening for future fall risk (CMS0139v14)*. U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. <https://ecqi.healthit.gov/ecqm/ec/2026/cms0139v14>.

³ Centers for Medicare & Medicaid Services. (2026). *Initial preventive physical exam*. U.S. Department of Health and Human Services. <https://www.cms.gov/medicare/coverage/preventive-services/medicare-wellness-visits/initial-preventive-physical-exam>.

released by the Centers for Medicare & Medicaid Services on May 8, 2025, for use by eligible providers. Aligning clinical performance measures across national programs promotes data standardization, quality, and transparency, and decreases the reporting burden for providers and organizations participating in multiple federal programs.

Table 8A: Financial Costs

Removals

- *Allocation of Facility and Non-Clinical Support Services—Allocation of Facility and Non-Clinical Support Services*, Column B, and the requirement to report overhead costs on Table 8A will be removed.

- *Enabling Services*—Costs of each type of enabling service (Lines 11a, 11b, 11c, 11d, 11e, 11f, 11g, and 11h) will be removed. These costs will be consolidated into a single line to reflect all *Patient Support Services* costs (Line 11) (previously known as Enabling Services).

- *Donations*—Line 18, *Value of Donated Facilities, Services, and Supplies (specify)*, will be removed.

These updates are being made to reduce the reporting burden and address stakeholder feedback.

Table 9D: Accrued Patient Service Revenue

Removals

- *Retroactive Settlements, Receipts, and Paybacks*—revenue associated with Columns c1—c4 for classification of types of collections will be removed:

- Collection of Reconciliation/ Wraparound Current Year (c1)
- Collection of Reconciliation/ Wraparound Previous Years (c2)
- Collection of Other Payments: Pay for Performance, Risk Pools, etc. (c3)
- Penalty/Payback (c4)

These collections will be consolidated into a single column to reflect all Collections (Column B).

- *Payer Category*—Form of payment (non-managed care, capitated managed care, and fee-for-service managed care) lines have been collapsed into a single total line by the third-party payer. *Total Medicaid* (Line 3), *Total Medicare* (Line 6), *Total Other Public (specify)* (Line 9), and *Total Private* (Line 12) will be reported, and the following lines will be removed as a result:

- Medicaid Non-Managed Care (Line 1)
- Medicaid Managed Care (capitated) (Line 2a)
- Medicaid Managed Care (fee-for-service) (Line 2b)
- Medicare Non-Managed Care (Line 4)

- Medicare Managed Care (capitated) (Line 5a)
- Medicare Managed Care (fee-for-service) (Line 5b)
- Other Public, including Non-Medicaid Children's Health Insurance Program (CHIP), Non-Managed Care (Line 7)
- Other Public, including Non-Medicaid CHIP, Managed Care (capitated) (Line 8a)
- Other Public, including Non-Medicaid CHIP, Managed Care (fee-for-service) (Line 8b)
- Private Non-Managed Care (Line 10)
- Private Managed Care (capitated) (Line 11a)
- Private Managed Care (fee-for-service) (Line 11b)

- *Sliding Fee **—Sliding fee associated with Line 13, Column E for classification of sliding fee discounts provided to patients has been collapsed into the existing single total Self-Pay line (Line 13) and will be reported as Adjustments (Column D).

- *Patient Bad Debt **—Bad debt write-off associated with patients previously reported in Line 13, Column F has been removed and will be reported with all third-party payer bad debt write-offs and allowances (Line 15, Column G).

These updates are being made to reduce the reporting burden and address stakeholder feedback.

Additions

- *Bad Debt Write-Offs and Allowances **—A new line will be added as an offset to *Net Patient Service Revenue* for accrued *Bad Debt Write-Offs and Allowances* (Line 15, Column G).

- *Net Patient Services Revenue*—A new column and line will be added for *Net Patient Service Revenue (Charges Less Adjustments)* (Line 16, Column G).

- *Pharmacy Net Patient Service Revenue*—A new line will be added to reflect all *Pharmacy Net Patient Service Revenue* (Line 17, Column G).

- *Third-Party Incentive Revenue*—A new line will be added to reflect all *Third-Party Incentive Revenue* (Line 18, Column G).

These updates are being made to reduce reporting burden and to better assess financials in alignment with generally accepted accounting principles and health centers' financial statements.

Table 9E: Other Accrued Revenue

Removals

- *HRSA's Bureau of Primary Health Care (BPHC) Grants*—Health Center Program grant funding sources (formerly Lines 1a—1e) and other BPHC funding

detail lines (formerly Lines 1k—1q) will be removed. Grants with active funding will be aggregated and reported on a single, total line: *Total Health Center BPHC Grants* (Line 1).

- *Other Federal Grants*—Specific federal grant funding sources (formerly Lines 2, 3, and 3a) will be removed. All non-BPHC federal grants will be reported on Line 5, *Total Other Federal Grants (specify)*.

These updates are being made to align with supplemental funding being rolled into the base Health Center Program funding, remove outdated supplemental funding lines, reduce the reporting burden, and to better assess financials in alignment with generally accepted accounting principles and health centers' financial statements.

Appendix D: Health Center Information Technology (Health IT) Capabilities and Appendix E: Other Data Elements

Removals

- *Appendix D: Health IT Capabilities*—Several questions specific to Electronic Health Records implementation (Questions 1a, 1a2, 1a3, 1c, 1c1, and 10) will be removed from Appendix D.

- *Appendix D: Health IT Capabilities*—Upstream drivers of health screening questions (Questions 11, 11a, 12, 12a, and 12b) will be removed from Appendix D.

- *Appendix E: Other Data Elements*—Appendix E will be removed, and certain data elements will be combined with Appendix D. Outreach and enrollment assists (formerly Appendix E, Question 3) will be removed (aspects will be incorporated in the Table 6A Patient Support Services addition).

These updates are being made to reduce the reporting burden and address stakeholder feedback.

Additions

- *Appendix D: Health Center IT Capabilities and Other Data Elements*—Three questions on Alternative Payment Models (APM) will be added to Appendix D (Questions 17—19), to include:

- What payor arrangements do you have for value-based purchasing contracts?
- Please list the types of APMs your health center is involved in.
- What percentage of your health center's revenue during the year is tied to value-based payment contracts?

HRSA is adding new data elements to capture health centers' participation in APMs to improve understanding of the evolving payment landscape within the Health Center Program. As health centers increasingly engage in payment arrangements that emphasize value, care coordination, and outcomes, collecting information on APM participation will provide valuable insight into the range and scope of these models and inform technical assistance to support health centers' adoption of APMs.

- *Appendix D: Health IT Capabilities **—One question addressing the provision of sex rejecting services and procedures in health

centers will be added to Appendix D (Question 20), to include:

- For individuals under 19 years of age, does your health center provide services that use puberty blockers, sex hormones, or surgical procedures for the purpose of transforming their physical appearance to align with an identity that differs from their sex? *Puberty blockers may include GnRH agonists and other interventions, to delay the onset or progression of normally timed puberty in an individual. Sex hormones may include androgen blockers, estrogen, progesterone, or testosterone. Surgical procedures may include alteration or removal of an individual's sex organs.*

HRSA is making these updates to Appendix D based on internal agency review and approval processes to capture the breadth of integrated primary care services offered by health centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of

information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

In 2026, the estimated total burden hours for this ICR are approximately 304,616 hours, compared to 2025, when the burden was estimated at 377,317 hours—a decrease of approximately 72,701 hours collectively across health centers or an average of 42 hours per health center. This decrease is primarily attributable to HRSA's streamlining efforts, which were undertaken to reduce provider burden.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents *	Number of responses per respondent	Total responses	Average burden per response (in ours)	Total burden hours
UDS—Universal Report	1,596.00	1.00	1,596.00	184.20	293,983.20
UDS Grant Report	419.00	1.22	511.18	20.80	10,632.54
Total	2,015.00		2,107.18		304,615.74

* The estimated number of respondents for the Universal Report consists of 1,356 Health Center Program recipients, 170 Health Center Look-alikes, and 70 NEPQR and ANE recipients. The estimated number of respondents for the “Grant Report” is based on the number of reports submitted by health centers in 2025: 337 (one report), 71 (two reports), 11 (three reports).

Amy P. McNulty,
Deputy Director, Executive Secretariat.
[FR Doc. 2026–12046 Filed 6–15–26; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Proposed Healthy People 2030 Objectives and Request for Information on Screen Time To Inform Healthy People

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary of Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS), Office of Disease Prevention and Health Promotion (ODPHP) solicits written comments from the public on new objectives to be added to Healthy People 2030 and gather input to refine or expand the existing screen time objectives.

DATES: Written comments will be accepted through 11:59 p.m. ET, July 16, 2026.

ADDRESSES: Written comments should be submitted by email to HP2030Comment@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Yen Lin, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Email: HP2030@hhs.gov.

SUPPLEMENTARY INFORMATION: Since 1980, Healthy People has provided science-based, measurable 10-year objectives to improve the nation’s health and well-being, established national priorities, and monitored progress throughout each subsequent decade. Shaped by input from individuals and organizations across all sectors and all levels of government, Healthy People solicits annual public comment to reflect current public health priorities.

ODPHP seeks written public comments on three new objectives to be added to Healthy People 2030. These new objectives were developed by federal Healthy People topic area workgroup agencies and have been reviewed by the Healthy People 2030 Federal Interagency Workgroup (FIW). They are:

1. *Access to Health Services (New Objective–10):* Reduce the proportion of persons who are unable to obtain or who delay obtaining mental health care due to cost. Data source: National Health Interview Survey, Centers for Disease Control and Prevention/ National Center for Health Statistics.
2. *Early and Middle Childhood (New Objective–05):* Increase the proportion of children who are developmentally ‘on

track’ and healthy and ready to learn at school. Data source: National Survey of Children’s Health, Health Resources and Services Administration/Maternal and Child Health Bureau.

3. *Social Determinants of Health (New Research Objective–03):* Explore the impact of referrals to non-clinical activities (e.g., art, music, movement, nature, and community service) on improving health outcomes. Data source: No known reliable national data source is currently available.

Note:
Research objectives highlight critical emerging public health issues that lack the research or reliable national data needed to establish 10-year targets.

Recently, HHS released the Surgeon General’s Advisory on the Harms of Screen Use which warns of adverse health outcomes associated with screen time. Concerns at various age groups are discussed, beginning with exposure in young children through teenage years, and highlighting concerns with mental, cognitive, and behavioral health. Given the information cited in the advisory, ODPHP is seeking public comments to refine or expand two existing Healthy People 2030 objectives:

1. *Physical Activity–13:* Increase the proportion of children aged 2 to 5 years who get no more than 1 hour of screen time a day. Data Source: National Survey of Children’s Health, Health Resources and Services Administration.

2. Physical Activity Research

Objective—02: Increase the proportion of parents who follow American Academy of Pediatrics recommendations on limiting screen time for children aged 6 to 17 years. Data Source: No known reliable national data source is currently available.

Written comments should be submitted by email to HP2030Comment@hhs.gov by 11:59 p.m. ET July 16, 2026. Comments received in response to this notice will be reviewed by the Healthy People topic area workgroups, Healthy People 2030 (FIW), and other federal subject matter experts. For more information on Healthy People 2030, visit <https://healthypeople.gov/>.

For the latest information and guidance from HHS on screen time, please see the Surgeon General's Advisory on the Harms of Screen Use and toolkit for families, schools, health care providers, researchers, and technology companies, available at: <https://www.hhs.gov/surgeongeneral/reports-and-publications/screen-use-harms/index.html>.

Katrina L. Piercy,

Deputy Director, Office of Disease Prevention and Health Promotion.

[FR Doc. 2026–12090 Filed 6–15–26; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0010]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of Grants, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on the ICR must be received on or before July 16, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by selecting “Currently under Review” and “Select Agency: Department of Health and Human Services”.

FOR FURTHER INFORMATION CONTACT: Sagal Musa, sagal.musa@hhs.gov or (202) 578–5441. When submitting comments or requesting information, please include the document identifier 4040–0010–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collections: Project/Performance Site Location(s), Project Abstract, and Key Contacts forms.

Type of Collection: Extension.

OMB No.: 4040–0010.

Abstract

The Project/Performance Site Location(s), Project Abstract, and Key Contacts forms provide the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use Project/Performance Site Location(s), Project Abstract, and Key Contacts forms for grant programs not required to collect all the data that is required on the SF–424 core data set and form. Project/Performance Site Location(s), Project Abstract, and Key Contacts forms are used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review. The information collection (IC) expires on December 31, 2026. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents	Number of respondents	Number of responses per respondents	Average burden per response (hours)	Total burden hours
Project/Performance Site Location(s)	Grant Applicants	127,281	1	1	127,281
Project Abstract	Grant Applicants	230	1	1	230
Key Contacts	Grant Applicants	4,566	1	1	4,566
Total		132,077			132,077

The estimated annual burden hours reflect the number of applications *Grants.gov* received during the most

recent fiscal year that included these forms. The increase is attributable to higher form usage by agencies in

application packages, not to changes to the forms or burden per response.

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Department of Health and Human Services, Office of the Secretary.

[FR Doc. 2026–12107 Filed 6–15–26; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Establishment and Characterization of the A1847 Human Ovarian Carcinoma Line

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks licensees for a tumorigenic cell line, A1847, from a patient with metastatic ovarian cancer. As a BRCA1 deficient cell line, it serves as a model to researchers studying cell cycle regulation, tumor suppression and effective drugs aiding in repair of DNA damage.

FOR FURTHER INFORMATION CONTACT: Mutations, Inquiries related to this license opportunity should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: suna.gulay@nih.gov or Phone: 240-276-7424.

SUPPLEMENTARY INFORMATION: Mutations, such as loss of function, in the BRCA1 gene increase the risk of developing ovarian cancer. In its early stages, ovarian cancer may not cause any definitive symptoms but can rapidly progress within a year to advanced stage. This metastatic growth can occur by shedding cancerous cells into peritoneal fluid, often associated with epithelial ovarian cancer, its most common type. While treatments exist, it is limited by the development of drug resistance that is not succumbed to damage in cell death.

The National Cancer Institute (NCI) researchers derived a metastatic ovarian carcinoma cell line, A1847, from a 50-year-old female. It was established as a continuous tumorigenic cell line and characterized by isozyme phenotype, short tandem repeat (STR) analysis and karyotypically with modal number 68 and 3 marker chromosomes. This cell line may be used to identify therapeutic targets and to screen drug candidates against ovarian cancer.

NCI is seeking parties to nonexclusively license the A1847 human ovarian carcinoma cell line. "This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses."

NIH Reference Number: E-137-2023-0.

Related Technologies: E-018-2020-0. *Product Type:* Research Material/ Tool.

Therapeutic Area(s): Oncology.

Publications:

- Standing, D., et al. Selective targeting of IRAK1 attenuates low molecular weight hyaluronic acid-induced stemness and non-canonical STAT3 activation in epithelial ovarian cancer. (PMID 38796478).
- Sethi, G., et al. An RNA interference lethality screen of the human druggable genome to identify molecular vulnerabilities in epithelial ovarian cancer. (PMID 23056589).
- Godwin, A.K., et al. High resistance to cisplatin in human ovarian cancer cell lines is associated with marked increase of glutathione synthesis. (PMID 1348364.)

Potential Commercial Applications:

- Tool to conduct preclinical proof-of-concept studies required for commercial development of anti-cancer agents and targeted therapies in ovarian cancer.
- Research model to investigate epithelial ovarian cancer.
- Research model for mechanistic studies of ovarian cancer and BRCA1-deficient tumors.

Competitive Advantages:

- Well-characterized metastatic ovarian cancer cell line.
- Tumorigenic cell line to generate animal models of metastatic ovarian cancer for commercial and research development.

Collaboration Opportunity:

Researchers at the NCI seek licensing for the A1847 ovarian cancer cell line.

Dated: June 10, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026-12070 Filed 6-15-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Contracts: Alcohol Registry.

Date: July 1, 2026.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vanessa S. Boyce, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4185, MSC 7850, Bethesda, MD 20892, (301) 402-3726, boycevs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurovascular, Blood-brain Barrier, and Clearance Pathways.

Date: July 14-15, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nilkantha Sen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-9223, nilkantha.sen@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Musculoskeletal and Oral Sciences.

Date: July 14, 2026.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Robert Gersch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800K, Bethesda, MD 20817, (301) 402-4789, robert.gersch@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Preclinical Discovery and Validation of Pharmacotherapeutic and Immunotherapeutic Agents for Non-Cancer Disorders.

Date: July 14, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Andrea Samantha Gobin, Ph.D., Scientific Review Officer,

Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-4959, andi.gobin@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biodata Management and Computational Modeling.

Date: July 14, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Christopher Ryan Mahone, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 710F, Bethesda, MD 20892, (240) 338-9679, mahonecr@csr.nih.gov

Name of Committee: Center for Scientific Review, Special Emphasis Panel; RFA Panel: Technologies and Instrumentation for Recording and Modulation in the Nervous System.

Date: July 14, 2026.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Cristina Backman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, (301) 480-9069, cbackman@mail.nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; RFA Panel: Animal and biological Material Resource Centers and Resource-related Projects.

Date: July 14, 2026.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 6188, MSC 7804, Bethesda, MD 20892, 301-435-1267, belangerm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Diseases and Immunology.

Date: July 14-15, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, 710-C, Bethesda, MD 20892, (301) 496-8947, rosenthalla@nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; Member Conflict: Topics on Autoimmunity, Immunology and Transplantation.

Date: July 14, 2026.

Time: 11:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 627-3255, marci.scidmore@nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; Fellowships: Kidney, Urology, and Skin.

Date: July 14, 2026.

Time: 12:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 721-B, Bethesda, MD 20892, (301) 451-1322, ryan.morris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 11, 2026.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-12074 Filed 6-15-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; NIH Extramural Harassment Web Form (Office of the Director, Office of Extramural Research)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received by July 16, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patricia Valdez, Chief Extramural Research Integrity Officer, Office of Extramural Research, National Institutes of Health, 6705 Rockledge Dr, Room 705-C, Bethesda, Maryland 20892 or call non-toll-free number (301) 451-2160 or email your request, including your address to: patricia.valdez@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 12, 2026, pages 12203-12204 (91 FR No. 48) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of Extramural Research (OER), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to any information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: NIH Extramural Harassment Web Form, 0925–0777, expiration date March 31, 2026, Reinstatement without change, National Institutes of Health (NIH) Office of the Director (OD), Office of Extramural Research (OER).

Need and Use of Information Collection: The purpose of this web form is to assist extramural institutions with complying with Section 239 of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103), Division H, Title II,

which requires that “institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions.” The Harassment Web Form will be used as a secure and confidential portal by which recipient institutions notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions, as

specified in NOT–OD–22–129. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through the Harassment Web Form. All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 60.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Private Sector	240	1	15/60	60
Total		240		60

The Deputy Director for Extramural Research, Jon Lorsch, having reviewed and approved this document, authorizes Alycia Booth, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: June 12, 2026.

Alycia Booth,

Federal Register Liaison, National Institutes of Health.

[FR Doc. 2026–12106 Filed 6–15–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2026–0463]

Commercial Customs Operations Advisory Committee

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (Committee) will hold its quarterly meeting on Wednesday, July 15, 2026,

in Washington, DC. The meeting will be open to the public via webinar only.

DATES: The Committee will meet on Wednesday, July 15, 2026, from 1:00 p.m. to 5:00 p.m. Eastern Daylight Time (EDT). Please note the meeting may close early if the Committee has completed its business. Comments must be submitted in writing no later than 5:00 p.m. EDT on July 10, 2026.

ADDRESSES: The meeting will be open to the public via webinar only. The webinar link will be posted by 5:00 p.m. EDT on July 14, 2026, at <https://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings>. For information or to request special assistance for the meeting, contact Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, at (202) 344–1440, as soon as possible.

Comments may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Search for Docket Number USCBP–2026–0463. To submit a comment, click the “Comment” button located on the top-left hand side of the docket page.

- **Email:** tradeevents@cbp.dhs.gov. Include Docket Number USCBP–2026–0463 in the subject line of the message.

Comments must be submitted in writing no later than 5:00 p.m. EDT on

July 10, 2026, and must be identified by Docket No. USCBP–2026–0463. All submissions received must also include the words “Department of Homeland Security.” All comments received will be posted without change to <https://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings> and www.regulations.gov. Therefore, please refrain from including any personal information you do not want to be posted. You may view the Privacy and Security Notice, which is available via a link on www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229, (202) 344–1440; or Mr. Christopher J. Siepmann, Designated Federal Officer, at (202) 344–1440 or tradeevents@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the authority of the Federal Advisory Committee Act, Title 5 U.S.C., ch. 10. The Committee provides advice to the Secretary of the Department of Homeland Security, the Secretary of the Department of the Treasury, and the Commissioner of U.S. Customs and Border Protection on matters pertaining to the commercial operations of U.S. Customs and Border Protection and

related functions within the Department of Homeland Security and the Department of the Treasury.

The Committee is dedicated to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation due to a disability to fully participate, please contact Mrs. Latoria Martin at (202) 344-1440 as soon as possible.

Please feel free to share this information with other interested members of your organization or association.

To facilitate public participation, we are inviting public comments on the issues the Committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

There will be a public comment period during the meeting on July 15, 2026. Comments may also be submitted via the trade events mailbox at tradeevents@cbp.dhs.gov or through the Microsoft Teams chat feature during the meeting. Please note the public comment period for speakers may end before the time indicated on the schedule that is posted on the U.S. Customs and Border Protection web page: <http://www.cbp.gov/trade/stakeholder-engagement/coac>.

Agenda

The ability for the Committee to meet has been affected by the lapse in funding for the Department of Homeland Security. While U.S. Customs and Border Protection continued operations, the Committee did not engage with U.S. Customs and Border Protection. Despite that, recommendations will be made for the July Public Meeting relating to the Customs Trade Partnership Against Terrorism (CTPAT) Minimum Security Criteria and the development and implementation of an outreach strategy designed to disseminate essential supplemental guidance to the trade community.

Meeting materials will be available on July 6, 2026, at: <http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings>.

Christopher J. Siepmann,

Executive Director, Office of Trade Relations.

[FR Doc. 2026-12091 Filed 6-15-26; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRNL-DTS#-42962; PPWOCRADIO, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before May 30, 2026, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by July 1, 2026.

ADDRESSES: Comments are encouraged to be submitted electronically to National_Register_Submissions@nps.gov with the subject line "Public Comment on <property or proposed district name, (County) State>." If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 2013, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 2013, Washington, DC 20240, sherry_frear@nps.gov, 202-913-3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before May 30, 2026. Pursuant to 36 CFR 60.13, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers: Key: State, County, Property Name, Multiple Name (if applicable), Address/ Boundary, City, Vicinity, Reference Number.

CALIFORNIA

San Francisco County

Raymond Hotel Apartments, 20 Franklin Street, San Francisco, SG100013199

FLORIDA

Putnam County

St. Mary's Episcopal Church, (Florida's Carpenter Gothic Churches MPS), 809 St. Johns Avenue, Palatka, MP100013184

St. Johns County

Model Land Company Historic District (Boundary Increase), Roughly bounded by King, Cordova, and Orange Streets, U.S. 1, and the San Sebastian River, St. Augustine, BC100013186

GEORGIA

Fulton County

South-View Cemetery, 1990 Jonesboro Road SE, Atlanta, SG100013193

MARYLAND

Kent County

Chestertown Historic District (Boundary Increase II), High Street, Water Street, Cannon Street, Calvery Street, Mill Street, Kent Street, Spring Avenue, Washington Avenue, Prospect Street, N College Avenue, Court Street, Philosophers Terrace, Chestertown, BC100013208

Prince George's County

Cedar Haven Historic District, (African-American Historic Resources of Prince George's County, Maryland), 22907-23110 Crispus Attucks Blvd.; 23118 Bethune Ave.; 18402 Trueman Point Rd.; 22904-23100 Paul Dunbar Ave.; 18101-18410 Richard Allen St.; 22801-23200 Benjamin Banneker Blvd.; 22901-23007 Frederick Douglas Ave.; 22801-22815 Booker Washington Ave.; 23305-23013 C, Aquasco, MP100013190

NORTH DAKOTA

Billings County

Short Ranch Historic District, Wannagan Creek Road, Medora, SG100013187

Towner County

Pleasant Home Farm, 7187 70th Street NE, Cando vicinity, SG100013203

WISCONSIN

Milwaukee County

Calvary Baptist Church, 2959 North Teutonia Avenue, Milwaukee, SG100013194

An owner objection received for the following resource(s):

MARYLAND**Washington County**

Herald-Mail Building, 100 Summit Avenue, Hagerstown, SG100013181

A request for removal has been made for the following resource(s):

NEVADA**Washoe County**

Virginia Street Bridge, Spans Truckee River, Reno, OT80002471

An additional documentation has been received for the following resource(s):

FLORIDA**Leon County**

Union Bank, Apalachee Pkwy. and Calhoun St., Tallahassee, AD71000242

St. Johns County

Model Land Company Historic District (Additional Documentation), Roughly bounded by Ponce de Leon Blvd., King, Cordova, and Orange Sts., St. Augustine, AD83001439

MARYLAND**Kent County**

Chestertown Historic District (Additional Documentation), Roughly bounded by Maple Ave., Chester River, Cannon and Cross Sts., Chestertown, AD70000263

Chestertown Historic District (Boundary Increase) (Additional Documentation), Roughly bounded by Chester River, Lynchberg, and Cannon Sts., College Ave., Philosophers and Riverside Terrs., Chestertown, AD84001808
Authority: 36 CFR 60.13.

Lisa P. Davidson,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2026-12040 Filed 6-15-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF JUSTICE

[OMB Number 1123-1NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New collection; Requests for DOJ Certification Letters for T Visa Holders

AGENCY: Human Rights and Special Prosecutions Section, Criminal Division, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of Justice Programs, Department of Justice (DOJ), will be submitting the following

information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 17, 2026.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ayn Ducao, Human Rights and Special Prosecutions Section, Criminal Division, 1301 New York Ave. NW, Suite 1200, Washington, DC 20530, *T-visa.System@usdoj.gov* or (202) 616-2492.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the (component), including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. Type of Information Collection: New collection.
2. The Title of the Form/Collection: Requests for Department of Justice (DOJ) Certification Letters for T Visa Holders.
3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: 1123-1NEW.

Affected public who will be asked or required to respond, as well as a brief abstract: Affected Public: Primary: Individuals or households. well as a

brief abstract: Eligible non-citizen victims of human trafficking victims are entitled to petition the U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS), for temporary non-immigrant “T visas” pursuant to 8 U.S.C. 1101(a)(15)(T). T visas allow qualifying human trafficking victims to legally remain in the U.S. for up to 4 years if they comply with reasonable law enforcement requests for assistance. 8 U.S.C. 1101(a)(15)(T). Minors and those too traumatized to assist are exempt from assisting law enforcement. 8 U.S.C. 1101(a)(15)(T)(i)(III).

Qualifying T visa holders can petition DHS to adjust to Lawful Permanent Resident status if they meet statutory requirements under 8 U.S.C. 1255(l). To apply for an adjustment of status, a T visa holder must have remained continuously present in the U.S. for at least 3 years, or until completion of the investigation or prosecution, whichever is shorter. § 1255(l); 8 CFR 245.23(a). To apply for early adjustment of status within 3 years of receiving the T visa, the T visa holder must establish that the “Attorney General has determined that the investigation or prosecution is complete.” 8 U.S.C. 1255(l)(A). To establish their eligibility for early adjustment with USCIS, applicants with less than 3 years of continuous physical presence as T visa holders “must submit a document signed by the Attorney General or their designee, attesting that the investigation or prosecution is complete.” 8 CFR 245.23(e)(2)(i)(B).

4. Obligation to Respond: To apply for early adjustment of status within 3 years of receiving the T visa, the T visa holder must establish that the “Attorney General has determined that the investigation or prosecution is complete.” 8 U.S.C. 1255(l)(A). To establish their eligibility for early adjustment with USCIS, applicants with less than 3 years of continuous physical presence as T visa holders “must submit a document signed by the Attorney General or their designee, attesting that the investigation or prosecution is complete.” 8 CFR 245.23(e)(2)(i)(B) (emphasis added).

5. Total Estimated Number of Respondents: An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: DHS reported that between 2021 and 2025, DHS approved over 9,000 T visa applications. Some portion of these approved applicants have applied or will apply for DOJ Certification letters.

6. Estimated Time per Respondent: Will vary depending on the documentation available to the

applicant but estimated time for applicant to compile application would be on average three hours.

7. Frequency: Constant.

8. Total Estimated Annual Time Burden—Assuming 2,000 applications from respondents annually with an average time per respondent of 3 hours, then the annual time burden is 6,000 hours (2,000 × 3 hours).

9. Total Estimated Annual Other Costs Burden—N/A.

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Enterprise Portfolio Management, Two Constitution Square, 145 N Street NE, 4W-218, Washington, DC.

Dated: June 12, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026-12065 Filed 6-15-26; 8:45 am]

BILLING CODE 4410-14-P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

[OMB Control No. 1240-0037]

Proposed Extension of Information Collection; Medical Travel Refund Request—Mileage (OWCP-957A), Medical Travel Refund Request—Expenses (OWCP-957B)

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance request for comment to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This request helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments on the information collection for the OWCP Medical Travel Refund Request—Mileage (OWCP-957A) and OWCP Medical Travel Request—Expenses (OWCP-957B).

DATES: All comments must be received on or before August 17, 2026.

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

Electronic Submissions

Submit electronic comments in the following way:

- Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments for WCPO-2026-0430. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket, with no changes. Because your comment will be made public, you are responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as your or anyone else's Social Security number or confidential business information.

- If your comment includes confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission.

Written/Paper Submissions

Submit written/paper submissions in the following way:

- *Mail/Hand Delivery:* Mail or visit DOL-OWCP, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Ave. NW, Room S-3524, Washington, DC 20210.

- OWCP will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs, Office of Workers' Compensation Programs, at suggs.anjanette@dol.gov @dol.gov (email); (202) 354-9660.

SUPPLEMENTARY INFORMATION:

I. Background

The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Office of Workers' Compensation Programs (OWCP) is the agency responsible for administration of the Federal Employees' Compensation Act (FECA), 5 U.S.C. 8101 *et seq.*, the Black Lung Benefits Act (BLBA), 30 U.S.C. 901 *et seq.*, and the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384 *et seq.* All three of these statutes require that OWCP reimburse beneficiaries for travel expenses for covered medical treatment. In order to determine whether amounts requested as travel expenses are appropriate, OWCP must receive certain data elements, including the signature of the physician for medical expenses claimed under the BLBA. Form OWCP-957 is the standard format for the collection of these data elements. The regulations implementing these three statutes allow for the collection of information needed to enable OWCP to determine if reimbursement requests for travel expenses should be paid.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention 1240-0037.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

II. Desired Focus of Comments

OWCP is soliciting comments concerning the proposed information collection related to the Medical Travel Refund Request—Mileage (OWCP-957A), Medical Travel Refund Request—Expenses (OWCP-957B)

OWCP is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of OWCP/DFEC's estimate of the burden related to the information collection, including the validity of the methodology and assumptions used in the estimate;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the information collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Documents related to this information collection request are available at <https://regulations.gov> and at DOL-OWCP located at 200 Constitution Ave. NW, Room S-3524, Washington, DC 20210. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This information collection request concerns the Medical Travel Refund Request—Mileage (OWCP-957A), Medical Travel Refund Request—Expenses (OWCP-957B) OWCP has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension without change of a previously approved collection.

Agency: Office of Workers' Compensation Programs, OWCP.

OMB Number: 1240-0037.

Affected Public: Individuals.

Number of Respondents: 564,388.

Frequency: On Occasion.

Number of Responses: 1,128,776.

Annual Burden Hours: 56,438.80.

Annual Respondent or Recordkeeper Cost: \$1,896,343.68 OWCP/DFEC 1240-0037: OWCP Medical Travel Refund Request—Expenses and Medical Travel Refund Request—Mileage.

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and

will be available at <https://www.reginfo.gov>.

Anjanette Suggs,
Certifying Officer.

[FR Doc. 2026-12053 Filed 6-15-26; 8:45 am]

BILLING CODE 4510-CR-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NASA Document Number: 26-036; NASA Docket Number: NASA-2026-0298]

Name of Information Collection: NASA Small Business Supplier Development Program (Formerly Known as the NASA Mentor-Protégé Program)

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of Revision of a Currently Approved Collection.

SUMMARY: NASA, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA).

DATES: Comments are due by August 17, 2026.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 60 days of publication of this notice at <http://www.regulations.gov> and search for NASA Docket: NASA-2026-0298.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to NASA PRA Clearance Officer, Stayce Hault, NASA Headquarters, 300 E Street SW, JC0000, Washington, DC 20546, or email hq-ocio-pra-program@mail.nasa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The NASA Small Business Supplier Development Program (formerly known as the NASA Mentor-Protégé Program) is authorized by the U.S. Small Business Administration in accordance with 15 U.S.C. 657r and 13 CFR 125.10. The purpose of the Program is to provide incentives to NASA prime contractors (mentors) to assist small businesses and other protégés to enhance their capabilities and increase their participation in NASA, other Government, and in commercial contracts and subcontracts. Under the Program, mentor-protégé agreements

specify the assistance to be provided by the mentor and agreement milestones, as well as reporting requirements for the mentor and protégé firm. This information collection (*i.e.*, reports submitted pursuant to mentor-protégé agreements) is required by NASA to monitor the performance and progress of both the mentor and the protégé in this developmental assistance program.

NASA is committed to effectively performing the Agency's communication function in accordance with Section 203(a)(3) of the National Aeronautics and Space Act of 1958 (as amended) dictates that NASA "provide for the widest practicable and appropriate dissemination of information concerning its activities and the results thereof", and to enhance public understanding of, and participation in, the nation's aeronautical and space program.

II. Methods of Collection

Electronic via Email

III. Data

Title: NASA Small Business Supplier Development Program.

OMB Number: 2700-0078.

Type of review: Revision of a Currently Approved Collection.

Affected Public: Vendors participating in the NASA Small Business Supplier Development Program.

Estimated Annual Number of Activities: 1.

Estimated Number of Respondents per Activity: 10.

Annual Responses: 10.

Estimated Time per Response: 1.5.

Estimated Total Annual Burden Hours: 15.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection.

They will also become a matter of public record.

Stayce Hoult,

PRA Clearance Officer, National Aeronautics and Space Administration.

[FR Doc. 2026–12076 Filed 6–15–26; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2026–025]

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming meeting of the Advisory Committee on the Records of Congress in accordance with the Federal Advisory Committee Act. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives.

DATES: The meeting will be on June 16, 2026, from 2 p.m. to 2:30 p.m. ET.

ADDRESSES: The meeting will be virtual.

Meeting Link: <https://ushr.webex.com/weblink/register/r97101deaa4343b08c08fcc3ae9dafc7d>

FOR FURTHER INFORMATION CONTACT: James Wyatt, National Archives, Center for Legislative Archives, by email at James.Wyatt@nara.gov or by phone at 202–357–5016.

SUPPLEMENTARY INFORMATION: This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations.

Agenda

1. Opening Remarks of the Chair—Kevin McCumber, Clerk of the House
2. Recognition of Co-Chair—Jackie Barber, Secretary of the Senate
3. Approval of the Minutes of the Last Meeting
4. Adjournment

Merrily Harris,

Committee Management Officer.

[FR Doc. 2026–12056 Filed 6–15–26; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2026–024]

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming meeting of the Advisory Committee on the Records of Congress in accordance with the Federal Advisory Committee Act. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives.

DATES: The meeting will be on June 17, 2026, from 2 p.m. to 2:30 p.m. ET.

Location: The meeting will be virtual.

Meeting Link: <https://ushr.webex.com/weblink/register/r4cafd89570b493da9749d784cb110f76>

FOR FURTHER INFORMATION CONTACT: James Wyatt, National Archives, Center for Legislative Archives, by email at James.Wyatt@nara.gov or by phone at 202–357–5016.

SUPPLEMENTARY INFORMATION: This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations.

Agenda

1. Opening Remarks of the Chair—Kevin McCumber, Clerk of the House
2. Recognition of Co-Chair—Jackie Barber, Secretary of the Senate
3. Approval of the Minutes of the Last Meeting
4. Adjournment

Merrily Harris,

Committee Management Officer.

[FR Doc. 2026–12057 Filed 6–15–26; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2026–2179]

NUREG: Report to Congress on Abnormal Occurrences: Fiscal Year 2025; Dissemination of Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Final report; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing NUREG–0090, Volume 48, “Report to Congress on Abnormal Occurrences: Fiscal Year

2025.” The report describes those events that the NRC or an Agreement State identified as abnormal occurrences (AOs) during fiscal year (FY) 2025, based on the criteria defined by the Commission. The report describes seven events involving Agreement State licensees and two events involving NRC licensees.

DATES: NUREG–0090, Volume 48, is available June 16, 2026.

ADDRESSES: Please refer to Docket ID NRC–2026–2179 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–2179. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The FY 2025 AO Report, NUREG–0090, Volume 48, “Report to Congress on Abnormal Occurrences: Fiscal Year 2025,” is available in ADAMS under Accession No. ML26148A406.

FOR FURTHER INFORMATION CONTACT: Rigel Flora, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3890; email: Rigel.Flora@nrc.gov.

SUPPLEMENTARY INFORMATION: Section 208 of the Energy Reorganization Act of 1974, as amended (Pub. L. 93–438), defines an “abnormal occurrence” as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. The FY 2025 AO Report, NUREG–0090, Volume 48, “Report to Congress on Abnormal Occurrences: Fiscal Year 2025,” describes those events that the NRC identified as AOs during FY 2025.

This report describes seven events involving Agreement State licensees and two events involving NRC licensees. Four AOs were medical events, as

defined in part 35 of title 10 of the *Code of Federal Regulations*, “Medical Use of Byproduct Material.” The remaining five AOs consisted of one loss of an industrial radiography source, two events involving overexposure of declared pregnant radiation workers, one significant breakdown in radiological controls, and one unintended fetal/embryo exposure during a medical procedure. No events at commercial nuclear power plants met the AO criteria.

The NRC identified no events at NRC-licensed facilities during FY 2025 that met the guidelines for inclusion in Appendix B, “Other Events of Interest.”

One event met the guidelines for inclusion in Appendix C, “Updates on Previously Reported Abnormal Occurrences.”

Agreement States are those States that have entered into formal agreements with the NRC pursuant to section 274 of the Atomic Energy Act of 1954, as amended (AEA), to regulate certain quantities of AEA material at facilities located within their borders.

The Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104–66) requires that AOs be reported to Congress annually. The full report, NUREG–0090, Volume 48, “Report to Congress on Abnormal Occurrences: Fiscal Year 2025,” is also available electronically at the NRC’s public website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff>.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: June 12, 2026.

For the Nuclear Regulatory Commission.

Carrie Safford,

Secretary of the Commission.

[FR Doc. 2026–12060 Filed 6–15–26; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–298; NRC–2026–2344]

Nebraska Public Power District; Cooper Nuclear Station; Notice of Intent To Conduct Scoping Process and Prepare Supplemental Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will conduct a scoping process to gather information necessary to prepare a supplemental environmental impact statement (EIS) to evaluate the environmental impacts for the subsequent renewal of the renewed

facility operating license for Cooper Nuclear Station (Cooper). The NRC is seeking public comment on this action.

DATES: Submit comments on the scope of the supplemental EIS by July 16, 2026. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

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

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–2344. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email comments to:* CooperEnvironmental@nrc.gov.

- *Mail comments to:* Office of Administration, Mail Stop: TWFN–5–A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Lance Rakovan, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2589; email: Lance.Rakovan@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–2344 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–2344.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For

problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The Cooper subsequent license renewal application is available in ADAMS under Package Accession No. ML26127A279.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.

- *Public Library:* A copy of the Cooper subsequent license renewal application, including the environmental report (ER), will be available for public review at the following public library locations: Auburn Memorial Library, 1810 Courthouse Avenue, Auburn, NE 68305, and Atchison County Library, 200 South Main Street, Rock Port, MO 64482.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2026–2344 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS.

The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

By letter dated May 7, 2026, Nebraska Public Power District (NPPD) submitted to the NRC an application for subsequent license renewal (SLR) of Cooper Renewed Facility Operating License No. DPR–46 for an additional 20 years of operation. This submission

initiated the NRC's proposed action of determining whether to grant the SLR. Cooper is located in Brownville, Nebraska. The current Cooper license expires at midnight on January 18, 2034. The SLR application was submitted pursuant to part 54 of title 10 of the *Code of Federal Regulations* (10 CFR), "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," and seeks to extend the license for Cooper to midnight on January 18, 2054. A notice of receipt and availability of the application was published in the **Federal Register** on May 21, 2026 (91 FR 29989). A notice of acceptance for docketing of the application and of an opportunity to request a hearing was published in the **Federal Register** on June 10, 2026 (91 FR 35275) and is available on the Federal Rulemaking website (<https://www.regulations.gov>) by searching for Docket ID NRC-2026-2344.

III. Request for Comment

This notice informs the public of the NRC's intention to conduct environmental scoping and prepare an supplemental EIS related to the SLR application for Cooper and provides the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR 51.29, "Scoping-environmental impact statement and supplement to environmental impact statement," and 10 CFR 51.116, "Notice of intent."

In accordance with 10 CFR 51.53(c) and 10 CFR 54.23, NPPD submitted an ER as part of the SLR application. The ER was prepared pursuant to 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," and is publicly available in ADAMS under Accession No. ML26127A283. The ER will also be available for viewing at <https://www.nrc.gov/reactors/operating/licensing/renewal/applications/cooper>.

The NRC intends to gather the information necessary to prepare the supplemental EIS as a plant-specific supplement to NUREG-1437, Revision 2, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants" (ADAMS Package Accession No. ML24087A133). The supplemental EIS will evaluate the environmental impacts of SLR for Cooper, and a reasonable range of alternatives, including the no-action alternative. This notice is being published in accordance with NEPA and the NRC's regulations at 10 CFR part 51.

As part of its environmental review, the NRC will first conduct a scoping process for the supplemental EIS and, as

soon as practicable thereafter, will prepare a draft supplemental EIS for public comment. Participation in this scoping process by members of the public and local, State, Tribal, and Federal government agencies is encouraged. The scoping process for the supplemental EIS will be used to accomplish the following:

- a. Define the proposed action that is to be the subject of the supplemental EIS;
- b. Determine the scope of the supplemental EIS and identify the significant issues to be analyzed in depth;
- c. Identify and eliminate from detailed study those issues that are peripheral or are not significant or that have been covered by prior environmental review;
- d. Identify any environmental assessments and other environmental impact statements that are being or will be prepared that are related to, but are not part of, the scope of the supplemental EIS under consideration;
- e. Identify other environmental review and consultation requirements related to the proposed action;
- f. Indicate the relationship between the timing of the preparation of the environmental analyses and the NRC's tentative planning and decision-making schedule;
- g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the supplemental EIS to the NRC and any cooperating agencies; and
- h. Describe how the supplemental EIS will be prepared, including any contractor assistance to be used.

The NRC invites the following entities to participate in scoping:

- a. The applicant, NPPD;
- b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards;
- c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards;
- d. Any affected Indian Tribe;
- e. Any person who requests or has requested an opportunity to participate in the scoping process; and
- f. Any person who has petitioned or intends to petition for leave to intervene under 10 CFR 2.309.

Participation in the scoping process for the Cooper SLR supplemental EIS does not entitle participants to become parties to the proceeding to which the supplemental EIS relates.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: June 12, 2026.

For the Nuclear Regulatory Commission.

Kimyata Savoy,

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

[FR Doc. 2026-12109 Filed 6-15-26; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 30-39013, 30-38619, 50-305, 50-320, 72-64, 72-80, 11005620 and 11005897; NRC-2026-2707]

EnergySolutions, LLC and Bridgepoint Group PLC; Consideration of Approval of Transfer of Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Application for indirect transfer of licenses; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) received and is considering approval of an application filed by EnergySolutions, LLC (EnergySolutions), and Bridgepoint Group, PLC (Bridgepoint), on April 24, 2026. The application seeks NRC approval of the indirect transfer of NRC license numbers 39-35044-01, DPR-43, DPR-73, Independent Spent Fuel Storage Installation general license No. 40, XW010, and XW018 from the current holder, EnergySolutions, to Bridgepoint. The application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Submit comments by July 16, 2026. A request for a hearing or petition for leave to intervene must be filed by July 6, 2026. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must follow the instructions in Section VI of the **SUPPLEMENTARY INFORMATION** section of this notice.

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

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2026-2707. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s)

listed in the “For Further Information Contact” section of this document.

- *Email comments to:*

Hearing.Docket@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time (ET) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Chris Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6877; email: *William.Allen@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2026-2707 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2026-2707.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to *PDR.Resource@nrc.gov*. The application is available in ADAMS under Accession No. ML26117A088.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. ET,

Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking Website (<https://www.regulations.gov>). Please include Docket ID NRC-2026-2707 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering the issuance of an order under 10 CFR 30.34, “Terms and conditions of licenses,” 10 CFR 50.80, “Transfer of licenses,” 10 CFR 72.50, “Transfer of license,” and 10 CFR 110.50, “Terms,” approving the indirect transfer of control of the NRC licenses held by EnergySolutions. The licenses would be transferred to Bridgepoint. The application proposes neither physical changes nor operational changes to the licensed activities. The application also states that the transaction will not affect operations associated with the licenses, and that the licensees will maintain responsibility for all licensed activities. The application further states that, following the closing of the transaction, the same legal entities will remain the licensees for the subject facilities and operations, and their names will not change. Thus, no conforming license amendments are necessary.

The NRC’s regulations at 10 CFR 30.34(b)(1), 50.80, and 72.50 provide that no license, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing. The NRC’s

regulation at 10 CFR 110.50(d) states that a specific export license may be transferred only with the approval of the Commission. The Commission will approve an application for the indirect transfer of a license if the Commission determines that the proposed transfer of control will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

III. Opportunity To Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the **ADDRESSES** section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 20 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission’s “Agency Rules of Practice and Procedure,” in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 20 days from the date of publication of this notice in accordance with the filing instructions in the “Electronic Submissions (E-Filing),” section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 20 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053>) and on the NRC's public website at <https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>.

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the "Guidance for Electronic Submissions to the NRC," (ADAMS Accession No. ML13031A056) and on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/>

[site-help/electronic-sub-ref-mat.html](https://www.nrc.gov/site-help/electronic-sub-ref-mat.html). A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the

NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing. For further details with respect to this application, see the application dated April 24, 2026 (ADAMS Accession No. ML26117A088).

VI. Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Any person who desires access to proprietary, confidential commercial information that has been redacted from the application should contact the applicant by contacting Amy Hazelhoff at achazelhoff@energysolutions.com for the purpose of negotiating a confidentiality agreement or a proposed protective order with the applicant. If no agreement can be reached, persons who desire access to this information may file a motion with the Secretary and address the motion to the Commission requesting the issuance of a protective order.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: June 11, 2026.

For the Nuclear Regulatory Commission.

Michelle Sutherland,

Acting Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2026-12045 Filed 6-15-26; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC–2026–2411]

Applications for Amendments to Facility Operating Licenses Involving Proposed No Significant Hazards Consideration Determination and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) received, and is considering approval of, two requests to amend eight licenses. The license amendment requests are for Catawba Nuclear Station, Units 1 and 2; McGuire Nuclear Station, Units 1 and 2; Oconee Nuclear Station, Units 1, 2 and 3; and Fort Calhoun Station, Unit No. 1. For each license amendment request, the NRC proposes to determine that it involves no significant hazards consideration (NSHC). Because the amendment requests contain sensitive unclassified non-safeguards information (SUNSI), the NRC is issuing an order imposing procedures to obtain access to SUNSI for contention preparation by persons who file a hearing request or petition for leave to intervene.

DATES: Comments must be filed by July 16, 2026. A request for a hearing or petitions for leave to intervene must be filed by August 17, 2026. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information (SUNSI) is necessary to respond to this notice must request document access by June 26, 2026.

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

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–2411. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail Comments to:* Office of Administration, Mail Stop: TWFN–5–A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Angela Baxter, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8209; email: Angela.Baxter@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–2411, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–2411.
- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2026–2411, facility

name, unit number(s), docket number(s), application date, and subject, in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to section 189a.(1)–(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves NSHC, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of license amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following license amendment requests involve NSHC. Under the Commission’s regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this

proposed determination for each license amendment request is shown as follows.

The Commission is seeking public comments on these proposed NSHC determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the license amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action on any of these license amendments prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination for any of these license amendments, any hearing on those amendments will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause

by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration, which will serve to establish when the hearing is held. If the final determination is that the license amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the license amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053>) and the NRC's public website (<https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>).

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the "Guidance

for Electronic Submissions to the NRC" (ADAMS Accession No. ML13031A056), and on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals.html>).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to: (1) request a digital identification (ID) certificate which allows the participant (or their counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or their counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals/getting-started.html>). After a digital ID certificate is obtained and a docket is created, the participant must submit adjudicatory documents in the Portable Document Format. Guidance on submissions is available on the NRC's public website (<https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>). A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed in order to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the

NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals.html>), by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption

under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available on the NRC's public website (<https://adams.nrc.gov/ehd>), unless otherwise excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings

unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The following table provides the plant name, docket numbers, date of application, ADAMS accession number, and location in the application of the licensee's proposed NSHC determination. For further details with respect to these license amendment applications, see the applications for amendment, publicly available portions of which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

Duke Energy Carolinas, LLC; Catawba Nuclear Station, Units 1 and 2; York County, SC; Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC; Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3; Oconee County, SC

Docket Nos	50-413, 50-414, 50-369, 50-370, 50-269, 50-270, 50-287.
Application Date	March 24, 2026.
ADAMS Accession No	ML26083A340.
Location in Application of NSHC	Enclosure 2, Pages 24-26.
Brief Description of Amendments	The proposed license amendments would revise the thermal hydraulic methodology for the Renewed Facility Operating Licenses for Catawba Nuclear Station, Units 1 and 2; McGuire Nuclear Station, Units 1 and 2; and Oconee Nuclear Station Units 1, 2 and 3. Specifically, the licensee requests the NRC to review and approve the proposed changes set forth in Revision 4 of DPC-NE-2003-P, "Core Thermal-Hydraulic Methodology using VIPRE-01," Revision 3 of DPC-NE-2004-P, "Core Thermal-Hydraulic Methodology using VIPRE-01," and Revision 7 of DPC-NE-2005-P, "Thermal-Hydraulic Statistical Core Design Methodology."
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Tracey Mitchell LeRoy, Deputy General Counsel, Duke Energy Corporation, 525 S Tryon Street, Charlotte, NC 28202.
NRC Project Manager, Telephone Number	John Klos, 301-415-5136.

Omaha Public Power District; Fort Calhoun Station, Unit No. 1; Washington County, NE

Docket No	50-285.
Application Date	February 24, 2026.
ADAMS Accession No	ML26061A204.
Location in Application of NSHC	Enclosure 1, Attachment 1, Pages 8-9.
Brief Description of Amendment	The proposed amendment would approve Revision 3 of the Fort Calhoun Station (FCS), Unit No. 1, License Termination Plan (LTP) to revise the dose calculation for the FCS Auxiliary Building basement, the requirements for remediation, and survey methodologies in the LTP. Omaha Public Power District has concluded that additional flexibility in the methodologies described in the LTP is needed, and that a revision to the LTP is necessary in order to achieve these flexibilities.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Stephen M. Bruckner, Attorney, Fraser Stryker PC LLO, 500 Energy Plaza, 409 South 17th Street, Omaha, NE 68102.
NRC Project Manager, Telephone Number	Marlayna Doell, 301-415-3178.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Duke Energy Carolinas, LLC; Catawba Nuclear Station, Units 1 and 2; York County, SC; Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC; Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3; Oconee County, SC; Omaha Public Power District; Fort Calhoun Station, Unit No. 1; Washington County, NE

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing or opportunity for hearing, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A “potential party” is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Licensing, Hearings, and Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email addresses for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov*, respectively.¹ The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party’s particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor’s basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2), the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order² setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner’s receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite

need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff’s adverse determination by filing a challenge within five days of receipt of that determination with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party’s interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.³

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have

¹ While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC’s “E-Filing Rule,” the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

² Any motion for Protective Order or proposed Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

³ Requestors should note that the filing requirements of the NRC’s E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012, 78 FR 34247, June 7, 2013) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order

summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: June 12, 2026.

For the Nuclear Regulatory Commission.

Carrie Safford,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of Federal Register notice of hearing or opportunity for hearing, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: (i) supporting the standing of a potential party identified by name and address; and (ii) describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requestor to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and proposed Non-Disclosure Agreement or Affidavit. Deadline for applicant/licensee to file proposed Non-Disclosure Agreement or Affidavit for SUNSI.
A	If access is granted: issuance of presiding officer or other designated officer decision on motion for Protective Order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Agreements or Affidavits. Access provided to SUNSI consistent with decision issuing the Protective Order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or notice of opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2026-12062 Filed 6-15-26; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2026-272 and K2026-269]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by

telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via

the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any

¹ See Docket No. RM2018-3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19-22 (Order No. 4679).

individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone

advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

None. *See* Section III for summary proceedings.

III. Summary Proceeding(s)

1. *Docket No(s)*: MC2026–272 and K2026–269; *Filing Title*: USPS Request to Add New Mid-Market Standardized Distinct Product, PM–GA Contract 1012, and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: June 11, 2026; *Filing Authority*: 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,
Legal Assistant.

[FR Doc. 2026–12063 Filed 6–15–26; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change–Priority Mail, and USPS Ground Advantage Negotiated Service Agreements; Priority Mail Negotiated Service Agreements

AGENCY: Postal Service.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* June 16, 2026.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), it filed with the Postal Regulatory Commission the following requests:

Date filed with postal regulatory commission	Negotiated service agreement product category and number	MC docket No.	K docket No.
06/08/26	PM–GA 1009	MC2026–267	K2026–265.
06/08/26	PM–GA 1010	MC2026–268	K2026–266.
06/08/26	PM 956	MC2026–269	K2026–267.
06/10/26	PM–GA 1011	MC2026–270	K2026–268.

Documents are available at
www.prc.gov.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2026–12009 Filed 6–15–26; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105661; File No. SR–NYSETEX–2026–21]

Self-Regulatory Organizations; NYSE Texas, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Partial Cabinet Solution Bundles

June 11, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934

(“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on June 1, 2026, the NYSE Texas, Inc. (“NYSE Texas” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. The description of the Partial Cabinet Solution bundles and related fees in the Connectivity Fee Schedule (“Fee Schedule”) would be updated

accordingly. The proposed rule change is available on the Exchange's website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

¹ 15 U.S.C. 78s(b)(1).

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. Specifically, the Exchange proposes to delete the current 1 kW Partial Cabinet Solution ("PCS") bundle and change the fee charged for the 2 kW PCS bundle. The description of the PCS bundles and related fees in the Fee Schedule would be updated accordingly.

The Exchange expects that the proposed rule change would become operative no later than October 31, 2026. The Exchange will announce the date through a customer notice.

Background

Currently, there are two PCS bundles available to Users,⁴ each of which includes a partial cabinet; access to the Liquidity Center Network ("LCN") and internet protocol ("IP") network, the

local area networks available in the data center; two NMS network⁵ connections, two fiber cross connections; and connectivity to one of two time feeds.⁶ Option A has a 1 kW partial cabinet, and Option B has a 2 kW partial cabinet. In addition to other requirements, a User and its Affiliates⁷ must have an Aggregate Cabinet Footprint⁸ of 2 kW or less to qualify for either Option A or Option B.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.⁹ That has not changed. But as hardware and other infrastructure has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may find the 1 kW PCS bundle inadequate to meet their needs.

At the same time, the monthly recurring fees that Users pay for IP and LCN ports (also referred to as

"connections" and "network access") increased¹⁰ but the fees for the 2 kW PCS bundle did not.

Proposed Changes

The Exchange proposes to make the following changes. First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle and therefore proposes to delete it from the Fee Schedule as obsolete.

Second, the Exchange proposes to change the monthly recurring charge for the 2 kW PCS bundle. With this proposal, the Exchange proposes to increase the monthly recurring fees by 10.0% (the initial charge would not change). Because it would be the only PCS bundle that remained, the Exchange also proposes to delete "Option B".

To implement the changes, the Exchange would amend the Fee Schedule as follows (proposed deletions bracketed, proposed addition italicized):

Type of service	Description	Amount of charge
Partial Cabinet Solution bundles	[<i>Option A:</i> 1 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol].	[10,000 initial charge per bundle plus \$14,000 monthly charge per bundle].
Note: A User and its Affiliates are limited to one Partial Cabinet Solution bundle at a time. A User and its Affiliates must have an Aggregate Cabinet Footprint of 2 kW or less to qualify for a Partial Cabinet Solution bundle. See Note 1 under "Colocation Notes." A purchaser of a Partial Cabinet Solution bundle must select NMS Network connections of the same size (i.e. 10 Gb or 40 Gb) as the related LCN and IP network connections.	[<i>Option B:</i> 2 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.	\$10,000 initial charge per bundle plus \$[15,000]16,500 monthly charge per bundle.

The proposed fee increase would enable the Exchange to maintain and improve its market technology and

services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-

throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to

⁴ For purposes of the Exchange's colocation services, a "User" means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 at n.6 (November 1, 2019) (SR-NYSECHX-2019-12). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same

proposed rule change to propose the change described herein.

⁵ The NMS Network is an alternate dedicated network connection that Users use to access the NMS feeds for which the Securities Industry Automation Corporation is engaged as the securities information processor. See Securities Exchange Act Release No. 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR-NYSECHX-2020-18).

⁶ See Securities Exchange Act Release No. 97751 (June 16, 2023), 88 FR 41178 (June 23, 2023) (SR-NYSECHX-2023-12).

⁷ An "Affiliate" of a User is any other User or Hosted Customer that is under 50% or greater

common ownership or control of the first User. Fee Schedule, p. 1.

⁸ The "Aggregate Cabinet Footprint" of a User is the total kW of the User's cabinets, including both partial and dedicated cabinets. Fee Schedule, p. 1.

⁹ See 84 FR 58778, *supra* note 4, at 58782. See also Securities Exchange Act No. 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR-NYSE-2015-53).

¹⁰ See Securities Exchange Act No. 104065 (September 25, 2025), 90 FR 46966 (September 30, 2025) (SR-NYSETEX-2025-35) (increasing the monthly recurring fees for IP and LCN ports by between 9.1% and 11.1%) (the "2025 Price Change").

invest in maintaining, improving, and enhancing its connectivity products, services, and facilities for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing colocation facility to offer customers additional space and power.¹¹

Nevertheless, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016¹² while inflation has been 15.98% since February 2016 as measured using the "Data PPI" metric described below¹³ and the monthly recurring fees that Users pay for IP and LCN ports recently increased.¹⁴

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees for the 2 kW PCS bundle frozen at 2016 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increase the Exchange proposes is based on an industry-specific Producer Price Index ("PPI"), which is a tailored measure of inflation.¹⁵ As a general matter, the PPI is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index ("CPI"), that measure price change from the purchaser's perspective.¹⁶ About 10,000 PPIs for individual products and groups of products are tracked and released each month.¹⁷ PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers

approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI ("Data PPI"), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics ("BLS") as part of an ongoing effort to expand PPI coverage of the services sector of the U.S. economy and is identified as NAICS 518210 in the North American Industry Classification System.¹⁸ According to the BLS,

[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.¹⁹

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the monthly fee for the 2 kW PCS bundle because the Exchange uses its "own computer systems" and "proprietary software," *i.e.*, its own data center, including the hardware and equipment that it uses to bring customers' orders, transactions, and other data into the data center for processing, routing, and execution. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from February 2016 through December 2025 (the last month for which finalized data is available).²⁰ The Data PPI had a

starting value of 106.6 in February 2016 and an ending value of 123.64 in December 2025, a 15.98% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 15.98% during this period. Based on that percentage change, the Exchange proposes to increase its monthly recurring fees for the 2 kW PCS bundle by 10.0%—below the Data PPI increase of 15.98%—which reflects an increase covering the entire period since the last price adjustment to these fees was made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 3.3% increase for any one calendar year period since it was introduced. The average calendar year change from 2002 to 2025 was 0.8%, with a cumulative increase of 19.7% over this period.²¹ The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar year increases averaging 2.5%, and a cumulative increase of 83.0% during the same period.²²

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increase.²³

Application and Impact of the Proposed Change

The proposed change would apply to all PCS bundles. The proposed change would not apply differently to distinct types or sizes of market participants.

²¹ See *id.*

²² See <https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/>.

²³ See *supra* discussion of system performance advancements. Additionally, other exchanges, including the Affiliate SROs, have filed for increases in certain fees, based in part on comparisons to inflation. See, e.g., Securities Exchange Act Release Nos. 102073 (January 2, 2025), 90 FR 1558 (January 8, 2025) (SR-BOX-2024-30); 102103 (January 3, 2025), 90 FR 2045 (January 10, 2025) (SR-NASDAQ-2024-087); 102574 (March 11, 2025), 90 FR 12439 (March 17, 2025) (SR-NYSEARCA-2025-20); 104061 (September 25, 2025), 90 FR 47009 (September 30, 2025) (SR-NYSE-2025-37); 104062 (September 25, 2025), 90 FR 46950 (September 30, 2025) (SR-NYSEamer-2025-60); 104063 (September 25, 2025), 90 FR 47038 (September 30, 2025) (SR-NYSEARCA-2025-71); 104064 (September 25, 2025), 90 FR 46960 (September 30, 2025) (SR-NYSEAT-2025-23); and 100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR-NYSEARCA-2024-79).

¹¹ In addition, in 2020, the Exchange began providing Users, at no additional charge, one port on the new NMS Network for each 10 Gb or 40 Gb IP Network port or LCN port that Users purchased. The Exchange did not increase the underlying IP Network or LCN port fees at the time. See note 5, *supra*.

¹² The price was originally reduced for PCS bundles for 24 months so long as the User ordered its PCS bundle by a given date. If the PCS bundle was ordered after that date, it paid the full fee. See note 9, *supra*.

¹³ See <https://fred.stlouisfed.org/series/PCU51825182#0>.

¹⁴ See 2025 Price Change, note 10, *supra*.

¹⁵ See note 13, *supra*.

¹⁶ See <https://www.bls.gov/ppi/overview.htm>.

¹⁷ *Id.*

¹⁸ NAICS appears in table 5 of the PPI Detailed Report and is available at <https://data.bls.gov/timeseries/PCU518210518210>.

¹⁹ See <https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm>.

²⁰ See note 18, *supra*.

Rather, it would apply to all Users equally.

Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List is applied uniformly to all Users.

As no Users have the 1 kW PCS bundle, none would be impacted by its deletion. The Exchange expects to obtain no new Users as a result of changing the fees for 2 kW PCS bundles.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,²⁶ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees for the 2 kW PCS bundle do not properly reflect the quality of the services and products, as fees for the 2 kW PCS bundle have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems has increased the performance of these ports.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016. However, in the

years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefited, while the Exchange's ability to recoup its investments has been hampered.

Between February 2016 and December 2025, the total inflation rate was 36.7%.²⁷ Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 15.98%. The Exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees for the 2 kW PCS bundle for more than eight years. The price change would be commensurate with the 2025 fee changes to the LCN and IP network and below the amount of the increase in the Data PPI. The proposed fee change therefore represents a modest increase from the current fees.

The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing several aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities. The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize its technology so that it may benefit its members in offering connectivity products and services.

Additional Considerations

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users

may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be reasonable.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increase is equitably allocated and not unfairly discriminatory because it would apply to all market participants that choose to purchase the 2 kW PCS bundle from the Exchange. Any participant that chooses to purchase the 2 kW PCS bundle would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the products and services. Additionally, the fee increases would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities.

The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule changes will not impose any burden on competition that is not necessary or appropriate in

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78f(b)(4).

²⁷ See note 22, *supra*.

furtherance of the purposes of Section 6(b)(8) of the Act.²⁸

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the Fee Schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today, albeit at inflation-adjusted rates for the 2 kW PCS bundle, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the deletion of the 1 kW PCS bundle and the level of the proposed fees neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition.

Intermarket Competition. The Exchange believes that the removal of the 1 kW PCS bundle and the proposed fees for the 2 kW PCS bundle do not impose a burden on competition or on other SROs that is not necessary or appropriate.

First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle, and so no Users would be impacted by its deletion.

Second, in determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and facilities would not impose a burden on competition.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

D. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁹ and Rule 19b-4(f)(6) thereunder.³⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³¹ and Rule 19b-4(f)(6)³² thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

²⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁰ 17 CFR 240.19b-4(f)(6).

³¹ 15 U.S.C. 78s(b)(3)(A).

³² Rule 19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSETEX-2026-21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSETEX-2026-21. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSETEX-2026-21 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12026 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105658; File No. SR-NYSE-2026-27]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Partial Cabinet Solution Bundles

June 11, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 ("Act")² and Rule 19b-4 thereunder,³ notice is hereby given that on June 1, 2026, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the

³⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

²⁸ 15 U.S.C. 78f(b)(8).

Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. The description of the Partial Cabinet Solution bundles and related fees in the Connectivity Fee Schedule (“Fee Schedule”) would be updated accordingly. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. Specifically, the Exchange proposes to delete the current 1 kW Partial Cabinet Solution (“PCS”) bundle and change the fee charged for the 2 kW PCS bundle. The description of the PCS bundles and related fees in the Fee Schedule would be updated accordingly.

The Exchange expects that the proposed rule change would become operative no later than October 31, 2026. The Exchange will announce the date through a customer notice.

Background

Currently, there are two PCS bundles available to Users,⁴ each of which includes a partial cabinet; access to the Liquidity Center Network (“LCN”) and internet protocol (“IP”) network, the local area networks available in the data center; two NMS network⁵ connections, two fiber cross connections; and connectivity to one of two time feeds.⁶ Option A has a 1 kW partial cabinet, and Option B has a 2 kW partial cabinet. In addition to other requirements, a User and its Affiliates⁷ must have an Aggregate Cabinet Footprint⁸ of 2 kW or less to qualify for either Option A or Option B.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space

demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.⁹ That has not changed. But as hardware and other infrastructure has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may find the 1 kW PCS bundle inadequate to meet their needs.

At the same time, the monthly recurring fees that Users pay for IP and LCN ports (also referred to as “connections” and “network access”) increased¹⁰ but the fees for the 2 kW PCS bundle did not.

Proposed Changes

The Exchange proposes to make the following changes. First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle and therefore proposes to delete it from the Fee Schedule as obsolete.

Second, the Exchange proposes to change the monthly recurring charge for the 2 kW PCS bundle. With this proposal, the Exchange proposes to increase the monthly recurring fees by 10.0% (the initial charge would not change). Because it would be the only PCS bundle that remained, the Exchange also proposes to delete “Option B”.

To implement the changes, the Exchange would amend the Fee Schedule as follows (proposed deletions bracketed, proposed addition italicized):

Type of service	Description	Amount of charge
Partial Cabinet Solution bundles. Note: A User and its Affiliates are limited to one Partial Cabinet Solution bundle at a time. A User and its Affiliates must have an Aggregate Cabinet Footprint of 2 kW or less to qualify for a Partial Cabinet Solution bundle. See Note 1 under “Colocation Notes.” A purchaser of a Partial Cabinet Solution bundle must select NMS Network connections of the same size (<i>i.e.</i> , 10 Gb or 40 Gb) as the related LCN and IP network connections.	[<i>Option A:</i> 1 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol].	[10,000 initial charge per bundle plus \$14,000 monthly charge per bundle].

⁴ For purposes of the Exchange’s colocation services, a “User” means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by NYSE American LLC, NYSE Arca, Inc., NYSE National, Inc. and NYSE Texas, Inc. (together, the “Affiliate SROs”). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the change described herein.

⁵ The NMS Network is an alternate dedicated network connection that Users use to access the NMS feeds for which the Securities Industry Automation Corporation is engaged as the securities information processor. See Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19).

⁶ See Securities Exchange Act Release No. 97747 (June 16, 2023), 88 FR 41455 (June 26, 2023) (SR–NYSE–2023–23).

⁷ An “Affiliate” of a User is any other User or Hosted Customer that is under 50% or greater

common ownership or control of the first User. Fee Schedule, p. 1.

⁸ The “Aggregate Cabinet Footprint” of a User is the total kW of the User’s cabinets, including both partial and dedicated cabinets. Fee Schedule, p. 1.

⁹ See Securities Exchange Act No. 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR–NYSE–2015–53).

¹⁰ See Securities Exchange Act No. 104061 (September 25, 2025), 90 FR 47009 (September 30, 2025) (SR–NYSE–2025–37) (increasing the monthly recurring fees for IP and LCN ports by between 9.1% and 11.1%) (the “2025 Price Change”).

Type of service	Description	Amount of charge
	[Option B:] 2 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.	\$10,000 initial charge per bundle plus \$[15,000] 16,500 monthly charge per bundle.

The proposed fee increase would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity products, services, and facilities for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing colocation facility to offer customers additional space and power.¹¹

Nevertheless, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016¹² while inflation has been 15.98% since February 2016 as measured using the "Data PPI" metric described below¹³ and the monthly recurring fees that Users pay for IP and LCN ports recently increased.¹⁴

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees for the 2 kW PCS bundle frozen at 2016 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increase the Exchange proposes is based on an industry-specific Producer Price Index ("PPI"), which is a tailored measure of inflation.¹⁵ As a general matter, the PPI is a family of indexes that measures the

average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index ("CPI"), that measure price change from the purchaser's perspective.¹⁶ About 10,000 PPIs for individual products and groups of products are tracked and released each month.¹⁷ PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI ("Data PPI"), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics ("BLS") as part of an ongoing effort to expand PPI coverage of the services sector of the U.S. economy and is identified as NAICS 518210 in the North American Industry Classification System.¹⁸ According to the BLS,

[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The

transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.¹⁹

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the monthly fee for the 2 kW PCS bundle because the Exchange uses its "own computer systems" and "proprietary software," *i.e.*, its own data center, including the hardware and equipment that it uses to bring customers' orders, transactions, and other data into the data center for processing, routing, and execution. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from February 2016 through December 2025 (the last month for which finalized data is available).²⁰ The Data PPI had a starting value of 106.6 in February 2016 and an ending value of 123.64 in December 2025, a 15.98% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 15.98% during this period. Based on that percentage change, the Exchange proposes to increase its monthly recurring fees for the 2 kW PCS bundle by 10.0%—below the Data PPI increase of 15.98%—which reflects an increase covering the entire period since the last price adjustment to these fees was made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 3.3% increase for any one calendar year period since it was introduced. The average calendar year

¹¹ In addition, in 2020, the Exchange began providing Users, at no additional charge, one port on the new NMS Network for each 10 Gb or 40 Gb IP Network port or LCN port that Users purchased. The Exchange did not increase the underlying IP Network or LCN port fees at the time. See note 5, *supra*.

¹² The price was originally reduced for PCS bundles for 24 months so long as the User ordered its PCS bundle by a given date. If the PCS bundle was ordered after that date, it paid the full fee. See note 9, *supra*.

¹³ See <https://fred.stlouisfed.org/series/PCU51825182#0>.

¹⁴ See 2025 Price Change, note 10, *supra*.

¹⁵ See note 13, *supra*.

¹⁶ See <https://www.bls.gov/ppi/overview.htm>.

¹⁷ *Id.*

¹⁸ NAICS appears in table 5 of the PPI Detailed Report and is available at <https://data.bls.gov/timeseries/PCU518210518210>.

¹⁹ See <https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm>.

²⁰ See note 18, *supra*.

change from 2002 to 2025 was 0.8%, with a cumulative increase of 19.7% over this period.²¹ The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar year increases averaging 2.5%, and a cumulative increase of 83.0% during the same period.²²

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increase.²³

Application and Impact of the Proposed Change

The proposed change would apply to all PCS bundles. The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally.

Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List is applied uniformly to all Users.

As no Users have the 1 kW PCS bundle, none would be impacted by its deletion. The Exchange expects to obtain no new Users as a result of changing the fees for 2 kW PCS bundles.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of

trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,²⁶ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees for the 2 kW PCS bundle do not properly reflect the quality of the services and products, as fees for the 2 kW PCS bundle have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems has increased the performance of these ports.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefited, while the Exchange's ability to recoup its investments has been hampered.

Between February 2016 and December 2025, the total inflation rate was 36.7%.²⁷ Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 15.98%. The Exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees for the 2 kW PCS bundle for more than eight years. The price change would be commensurate with the 2025 fee changes to the LCN and IP network and below the amount of the increase in

the Data PPI. The proposed fee change therefore represents a modest increase from the current fees.

The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing several aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities. The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize its technology so that it may benefit its members in offering connectivity products and services.

Additional Considerations

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be reasonable.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increase is equitably allocated and not unfairly discriminatory because it would apply to all market participants that choose to purchase the 2 kW PCS bundle from the Exchange. Any participant that chooses to purchase the 2 kW PCS bundle would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the products and services. Additionally, the fee increases would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities.

²¹ *See id.*

²² See <https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/>.

²³ See *supra* discussion of system performance advancements. Additionally, other exchanges, including the Affiliate SROs, have filed for increases in certain fees, based in part on comparisons to inflation. See, e.g., Securities Exchange Act Release Nos. 102073 (January 2, 2025), 90 FR 1558 (January 8, 2025) (SR–BOX–2024–30); 102103 (January 3, 2025), 90 FR 2045 (January 10, 2025) (SR–NASDAQQ–2024–087); 102574 (March 11, 2025), 90 FR 12439 (March 17, 2025) (SR–NYSEARCA–2025–20); 104062 (September 25, 2025), 90 FR 46950 (September 30, 2025) (SR–NYSEAmer–2025–60); 104063 (September 25, 2025), 90 FR 47038 (September 30, 2025) (SR–NYSEArca–2025–71); 104064 (September 25, 2025), 90 FR 46960 (September 30, 2025) (SR–NYSEAT–2025–23); 104065 (September 25, 2025), 90 FR 46966 (September 30, 2025) (SR–NYSETEX–2025–35); and 100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78f(b)(4).

²⁷ See note 22, *supra*.

The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.²⁸

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the Fee Schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today, albeit at inflation-adjusted rates for the 2 kW PCS bundle, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the deletion of the 1 kW PCS bundle and the level of the proposed fees neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition.

Intermarket Competition. The Exchange believes that the removal of the 1 kW PCS bundle and the proposed fees for the 2 kW PCS bundle do not impose a burden on competition or on

other SROs that is not necessary or appropriate.

First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle, and so no Users would be impacted by its deletion.

Second, in determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and facilities would not impose a burden on competition.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁹ and Rule 19b-4(f)(6) thereunder.³⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³¹ and Rule 19b-4(f)(6)³² thereunder.

²⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁰ 17 CFR 240.19b-4(f)(6).

³¹ 15 U.S.C. 78s(b)(3)(A).

³² Rule 19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSE-2026-27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSE-2026-27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSE-2026-27 and should be submitted on or before July 7, 2026.

proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 15 U.S.C. 78s(b)(2)(B).

²⁸ 15 U.S.C. 78f(b)(8).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026–12023 Filed 6–15–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105665; File No. SR–NYSE–2025–43]

Self-Regulatory Organizations; NYSE Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on Proceedings to Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Section 802.01C of the NYSE Listed Company Manual

June 11, 2026.

On December 3, 2025, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² a proposed rule change to amend Section 802.01C of the NYSE Listed Company Manual (“Manual”). The proposed rule change was published for comment in the **Federal Register** on December 17, 2025.³ On January 22, 2026, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded the original proposed rule change in its entirety.⁴ On January 28, 2026, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designated a longer period within which to take action on the proposed rule change.⁶ On March 17,

2026, the Commission published notice of Amendment No. 1 and instituted proceedings under Section 19(b)(2)(B) of the Act ⁷ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.⁸

Section 19(b)(2) of the Act ⁹ provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on December 17, 2025.¹⁰ The 180th day after publication of the proposed rule change is June 15, 2026. The Commission is extending the time period for approving or disapproving the proposed rule change, as modified by Amendment No. 1, for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Amendment No. 1, so that it has sufficient time to consider the proposed rule change, as modified by Amendment No. 1, and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,¹¹ designates August 14, 2026, as the date by which the Commission shall either approve or disapprove the proposed rule change, as modified by Amendment No. 1 (File No. SR–NYSE–2025–43).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Vanessa A. Countryman,
Secretary.

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institute proceedings to determine whether to disapprove the proposed rule change. *See id.*

⁷ 15 U.S.C. 78s(b)(2)(B).

⁸ *See* Securities Exchange Act Release No. 105035, 91 FR 13683 (Mar. 20, 2026).

⁹ 15 U.S.C. 78s(b)(2).

¹⁰ *See supra* note 3 and accompanying text.

¹¹ 15 U.S.C. 78s(b)(2).

¹² 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105663; File No. SR–CBOE–2026–051]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Cboe Bitcoin U.S. ETF Index Options (“CBTX”) and Cboe Mini Bitcoin U.S. ETF Index Options (“MBTX”) Standard Transaction Fees

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on May 29, 2026, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) proposes to amend Cboe Bitcoin U.S. ETF Index options (“CBTX”) and Cboe Mini Bitcoin U.S. ETF Index options (“MBTX”) standard transaction fees. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission’s website (<https://www.sec.gov/rules/sro.shtml>), the Exchange’s website (https://www.cboe.com/us/options/regulation/rule_filings/cone/), and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³⁴ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ *See* Securities Exchange Act Release No. 104385 (Dec. 12, 2025), 90 FR 58669. The Commission has received no comment letters on the proposed rule change.

⁴ In Amendment No. 1, the Exchange: (1) clarified that a company subject to delisting under the proposal would not be eligible to follow the procedures in Section 802.01C of the Manual; (2) clarified the Exchange’s authority to suspend trading in or delist a security; (3) provided additional description of certain aspects of the proposal; and (4) made other technical and non-substantive changes. The full text of Amendment No. 1 can be found on the Commission’s website at <https://www.sec.gov/comments/sr-nyse-2025-47/srnyse202543-696267-2177015.pdf> (“Amendment No. 1”).

⁵ 15 U.S.C. 78s(b)(2).

⁶ *See* Securities Exchange Act Release No. 104708, 91 FR 4763 (Feb. 2, 2026). The Commission designated March 17, 2026, as the date by which the Commission shall approve, disapprove, or

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule.³

CBTX

The Exchange proposes to amend and adopt certain fees related to transactions in CBTX. Specifically, the proposed rule change amends and adopts certain fees for CBTX in the Rate Table for All Products Excluding Underlying Symbol List A, as follows:

- Amends fee code B2, currently appended to all Market-Maker (capacity “M”), Clearing TPHs (capacity “F”), Non-Clearing TPH Affiliates (capacity “L”), Broker-Dealer (capacity “B”), Joint Back-Office (capacity “J”), Non-TPH Market-Maker (capacity “N”), and Professional (capacity “U”) (collectively, “Non-Customer”) orders in CBTX and assesses a fee of \$1.00 per contract, to apply to all Non-Customer orders in CBTX that are executed manually (*i.e.*, open outcry).⁴
- Adopts fee code B3, appended to all Non-Customer orders in CBTX contra to non-customers that remove liquidity and that are executed electronically and assesses a fee of \$1.50 per contract.
- Adopts fee code B4, appended to all Market-Maker (capacity “M”) orders in CBTX contra to non-customers that add liquidity and that are executed electronically and provides a rebate of \$0.75 per contract.
- Adopts fee code B5, appended to all electronically executed Non-Customer orders in CBTX contra to customers and all electronically executed Non-Customer, Non-Market Maker orders in CBTX contra to non-customers that add liquidity, and assesses a fee of \$1.00 per contract.⁵

³ The Exchange initially filed the proposed fee change, among other changes, on April 1, 2026 (SR-CBOE-2026-031) (the “Original Filing”). On May 29, 2026, the Exchange withdrew that filing and submitted this proposal. The Exchange notes that subsequent to the Original Filing that proposed these changes, the Exchange amended its Fees Schedule to make changes in connection with the fees related to certain orders executed in Automated Improvement Mechanism (“AIM”) Auctions and to amend the Customer Volume Incentive Program and Affiliated Volume Plan; such changes are incorporated Exhibit 5 to this filing.

⁴ For avoidance of doubt, there are no practical changes to fee rates assessed for Non-Customer orders in CBTX that are executed manually as a result of the proposed rule change.

⁵ For avoidance of doubt, there are no practical changes to fee rates assessed for electronically executed Non-Customer orders in CBTX contra to customers and electronically executed Non-Customer, Non-Market Maker orders in CBTX contra to non-customers that add liquidity as a result of the proposed rule change.

MBTX

The Exchange proposes to amend and adopt certain fees related to transactions in MBTX. Specifically, the proposed rule change amends and adopts certain fees for MBTX in the Rate Table for All Products Excluding Underlying Symbol List A, as follows:

- Amends fee code M2, currently appended to all Non-Customer orders in CBTX and assesses a fee of \$0.50 per contract, to apply to all Non-Customer orders in MBTX that are executed manually (*i.e.*, open outcry).⁶
- Adopts fee code M3, appended to all Non-Customer orders in MBTX contra to non-customers that remove liquidity and that are executed electronically and assesses a fee of \$1.00 per contract.
- Adopts fee code M4, appended to all Market-Maker (capacity “M”) orders in MBTX contra to non-customers that add liquidity and that are executed electronically and provides a rebate of \$0.50 per contract.
- Adopts fee code M5, appended to all electronically executed Non-Customer orders in MBTX contra to customers and all electronically executed Non-Customer, Non-Market Maker orders in MBTX contra to non-customers that add liquidity, and assesses a fee of \$0.50 per contract.⁷

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁹ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market

system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its TPHs and other persons using its facilities.

The Exchange believes that the proposal to amend fee codes for transactions in CBTX and MBTX is reasonable, equitable and not unfairly discriminatory. The proposed changes differentiate rates based on capacity, execution method, capacity of contra-party, and whether the order adds or removes liquidity. The Exchange notes that it is not novel to charge different fees for different market participants based such on these differences and notes that options exchanges have routinely recognized such differences in their fee schedules.¹² Moreover, the Exchange believes that it is reasonable to assess lower fees for MBTX options orders (as compared to CBTX options orders), because of the relation between CBTX options and MBTX options, wherein MBTX options overlie an index with 1/10th the value of the index that underlies CBTX options.

The Exchange believes the proposed rebate for Market-Maker orders in CBTX and MBTX that add liquidity contra a non-customer, and the corresponding fee assessed on non-customer orders that remove liquidity contra a non-customer in those products are reasonable, equitably allocated, and not unfairly discriminatory. Market-Makers on the Exchange are obligated to post continuous two-sided quotes, which represent standing commitments to trade at stated prices. In some instances identified by the Exchange, these resting quotes are accessed by non-bona fide non-customer order activity, which seek

¹⁰ *Id.*

¹¹ 15 U.S.C. 78f(b)(4).

¹² See, e.g., Exchange Fees Schedule, fee code XF, appended to electronic Non-Customer, Non-Market Maker orders in XSP, MRUT, or DJX, Contra Customer or Contra Non-Customer, which add liquidity, and fee code XB, appended to electronic Non-Customer, Non-Market Maker orders in XSP, MRUT, or DJX, Contra Customer or Contra Non-Customer, which remove liquidity. See also EDGX Options Fee Schedule, fee code PM, which is specific to Market-Maker orders in Penny Securities that add liquidity, and fee code PT, which is specific to Market-Maker orders in Penny Securities that remove liquidity. See also Exchange Fees Schedule.

⁶ For avoidance of doubt, there are no practical changes to fee rates assessed for Non-Customer orders in MBTX that are executed manually as a result of the proposed rule change.

⁷ For avoidance of doubt, there are no practical changes to fee rates assessed for electronically executed Non-Customer orders in MBTX contra to customers and electronically executed Non-Customer, Non-Market Maker orders in MBTX contra to non-customers that add liquidity as a result of the proposed rule change.

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

to put that passive Market-Maker at a disadvantage (via an identified price discrepancy or informational advantage, for example). The Exchange has observed that this activity has, over time, led to these Market-Makers widening quotes to avoid repeatedly being “picked off.” Wider quotes result in less competitive markets for all market participants.

The proposed fee structure addresses this problem in two ways. By assessing a fee on non-customer orders that remove liquidity contra a non-customer, the Exchange makes the opportunistic behavior described above less attractive, as any perceived advantage being obtained is offset by higher transaction fees. Further, by providing a rebate to Market-Makers whose resting quotes are accessed by a non-customer, the Exchange seeks to offset a portion of the adverse selection risk that these passive Market-Makers may bear, thereby reducing the incentive to widen quotes defensively. Overall, Market-Makers are encouraged to maintain tight quotes, and potential aggressors face a pricing disincentive that is calibrated to the market quality harm their behavior produces.

The Exchange believes the proposed fee structure reasonably addresses a recognized pattern of trading that impairs market quality, namely opportunistic non-customer aggression against passive Market-Maker quotes. The Exchange believes the proposed fee structure is reasonable because the removal fee is a targeted and proportionate response to a recognized form of market quality degradation, set at a level designed to discourage opportunistic aggression without penalizing legitimate trading activity. Further, the rebate is calibrated to compensate passive Market-Makers for the adverse selection risk which may lead to wider spreads and reduced market depth to the detriment of all market participants.

The Exchange believes the proposed fee structure is equitably allocated and not unfairly discriminatory. The rebate is available to all CBTX and MBTX Market-Maker orders that meet the applicable criteria. The removal fee applies uniformly to all non-customer orders removing liquidity contra a non-customer in those products. The differential treatment between these categories reflects meaningful and well-recognized distinctions in market function. Market-Makers are subject to affirmative quoting obligations, including requirements to maintain continuous two-sided markets, that impose ongoing regulatory and financial burdens not shared by other

participants. Compensating Market-Makers for those obligations through a rebate is equitable because the liquidity they provide benefits the entire market. Conversely, the Exchange believes assessing a fee on non-customer removal flow may disincentivize opportunistic aggression against passive Market-Makers, which imposes potential costs on the market that are allocated to contra-parties whose trading behavior generates such potential costs.

The Exchange believes the proposed rates, including the \$1.50 per contract fee assessed on non-customer orders removing liquidity contra a non-customer in CBTX, are reasonable and consistent with fees charged by other options exchanges for comparable order flow in Non-Penny products. The Exchange notes that multiple registered options exchanges currently assess standard transaction rates for non-customer orders in Non-Penny classes at or above \$1.20 per contract.¹³ The proposed CBTX fee for non-customer orders that remove liquidity contra a non-customer of \$1.50 per contract is therefore within the range of fees currently assessed by competing venues for comparable activity. The Exchange further notes that the \$1.50 per contract rate applies only in the specific circumstance where a non-customer order removes liquidity contra another non-customer in CBTX, which is a targeted application reflecting the market quality rationale described above. The Exchange acknowledges that CBTX and MBTX are proprietary products available exclusively on the Exchange. However, the Exchange notes that market participants retain the ability to migrate activity to economically similar products available at other venues,¹⁴ and that the proposed rates must therefore be set at levels that reflect the value of trading these products, not at levels that would drive participants toward substitutes.

¹³ See NYSE Arca Options Fees and Charges, TRANSACTION FEE FOR ELECTRONIC EXECUTIONS—PER CONTRACT, which assesses a standard transaction fee of \$1.20 per contract for Non-Customer Electronic Executions in Non-Penny Issues that Take Liquidity; MEMX Options Fee Schedule, which assesses a standard transaction fee of \$1.21 per contract for Non-Customer Executions in Non-Penny Issues that Remove Liquidity; and The Nasdaq Stock Market Rules, Options 7 Pricing Schedule, which assesses a standard transaction fee of \$1.25 per contract for Non-Customer orders that remove liquidity in Non-Penny Symbols. See also MEMX Options Fee Schedule, which assesses a Routing Fee of \$1.63 per contract for Non-Penny Orders.

¹⁴ Options overlying the components of the Cboe Bitcoin U.S. ETF Index, Cboe Mini Bitcoin U.S. ETF Index (and the underlying exchange-traded funds (“ETFs”)) are actively traded (as are the underlying ETFs) (for example, IBIT options).

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule changes related to standard transaction fees for CBTX or MBTX will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the fee amounts for each separate type of market participants will be assessed equally to all such market participants. While different fees are assessed to different market participants in some circumstances, the obligations and circumstances between these market participants differ, as discussed above.

The Exchange does not believe that the proposed rule changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed fees assessed apply to Exchange proprietary products, which are traded exclusively on the Exchange. As stated above, the Exchange notes that market participants retain the ability to migrate activity to economically similar products available at other venues.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and paragraph (f) of Rule 19b-4¹⁶ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CBOE-2026-051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CBOE-2026-051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CBOE-2026-051 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12028 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105674; File No. SR-NYSEARCA-2026-42]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Rule 8.201-E (Generic) To Modify the Generic Listing Standards for Commodity-Based Trust Shares

June 11, 2026.

On April 22, 2026, NYSE Arca, Inc. ("NYSE Arca" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Rule 8.201-E (Generic) to modify the generic listing standards for Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on April 30, 2026.³

Section 19(b)(2) of the Act⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is June 14, 2026. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates July 29, 2026, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-NYSEARCA-2026-42).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 105311 (Apr. 27, 2026), 91 FR 23327. The Commission has received no comment letters on the proposed rule change.

⁴ 15 U.S.C. 78s(b)(2).

⁵ 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12039 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105667; File No. SR-CboeBZX-2026-051]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule Related To Lead Market Maker Rebates

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 29, 2026, Cboe BZX Exchange, Inc. ("Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. ("BZX" or the "Exchange") is filing with the Securities and Exchange Commission ("Commission" or "SEC") a proposed rule change to amend its fee schedule applicable to its equities trading platform ("BZX Equities") to modify the liquidity provision incentive structure applicable to the Exchange's lead market maker ("LMM") program in BZX-listed exchange-traded product ("ETP") securities as provided in footnote 14(B) of the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/equities/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

⁶ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁷ 17 CFR 200.30-3(a)(12).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to BZX Equities to modify the liquidity provision incentive structure applicable to the Exchange's LMM program in BZX-listed ETP securities as provided in footnote 14(B) of the fee schedule. Specifically, the Exchange proposes to introduce three new incentive tiers to replace the existing provisions of footnote 14(B)(i) and (ii), effective July 1, 2026.³ The three new incentive tiers are as follows: (1) a volume-based tier pricing structure providing per-share or per-symbol rebates based on the consolidated average daily volume ("CADV")⁴ of each individual ETP LMM Security,⁵ to be set forth in new footnote 14(B)(6)(i); (2) incremental add rebates for Tape B⁶ displayed liquidity based on the percentage of total BZX-listed symbols for which a Member serves as ETP LMM, to be set forth in new footnote 14(B)(6)(ii); and (3) a low CADV tier stipend for ETP LMMs that maintain a minimum percentage of assignments in lower-volume securities, to be set forth in new footnote 14(B)(6)(iii). The Exchange proposes to adopt these changes to the Fee Schedule effective June 1, 2026. Although the new ETP LMM payout structure will be

formally implemented on July 1, 2026, the Exchange is filing these proposed changes and making them effective June 1, 2026 so that Members have advance notice of the new pricing structure prior to its operative date. This advance notice is particularly important given that eligibility for payouts is based, in part, on volume transacted during the prior calendar month (e.g., volume transacted in June will determine payouts effective in July). The Exchange is also adding text to the Fee Schedule to clearly label the provisions applicable through June 30, 2026 and those applicable on and after July 1, 2026.

The Exchange first notes that its listings business operates in a highly competitive market in which market participants, including issuers of securities, LMMs, and other liquidity providers, can readily transfer their listings, opt not to participate, or direct order flow to competing venues if they deem fee levels, liquidity provision incentive programs, or any other factor at a particular venue to be insufficient or excessive. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to participate as LMMs in the Exchange's LMM Program, which the Exchange believes will enhance market quality in all securities listed on the Exchange and encourage issuers to list new products and transfer existing products to the Exchange.

Background

The ETP LMM Program was adopted in 2019 and was designed to encourage LMMs to maintain better market quality in BZX-listed securities, and in particular, in lower volume securities where transaction-based compensation (i.e., rebates) may not be sufficient to incentivize meaningful liquidity provision. Most recently, the Exchange amended the Base and Enhanced Minimum Performance Standards applicable to the ETP LMM Program and memorialized those standards in the fee schedule.⁷

Currently, footnote 14(B) of the fee schedule provides daily incentives for ETP LMMs that meet the Base or Enhanced Minimum Performance Standards. Such daily incentives are determined based on two variables: (1) the aggregate average daily auction volume across all BZX-listed securities for which the Member is the ETP LMM ("ETP LMM Securities"); and (2) the total number of securities for which the Member qualifies as a Qualified ETP

LMM. Generally speaking, the more ETP LMM Securities for which the LMM meets the Minimum Performance Standards and the higher the aggregate auction volume across those securities, the greater the total daily incentive to the LMM.

While the Exchange believes the current program has been effective in incentivizing market quality, the Exchange has identified certain limitations with the existing structure. In particular, the current program aggregates auction volume across all of a Member's ETP LMM Securities to determine the applicable incentive rate, which means the same rate applies uniformly to all of a Member's qualifying securities regardless of the individual volume characteristics of each security. The Exchange believes this structure does not sufficiently differentiate incentives at the individual security level and may not optimally encourage LMMs to maintain strong market quality in securities across the full spectrum of CADV levels. The Exchange therefore proposes to adopt the tiered incentive structure described below.

Proposal

New Footnote 14(B)(6)(i)—Volume-Based Tier Pricing

The Exchange proposes to adopt a volume-based tier pricing structure under new footnote 14(B)(6)(i). Under the proposed structure, an ETP LMM that meets the "Base" or "Enhanced" Minimum Performance Standards⁸ for an ETP LMM Security for at least 75% of the trading days that the LMM was assigned the ETP LMM Security during the month will be eligible for a per-share or per-symbol rebate determined by reference to the CADV of each individual ETP LMM Security during the previous month.

For higher-volume securities, the rebate is calculated on a per-share basis. Specifically, ETP LMM Securities with a CADV greater than 1,000,000 shares will receive a Base Rate of \$0.0034 per share and an Enhanced Rate of \$0.0036 per share. Securities with a CADV between 500,001 and 1,000,000 shares will receive a Base Rate of \$0.0040 per share and an Enhanced Rate of \$0.0042 per share. Securities with a CADV between 250,001 and 500,000 shares will receive a Base Rate of \$0.0041 per share and an Enhanced Rate of \$0.0043 per share. Securities with a CADV between 100,001 and 250,000 shares will receive a Base Rate of \$0.0045 per

³ The Exchange will propose under a separate filing to remove the existing provisions of footnote 14(B)(i) and (ii) for effectiveness July 1, 2026.

⁴ "CADV" means consolidated average daily volume calculated as the average daily volume reported for a security by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the three calendar months preceding the month for which the fees apply and excludes volume on days when the market closes early and on the Russell Reconstitution Day.

⁵ "ETP LMM Security" refers to the BZX-listed securities for which the Member is the ETP LMM.

⁶ Fee code "B" refers to displayed orders that add liquidity to BZX (Tape B).

⁷ See Securities Exchange Act No. 104472 (December 19, 2025) 90 FR 60832 (December 29, 2025) (SR-ChoeBZX-2025-163).

⁸ The Base and Enhanced Minimum Performance Standards are set forth in footnote 14(B)(1)–(6) of the fee schedule.

share and an Enhanced Rate of \$0.0047 per share.

For lower-volume securities, the rebate is calculated on a per-symbol basis. ETP LMM Securities with a CADV between 50,001 and 100,000 shares will receive a Base Rate of \$400 per symbol and an Enhanced Rate of \$650 per symbol. Securities with a CADV between 25,001 and 50,000 shares will receive a Base Rate of \$425 per symbol and an Enhanced Rate of \$675 per symbol. Securities with a CADV of 25,000 shares or fewer will receive a Base Rate of \$450 per symbol and an Enhanced Rate of \$700 per symbol. For newly listed symbols in their first month of trading, the ETP LMM will be eligible for the Base Rate stipend of \$450 per symbol, pro-rated based on the number of days the security traded during that month.

Unlike the current structure, which applies a uniform daily incentive rate based on aggregate volume across all of a Member's ETP LMM Securities, the proposed structure evaluates each ETP LMM Security individually based on its own CADV. The Exchange believes this approach more directly ties the incentive to the volume and liquidity characteristics of each security, thereby creating stronger, more targeted incentives for LMMs to maintain market quality across securities of varying volume levels.

Incremental Add Rebates

The Exchange also proposes to adopt incremental add rebates under new footnote 14(B)(ii). Under the proposed structure, an ETP LMM that meets the Base or Enhanced Minimum Performance Standards for each ETP LMM Security for at least 75% of the trading days will be eligible for additional Tape B displayed add rebates. For purposes of this calculation, symbols that are assigned to the ETP LMM for only part of the month and symbols that are listed on BZX for only part of the month are each counted in fractional amounts, prorated based on the number of trading days during which the assignment or listing was in effect relative to the total number of trading days in that month.

Specifically, a Member with LMM assignments representing at least 10% of total BZX-listed symbols will receive an additional add rebate of \$0.0006 per share. A Member with assignments representing at least 7.5% will receive an additional add rebate of \$0.0005 per share. A Member with assignments representing at least 5.0% will receive an additional add rebate of \$0.0004 per share. A Member with assignments representing at least 2.5% will receive

an additional add rebate of \$0.0003 per share.

The Exchange believes the incremental add rebates are designed to incentivize LMMs to take on and maintain a meaningful number of assignments relative to the total BZX listings universe. By tying additional rebates to the breadth of a Member's LMM participation, the Exchange believes this component encourages LMMs to support market quality across a broad range of BZX-listed securities, which benefits issuers, investors, and the overall market ecosystem.

Low CADV Tier

Finally, the Exchange proposes to adopt a Low CADV Tier stipend under new footnote 14(B)(iii). For each ETP LMM Security with a CADV of 1,000,000 shares or fewer per month ("Low CADV ETP Securities"), an ETP LMM will be eligible for a monthly stipend of \$200 per ETP LMM Security, subject to the following criteria: (1) the ETP LMM is a registered LMM for at least 15% of the total Low CADV ETP Securities listed on the Exchange; and (2) the ETP LMM has met the Base or Enhanced Minimum Performance Standards in the previous month for at least 75% of its assigned Low CADV ETP Securities.

The Exchange believes the Low CADV Tier addresses a recognized challenge in the ETP listing ecosystem: the difficulty of attracting and retaining high-quality LMMs in lower-volume securities where transaction-based compensation is limited. By providing an additional per-symbol monthly stipend for LMMs that maintain a meaningful presence across lower-volume securities and consistently meet performance obligations in those securities, the Exchange believes this component directly supports market quality and issuer confidence in segments of the market where such incentives are most needed.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation

and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4)¹² as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed changes to the ETP LMM incentive structure represent an equitable allocation of reasonable fees and rebates among Members that choose to participate as LMMs in the Exchange's LMM Program. The proposed tiered incentive structure under new footnote 14(B)(6)(i) ties per-share and per-symbol rebates to the individual CADV of each ETP LMM Security, rather than applying a uniform rate based on aggregate volume across a Member's entire book of assignments. The Exchange believes this approach equitably allocates incentives based on the actual liquidity characteristics and volume levels of each security, creating more targeted and proportional compensation for the liquidity provision obligations undertaken by each LMM. The incentive rates applicable under new footnote 14(B)(6)(i) are reasonable in that they are designed to compensate LMMs for the costs and obligations associated with maintaining market quality in securities across a broad spectrum of volume levels, including lower-volume securities where transaction-based compensation alone may be insufficient to incentivize meaningful liquidity provision.

The incremental add rebates proposed under new footnote 14(B)(6)(ii) are also equitable and reasonable. These rebates are available to any Member that meets the applicable performance standards and maintains a sufficient breadth of LMM assignments as a percentage of total BZX-listed symbols. The tiered structure rewards Members that take on a broader share of the listings universe, which the Exchange believes equitably allocates additional compensation based on the relative scale of a Member's contribution to market quality across

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ *Id.*

¹² 15 U.S.C. 78f(b)(4).

BZX-listed securities. Any Member that satisfies the applicable threshold is eligible to receive the corresponding rebate, and the structure does not favor any particular Member or class of Members beyond what is justified by the scope of their LMM participation.

The Low CADV Tier stipend under new footnote 14(B)(6)(iii) is similarly equitable and reasonable. By providing an additional monthly per-symbol stipend for LMMs that maintain a minimum presence in lower-volume securities and meet applicable performance standards, the Exchange is targeting additional compensation to the segment of the listings universe where incentivizing liquidity provision is most challenging and most needed. The Exchange believes this stipend is a reasonable means of supporting market quality in low-volume securities and is equitably structured in that it is available to any ETP LMM that meets the eligibility criteria.

The Exchange believes the proposed changes are not unfairly discriminatory. The proposed incentive structure is available to all Members that choose to participate as ETP LMMs in the Exchange's LMM Program and is applied uniformly based on objective, transparent criteria, including the CADV of individual ETP LMM Securities, the breadth of a Member's LMM assignments as a percentage of total BZX-listed symbols, and satisfaction of applicable Minimum Performance Standards. Any differential treatment among Members or securities reflects meaningful differences in the nature and scope of their LMM obligations and is therefore not unfairly discriminatory. The Exchange notes that participation in the ETP LMM Program is voluntary, and Members may choose whether to seek LMM assignments and how many assignments to maintain.

The Exchange also notes that it operates in a highly competitive market for listings and liquidity provision services. The proposed changes are designed to make the Exchange's LMM Program more competitive and more effective at attracting and retaining high-quality LMMs across the full spectrum of BZX-listed securities. The Exchange believes the proposed structure is responsive to the competitive dynamics of the listings market and reflects reasonable judgments about how to appropriately incentivize liquidity provision in securities of varying volume characteristics.

The Exchange does not believe the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted

above, the Exchange operates in a highly competitive market in which issuers, LMMs, and other market participants may readily transfer listings or direct participation to competing venues. The proposed changes are intended to enhance the Exchange's competitive position by offering a more effective and targeted LMM incentive structure. To the extent the proposed rule change has any effect on competition, the Exchange believes any such effect is necessary and appropriate in furtherance of the purposes of the Act, as it is designed to improve market quality, support issuers, and promote the maintenance of fair and orderly markets in BZX-listed ETP securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. On the contrary, the Exchange believes the proposed rule change is designed to enhance competition in several respects.

The Exchange first notes that it operates in a highly competitive market for listings and liquidity provision services. Issuers of ETP securities may list their products on any number of national securities exchanges or other trading venues, and LMMs and other market participants may choose to direct their participation and order flow to whichever venue they determine offers the most attractive combination of fees, incentives, and market quality. In this environment, the Exchange must continually evaluate and, where appropriate, update its fee structures and incentive programs to remain competitive. The proposed changes to the ETP LMM incentive structure reflect this competitive dynamic and are designed to offer a more effective and attractive program for LMM participation in BZX-listed ETP securities.

The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed incentive structure is available to all Members that choose to participate as ETP LMMs and is applied uniformly based on objective, transparent criteria. Any differences in the incentives received by individual Members will reflect differences in the volume characteristics of their assigned securities, the breadth of their LMM assignments, and their satisfaction of applicable Minimum Performance Standards—all of which are factors

within each Member's control and directly tied to the scope and quality of their liquidity provision obligations. The Exchange does not believe this differential treatment imposes any burden on intramarket competition that is not necessary or appropriate, as it is designed to reward Members that take on greater liquidity provision responsibilities and maintain strong market quality across BZX-listed securities.

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes are designed to strengthen the Exchange's LMM Program and improve the Exchange's competitive position in the market for ETP listings and liquidity provision. Other exchanges and trading venues are free to adopt their own incentive programs and fee structures in response to competitive pressures, and the Exchange's proposed changes do not restrict the ability of other venues to compete for listings, LMM participation, or order flow. Rather, the Exchange believes the proposed changes will enhance intermarket competition by offering issuers, LMMs, and other market participants a more targeted and effective incentive program as an alternative to those offered by competing venues.

To the extent the proposed changes are successful in attracting additional LMM participation or encouraging existing LMMs to maintain a broader and higher-quality presence across BZX-listed securities, the Exchange believes the resulting improvements in market quality will benefit issuers, investors, and the national market system as a whole. The Exchange therefore believes that any effect the proposed changes may have on competition is not only necessary and appropriate, but affirmatively promotes the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹³ and paragraph (f) of Rule

¹³ 15 U.S.C. 78s(b)(3)(A).

19b-4¹⁴ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2026-051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CboeBZX-2026-051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBZX-2026-051 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Vanessa A. Countryman,
Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105672; File No. SR-NASDAQ-2026-032]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 1 and Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rule 5711(d) To Modify the Generic Listing Standards for Commodity-Based Trust Shares

June 11, 2026.

On April 14, 2026, the Nasdaq Stock Market LLC ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Rule 5711(d) to modify the generic listing standards for Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on April 28, 2026.³

On June 9, 2026, the Exchange filed Amendment No. 1 to the proposed rule change, which replaces and supersedes the original filing in its entirety. The proposed rule change, as modified by Amendment No. 1, is described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons, and to designate a longer period for Commission action on the proposed rule change, as modified by Amendment No. 1.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 5711(d) to modify the generic listing standards for Commodity-Based

Trust Shares (as defined below) to: (1) allow for a buffer of up to 15% of the net asset value ("NAV") of the Commodity-Based Trust Shares holdings to consist of certain assets that do not meet the eligibility criteria under the generic listing standards; (2) add a definition for digital commodity (as defined below); and (3) allow for actively-managed strategies.

The Exchange initially submitted this rule filing on April 14, 2026 (the "Initial Filing"). This Amendment No. 1 supersedes the Initial Filing and replaces it in its entirety. This Amendment No. 1 amends the Initial Filing by: (1) specifying what assets may be included in the 15% buffer; (2) adding "digital commodity" (as defined below) as a defined term; and (3) adding provisions to allow for actively-managed strategies.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange previously received approval to adopt generic listing standards ("GLS") for Commodity-Based Trust Shares.⁴ The Exchange proposes to amend Rule 5711(d) to modify the GLS for Commodity-Based Trust Shares⁵ to (1) allow for a buffer

⁴ See Securities Exchange Act Release No. 103995 (September 17, 2025), 90 FR 45414 (September 22, 2025) (SR-NASDAQ-2025-056; SR-CboeBZX-2025-104; SR-NYSEARCA-2025-54) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to Adopt Generic Listing Standards for Commodity-Based Trust Shares) ("GLS Approval Order").

⁵ The term "Commodity-Based Trust Shares" refers to a type of exchange-traded product ("ETP") and means a security that: (1) is issued by a trust, limited liability company, partnership, or other

Continued

¹⁴ 17 CFR 240.19b-4(f).

¹⁵ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 105293 (Apr. 23, 2026), 91 FR 22883. The Commission has received no comment letters on the proposed rule change.

of up to 15% of the NAV of the Commodity-Based Trust Shares holdings to consist of certain assets that do not meet the GLS eligibility criteria; (2) add a definition for digital commodity (as defined below); and (3) allow for actively-managed Commodity-Based Trust Shares. Each change is discussed in detail below.

15% Buffer and Digital Commodity

Today, the GLS in Rule 5711(d)(iii)(A)(3) contemplates that Commodity-Based Trust Shares may hold one or more commodities⁶ or commodity-based assets,⁷ and in addition to such commodities or commodity-based assets, may hold securities, cash, and cash equivalents.⁸ Rule 5711(d)(iv) sets forth specific

similar entity ("Trust") that, if applicable, is operated by a registered commodity pool operator pursuant to the Commodity Exchange Act, and is not registered as an investment company pursuant to the Investment Company Act of 1940, or series or class thereof; (2) is designed to reflect the performance of one or more reference assets or an index of reference assets, less expenses and other liabilities; (3) in order to reflect the performance as provided in (d)(iii)(A)(2) above, is issued by a Trust that holds (a) one or more commodities or commodity-based assets as defined in (d)(iii)(C) below, and (b) in addition to such commodities or commodity-based assets, may hold securities, cash, and cash equivalents; (4) is issued by such Trust in a specified aggregate minimum number in return for a deposit of (a) a specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents, or (b) a cash amount with a value based on the next determined net asset value per Trust share; and (5) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such Trust which will deliver to the redeeming holder (a) the specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents, or (b) a cash amount with a value based on the next determined net asset value per Trust share. *See* current Rule 5711(d)(iii)(A). As discussed later in this filing, the Exchange is proposing to amend this definition to allow for actively-managed strategies.

⁶ The term "commodity" is as defined in Section 1a(9) of the Commodity Exchange Act that is not an "excluded commodity" as defined in Section 1a(19) of the Commodity Exchange Act. *See* Rule 5711(d)(iii)(B).

⁷ The term "commodity-based asset" means any future, option, or swap on a commodity. *See* Rule 5711(d)(iii)(C).

⁸ The term "cash equivalent" means short-term instruments with maturities of less than three months as follows: (1) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (2) certificates of deposit issued against funds deposited in a bank or savings and loan association; (3) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (4) repurchase agreements and reverse repurchase agreements; (5) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (6) commercial paper, which are short-term unsecured promissory notes; and (7) money market funds. *See* Rule 5711(d)(iii)(D).

eligibility requirements that the commodity, commodity-based asset, and security holdings of Commodity-Based Trust Shares must meet on an initial and, with the exception of subparagraph (A)(3) as described below, on a continuing basis. In particular, subparagraph (A) sets forth the eligibility requirements for commodity and commodity-based asset holdings of Commodity-Based Trust Shares. Specifically, each commodity or commodity that underlies a commodity-based asset held by the Trust must fall into at least one of the following categories in subparagraphs (A)(1)–(3):

- (1) the commodity trades on a market that is an Intermarket Surveillance Group ("ISG") member; provided that the Exchange may obtain information about trading in such commodity from the ISG member; or
- (2) the commodity underlies a futures contract that has been made available to trade on a designated contract market for at least six months; provided that the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG, with such designated contract market; or
- (3) on an initial basis only, an exchange-traded fund ("ETF") designed to provide economic exposure of no less than 40% of its NAV to the commodity lists and trades on a national securities exchange.

The current GLS therefore requires that all commodity or commodity-based asset holdings of the Commodity-Based Trust Share must qualify under one or more of the above eligibility criteria. These criteria are generally designed to ensure that the Exchange can obtain information regarding trading in the commodities or commodities underlying commodity-based assets held by the Trust issuing the Commodity-Based Trust Shares, which would assist in monitoring trading in such Shares on the Exchange and to deter and detect violations of Exchange rules and applicable federal securities laws, thereby making the Commodity-Based Trust Shares less readily susceptible to fraud and manipulation.

In addition, subparagraph (B) of Rule 5711(d)(iv) sets forth the eligibility requirements for the Trust's security holdings. Specifically, if the Trust holds any securities, each security held by the Trust would need to meet the criteria of Rule 5735 (Managed Fund Shares), Sections b(1)(A) and (B), or if the security is a listed option, trades on an ISG market. Essentially, the GLS requires that the security holdings of the Commodity-Based Trust Shares be either an equity security or a fixed

income security, as defined in Rule 5735(b)(1)(A) and (B), respectively, and meet the listing standards thereunder, or if the security holdings are listed options, they trade on an ISG market. The Commission previously found that the generic listing standards for Managed Fund Shares consistent with the Exchange Act, including the requirements relating to component equity and fixed income securities underlying Managed Fund Shares.⁹ Further, with respect to listed options, ISG membership would help to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making the Commodity-Based Trust Shares less readily susceptible to manipulation.

The Exchange now proposes to amend Rule 5711(d)(iv) to allow up to 15% of the NAV of the Commodity-Based Trust Shares holdings to consist of certain assets that do not meet the GLS eligibility criteria in subparagraph (A) and (B) of Rule 5711(d)(iv) as described above. Specifically, new subparagraph (C) of Rule 5711(d)(iv) will provide that notwithstanding the eligibility requirements described above, up to 15% of the NAV of the Commodity-Based Trust Shares holdings in the aggregate may consist of (i) digital commodities that do not meet the criteria in subparagraph (A) of Rule 5711(d)(iv), or (ii) securities that do not meet the criteria in subparagraph (B) of Rule 5711(d)(iv). For purposes of calculating the 15% limitation, any derivatives held by the Trust will be calculated based on its gross notional value.¹⁰

In connection with the proposed adoption of the 15% buffer, the Exchange also proposes to add a definition for "digital commodity" in new subparagraph (D) of Rule 5711(d)(iii). In connection with this change, the Exchange will also renumber current subparagraphs (D)–(J) to proposed subparagraphs (E)–(K). As proposed, the term "digital commodity"

⁹ *See* Securities Exchange Act Release No. 78397 (July 22, 2016), 81 FR 49320 (July 27, 2016) (NYSEARCA–2015–110) (approving NYSE Arca's generic listing standards for Managed Fund Shares); Securities Exchange Act Release No. 78396 (July 22, 2016), 81 FR 49698 (July 28, 2016) (SR–BATS–2015–100) (approving BZX's generic listing standards for Managed Fund Shares); Securities Exchange Act Release No. 78918 (Sep. 23, 2016), 81 FR 67033 (Sep. 29, 2016) (SR–NASDAQ–2016–104) (approving Nasdaq's generic listing standards for Managed Fund Shares).

¹⁰ Today, the Exchange similarly calculates percentage limitations on listed and over-the-counter ("OTC") derivatives in its Managed Fund Shares rule based on the aggregate gross notional value of the listed and OTC derivatives. *See* Rule 5735(b)(1)(D) and (E).

will mean a commodity that is a digital asset and is intrinsically linked to and derives its value from the programmatic operation of a functional crypto system, as well as supply and demand dynamics, rather than from the expectations of profits from the essential managerial efforts of others. The Exchange is adopting this definition to make clear what types of digital assets may be included within the 15% buffer described above. The Exchange notes that the proposed definition of digital commodity is informed by the joint interpretative guidance issued by the SEC and the Commodity Futures Trading Commission (“CFTC”), effective March 23, 2026.¹¹ The Exchange represents that to the extent legislation is enacted defining “digital commodity” or a substantially similar term, the Exchange will submit a rule filing to conform the definition in the GLS to the statutory definition. The proposed changes would effectively exclude other commodities such as non-fungible assets or non-fungible collectibles from being included in the 15% buffer for generically listed Commodity-Based Trust Shares.¹² However, this would not preclude the Exchange from submitting a 19b–4 rule filing to seek the listing and trading of a Commodity-Based Trust Share that holds other commodities, including commodities that fall outside of the definition of digital commodity, if it determines to do so at a later date. The Exchange notes that generic listing standards are generally intended to apply to products that were known and contemplated at the time of adoption (e.g., Commodity-Based Trust Shares holding digital commodities). They are not intended to apply to novel products or materially distinct structures that were not considered when the standards were adopted. As it relates to the GLS for Commodity-Based Trust Shares, the products that were known and contemplated at the time of adoption included, for example, Commodity-Based Trust Shares holding digital commodities. The Exchange therefore believes it is appropriate to delineate

the scope of what can be included in the 15% buffer to digital commodities.

As proposed, the GLS will still require that at least 85% of the NAV of the Commodity-Based Trust Shares holdings be comprised of assets that are already allowed under the GLS.¹³ Further, the Trust must otherwise comply with all applicable requirements of the GLS (e.g., Rule 5711(d)(v)’s website disclosure requirements) in order for the Commodity-Based Trust Share to be generically listed. The sponsor of the Commodity-Based Trust Share must monitor compliance with this 85% threshold daily, and must promptly notify the Exchange if the Commodity-Based Trust Share breaches this requirement.¹⁴

The following examples illustrate how the 15% buffer will be applied:

1. A Commodity-Based Trust Share (“CBTS”) holds \$95 million in market value of Bitcoin, Ether, Solana, and XRP, which all presently qualify as eligible commodities under Rule 5711(d)(iv)(A)(2) and (3) (i.e., each commodity underlies a futures contract that has been trading on an ISG market for at least 6 months, and has an ETF that provides at least 40% economic exposure to the commodity). The CBTS also holds \$5 million in market value in several digital commodities that do not presently qualify as eligible commodities under the GLS. Because at least 95% of the Trust’s NAV (\$95 million/\$100 million = 95%) meets the eligibility criteria under Rule 5711(d)(iv)(2) and (3), and the additional 5% consists of digital commodities that do not meet the eligibility criteria, consistent with the 15% buffer, the CBTS would qualify under the proposed generic criteria.

2. A CBTS holds gold and gold futures contracts. Both assets presently qualify as an eligible commodity or commodity-based asset under Rule 5711(d)(iv)(A)(2) because the commodity (gold) underlies gold futures contracts that are listed and trading on an ISG market for at least six

months. The gold held by the Trust has a market value of \$80 million. The gold futures contract trading unit size is 100 troy ounces and an ounce of gold is currently worth \$4,000. The Trust holds 100 gold futures contracts with a gross notional value of \$40 million (100 contracts * 100 troy ounces * \$4,000). Both the gold and gold futures holdings of \$120 million in total (100% of NAV) would meet the eligibility criteria under Rule 5711(d)(iv)(A)(2). As such, the CBTS would qualify under the proposed generic criteria.

3. A CBTS holds bitcoin and OTC call options on a bitcoin ETF. Bitcoin presently qualifies as an eligible commodity under Rule 5711(iv)(A)(2) and (3) (i.e., bitcoin underlies a futures contract that has been trading on an ISG market for at least 6 months, and has an ETF that provides at least 40% economic exposure to bitcoin). The bitcoin held by the Trust currently has a market value of \$100 million. The Trust also holds 5,000 OTC call options (with each option contract representing 100 shares) on a bitcoin ETF with a current market price of \$80 per share, resulting in a gross notional value of \$40 million (5,000 option contracts * 100 option contract multiplier * \$80 share price). Because these options are traded over-the-counter rather than on an ISG market, they do not meet the GLS eligibility criteria for securities under Rule 5711(d)(iv)(B). Accordingly, only the bitcoin holdings of \$100 million or ~71% of NAV (\$100 million/\$140 million = 71.42%) would meet the GLS eligibility criteria under Rule 5711(d)(iv)(A)(2) and (3). While the CBTS could hold up to 15% of OTC options under the 15% buffer, here, the OTC options exceed the 15% limitation. Accordingly, the CBTS would not qualify under the proposed generic criteria.

The Exchange notes that the proposed 15% buffer for Commodity-Based Trust Shares is consistent with the thresholds recently approved by the Commission for similar digital commodity-based ETPs.¹⁵ In those filings, the Commission

¹¹ See “Application of the Federal Securities Laws to Certain Types of Crypto Assets and Certain Transactions Involving Crypto Assets,” 91 FR 13714 (March 23, 2026).

¹² The Exchange notes that this Amendment No. 1 removes the Initial Filing’s proposed exclusion of non-fungible assets and collectibles from the definition of commodity in Rule 5711(d)(iii)(B). With the proposed definition of digital commodity, combined with the specificity of the 15% buffer provision to apply to digital commodities and securities, the Exchange believes that the Initial Filing’s exclusion is no longer necessary.

¹³ Specifically, the Exchange will still require that at least 85% of the NAV of the Commodity-Based Trust Shares holdings consist of (i) commodities, commodity-based assets, and securities that meet the eligibility criteria in subparagraphs (A) and (B) of Rule 5711(d)(iv), and/or (ii) cash and cash equivalents.

¹⁴ The Exchange notes that generally speaking, a company with securities listed under the Rule 5700 Series must provide the Exchange with prompt notification after the company becomes aware of any noncompliance by the company with the requirements of the Rule 5700 Series. See Rule 5701(d). Further, the Commodity-Based Trust Shares rule requires that an issuer of Commodity-Based Trust Shares must notify the Exchange of any failure to comply with the continued listing requirements. See Supplementary Material .03 to Rule 5711(d).

¹⁵ See Securities Exchange Act Release Nos. 103996 (September 17, 2025) (SR–NYSEARCA–2024–87) (Order Setting Aside Action by Delegated Authority and Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.500–E (Trust Units) and to List and Trade Shares of the Grayscale Digital Large Cap Fund LLC under Amended NYSE Arca Rule 8.500–E (Trust Units)) (“Grayscale Order”); and 104212 (November 18, 2025) (SR–NYSEARCA–2024–98) (Order Setting Aside Action by Delegated Authority and Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.500–E (Trust Units) and to List and Trade Shares of the Bitwise 10 Crypto Index ETF

approved the listing and trading of digital commodity-based ETPs holding a diversified portfolio of underlying digital commodities that tracked transparent, rules-based indexes. There, the Commission found that the requirement that the Trusts hold at least 85% of its investments in assets approved by the Commission to underlie an ETP as primary investments (and the rest of its assets in other digital commodities) would enable adequate surveillance of the Shares on the Exchange, and found that the Exchange's rules were designed to prevent fraud and manipulation.¹⁶ Although the ETPs in the Grayscale Order and Bitwise Order were listed under a different listing rule for Trust Units,¹⁷ the Exchange believes that the policy rationale applies with equal force to Commodity-Based Trust Shares listed under Rule 5711(d). Here, the Exchange is proposing to require that at least 85% of the NAV of the Trust's holdings be composed of assets that already qualify under the GLS (*i.e.*, commodities, commodity-based assets, and securities that meet the eligibility criteria in Rule 5711(d)(iv) as well as cash and cash equivalents). These eligibility criteria are designed to assist the Exchange in monitoring trading in such Shares on the Exchange, thereby mitigating risks around fraud and manipulation. Also the Exchange is proposing to limit the 15% buffer to just digital commodities and securities that do not meet the eligibility criteria. The Exchange therefore believes that its proposal similarly strikes an appropriate balance between ensuring that the primary exposure of the ETP is to assets meeting established eligibility standards approved by the Commission, and allowing limited exposure to certain additional assets that enhance diversification and flexibility without undermining market integrity or investor protection.

Actively-Managed Commodity-Based Trust Shares

Rule 5711(d)(iii)(A)(2) currently requires Commodity-Based Trust Shares to be designed to reflect the performance of one or more reference assets or an index of reference assets, less expenses, and other liabilities. In other words, Commodity-Based Trust Shares are required to be passively managed under the GLS. The Exchange now proposes to delete paragraph (A)(2)

and a similar provision in paragraph (A)(3) in order to allow for both passively- and actively-managed strategies. The Exchange will also make non-substantive changes to renumber the paragraphs in the definition of Commodity-Based Trust Shares to reflect the deletion of paragraph (A)(2). The Exchange also proposes in proposed paragraph (A)(2) (currently paragraph (A)(3)) to add the phrase "consistent with the Trust's investment objective and policies" to align with language in the Exchange's Managed Fund Shares rule in Rule 5735(c)(1), which governs the listing of actively-managed ETFs today.

The Exchange also proposes to implement additional requirements around material non-public information in Rule 5711(d)(x) that would apply specifically to actively-managed Commodity-Based Trust Shares. In particular, proposed Rule 5711(d)(x)(3) will provide that any person associated with, or is an agent of (including Reporting Authority (defined below)), the Trust who has access to non-public information regarding the portfolio of the Commodity-Based Trust Shares, including any change thereto, must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the portfolio. In connection with this change, the Exchange proposes to add a definition for Reporting Authority in proposed Rule 5711(d)(iii)(L), which would provide that the term "Reporting Authority" with respect to Commodity-Based Trust Shares means an institution or reporting service designated by the Exchange or the Trust as the official source for calculating and reporting information relating to the CBTS, including, but not limited to, its portfolio, the amount of any cash distribution to holders of Commodity-Based Trust Shares, net asset value, or other information relating to the issuance, redemption or trading of Commodity-Based Trust Shares. Each Commodity-Based Trust Shares may have more than one Reporting Authority, each having different functions.¹⁸ In connection with the foregoing changes, the Exchange will also make a non-substantive change to renumber existing Rule 5711(d)(x)(3) to (4). These additional requirements are substantively rooted in the current prohibitions against the use and dissemination of material non-public information within the Exchange's rules governing actively-managed ETFs, and would apply to anyone associated with,

or is an agent of, the Trust who has access to non-public information regarding the Trust's portfolio. These proposed requirements would apply in addition to what is already required under Rule 5711(d)(x).¹⁹ The proposed requirements would provide additional protection against the potential misuse of material, non-public information relating to the Trust's actively-managed portfolio.

Additionally, while the actively-managed Commodity-Based Trust Share would be subject to the existing trading halt requirements of Rule 5711(d)(ix), proposed Rule 5711(d)(ix)(B) will provide that if the Exchange becomes aware that the information required by paragraph (v)(A) is not disseminated to all market participants at the same time, it will halt trading in the Commodity-Based Trust Shares until such time as the information required by paragraph (v)(A) is available to all market participants.²⁰ The Exchange also proposes to make aligning changes in Rule 5711(d)(ix)(A)(3), which currently provides that the Exchange may halt trading during the day in which the interruption to the information set forth in Rule 5711(d) is not being disclosed in accordance with the requirements of Rule 5711(d)(v), and that if the

¹⁹ See Rule 5735(g) (Managed Fund Shares) (setting forth firewall and procedure requirements that apply to the investment adviser to the investment company issuing Managed Fund Shares and to personnel who make decisions on the investment company's portfolio composition). See also Rules 5704(b)(1)(B)(i) (Exchange Traded Fund Shares) (setting forth firewall and procedure requirements that apply to the investment adviser to an Exchange Traded Fund and to personnel who make decisions on the Exchange Traded Fund's portfolio composition) and 5704(b)(1)(B)(ii) (setting forth procedure requirements that apply to the "Reporting Authority" that provides information relating to the Exchange Traded Fund's portfolio). Nasdaq Rule 5704(a)(1)(C) defines "Reporting Authority" to mean Nasdaq, a wholly-owned subsidiary of Nasdaq, or an institution or reporting service designated by Nasdaq or its subsidiary as the official source for calculating and reporting information relating to Exchange Traded Fund Shares series, including, but not limited to, any current index or portfolio value; the current value of the portfolio of any securities required to be deposited in connection with issuance of Exchange Traded Fund Shares; the amount of any dividend equivalent payment or cash distribution to holders of Exchange Traded Fund Shares, net asset value, and other information relating to the issuance, redemption or trading of Exchange Traded Fund Shares.

²⁰ Pursuant to paragraph (v)(A) of Rule 5711(d), the Trust must disclose prominently on its website, which is publicly available and free of charge, the following information: (A) Before the opening of regular trading on the Exchange, for the Trust's commodities, commodity-based assets, securities, cash and cash equivalent, to the extent applicable: (1) ticker symbol; (2) identifier; (3) description of the holding; (4) the quantity of each commodity, commodity-based asset, security, cash, and cash equivalent held; and (5) percentage weighting of the Trust's assets.

under Amended NYSE Arca Rule 8.500-E (Trust Units)) ("Bitwise Order").

¹⁶ See Grayscale Order and Bitwise Order, *supra* note 14.

¹⁷ "Trust Units" are listed on the Exchange under Rule 5711(i).

¹⁸ See, e.g., Rule 5735(c)(4) (Managed Fund Shares) for similar provisions.

interruption persists past the trading day in which it occurred, the Exchange would halt trading no later than the beginning of the trading day following the interruption. The Exchange now proposes to add a proviso at the end of this Rule that if the Exchange becomes aware that the information required by paragraph (v)(A) is not disseminated to all market participants at the same time, it will halt trading pursuant to proposed subparagraph (B), as described above. This additional trading halt requirement is substantively identical to the Exchange's rule governing the listing and trading of actively managed ETFs, and would apply in addition to what is required under Rule 5711(d)(ix).²¹ This additional trading halt requirement will help ensure that all market participants have transparency relating to the Trust's underlying portfolio, which information is key to pricing the Commodity-Based Trust Shares, and that no market participant has an unfair informational advantage. Ensuring such transparency relating to the Trust's underlying portfolio for all market participants will help facilitate a fair and orderly market for the Commodity-Based Trust Shares, as well as help to ensure that the Commodity-Based Trust Shares are not susceptible to manipulation.

Actively-managed ETFs have become a significant and growing segment of the U.S. and global ETF markets. For example, in 2024, around 49% of all ETFs launched globally were active, and in the U.S., active ETF launches outnumbered index launches by nearly 4:1.²² Active ETFs in the U.S. represent the vast majority of total ETF launches in 2025,²³ with over a third of U.S. ETF inflows coming from active strategies over the past two years.²⁴ By the end of

2025, approximately 83% of the year's new ETFs were actively managed.²⁵ The Exchange believes that these figures demonstrate substantial market demand in actively-managed strategies, and that this proposal would benefit investors by providing a transparent, regulated investment vehicle as an alternative to less regulated avenues that investors could use to obtain commodity (including digital commodity) exposure.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁶ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁷ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The proposed rule change is designed to perfect the mechanism of a free and open market, and, in general to protect investors and the public interest because it would facilitate the listing and trading of additional Commodity-Based Trust Shares, which would enhance competition among market participants, to the benefit of investors and the marketplace.

As discussed above, the Exchange is requiring at least 85% of the NAV of the Trust's holdings to be composed of assets that already qualify under the GLS (*i.e.*, cash, cash equivalents, as well as commodities, commodity-based assets, and securities that meet the eligibility criteria in Rule 5711(d)(iv)). By requiring that the primary exposure of Commodity-Based Trust Shares be in assets meeting established eligibility criteria under this Rule, the Exchange believes that its proposal will ensure flexibility for product innovation while maintaining robust investor protections. As discussed above, these eligibility criteria are generally designed to ensure that the Exchange can obtain information regarding trading in the assets held by the Trust issuing the Commodity-Based Trust Shares. This, in turn, would assist in monitoring the trading in such Shares on the Exchange and to deter and detect violations of Exchange rules and applicable federal securities laws, thereby making Commodity-Based Trust Shares less

readily susceptible to fraud and manipulation.

The Exchange also believes it is consistent with the Act to add the definition of digital commodity in the GLS, and to clearly delineate that the proposed 15% buffer could only include digital commodities that do not meet the GLS eligibility criteria as well as securities that do not meet the GLS eligibility criteria. As discussed above, this approach provides appropriate specificity as to the types of assets that may be included in the buffer, while maintaining flexibility for product innovation. With novel products that were not contemplated at the time of adoption, the Exchange may submit an individual 19b-4 rule filing to seek the listing and trading of such Commodity-Based Trust Shares if it determines to do so at a later date.

The Exchange also believes that the proposed expansion of the GLS to allow for actively-managed Commodity-Based Trust Shares is consistent with the Act. The Exchange notes that the Commission recently approved an individual 19b-4 for the listing and trading of an actively-managed Commodity-Based Trust Share under Rule 5711(d).²⁸ In the iShares Approval Order, the Commission found that the requirements under Rule 5711(d), coupled with the additional firewall and trading halt representations made by the Exchange regarding the listing and trading of the actively-managed product, were designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest consistent with Section 6(b)(5) of the Act.²⁹ Notably, the Commission cited a prior approval order where it had stated in the context of ETFs that "the mere addition of active management to a portfolio that would otherwise qualify for generic listing as an index-based ETF should not affect the portfolio's susceptibility to manipulation or the availability of arbitrage between the ETF and its underlying portfolio."³⁰ The

²¹ See Rule 5735(d)(2)(D) (Managed Fund Shares).

²² See "Decoding active ETFs," BlackRock, available at <https://www.ishares.com/us/literature/whitepaper/decoding-active-etfs.pdf>.

²³ See "How active ETFs are unlocking innovation and opportunity for investors," BlackRock, available at <https://www.ishares.com/us/insights/active-etf-investors> ("Active ETFs accounted for 88% of all U.S.-listed ETF launches through June 2025, and 51% of global ETF launches."); see also "Monthly Active ETF Monitor (August 31, 2025)," J.P. Morgan, available at <https://am.jpmorgan.com/content/dam/jpm-am-aem/americas/us/en/insights/etf-insights/monthly-active-etf.pdf> ("60 active ETFs were launched in August. Active ETFs represent 85% of total ETF launches in 2025.").

²⁴ See "Decoding active ETFs," BlackRock, available at <https://www.ishares.com/us/literature/whitepaper/decoding-active-etfs.pdf> ("31% of net asset inflows come from actively managed strategies," sourcing BlackRock Global Business Intelligence data through June 2024); see also "Monthly Active ETF Monitor (August 31, 2025)," J.P. Morgan, available at <https://am.jpmorgan.com/content/dam/jpm-am-aem/americas/us/en/insights/etf-insights/monthly-active-etf.pdf> ("Over 37% of

ETF flows in 2025 have gone into active strategies").

²⁵ See "2025 ETF & ETP Market Trends: Flow and Tell year in review," BlackRock, available at <https://www.ishares.com/us/insights/2025-etf-market-trends-record-flows>.

²⁶ 15 U.S.C. 78f(b).

²⁷ 15 U.S.C. 78f(b)(5).

²⁸ See Securities Exchange Act Release No. 105582 (May 29, 2026), 91 FR 33252 (June 3, 2026) (SR-NASDAQ-2025-085) (Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to List and Trade Shares of the iShares Bitcoin Premium Income ETF under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares)) ("iShares Approval Order").

²⁹ See iShares Approval Order at 33253.

³⁰ See iShares Approval Order at 33253 (citing to Securities Exchange Act Release Nos. 78396 (July 22, 2016), 81 FR 49698, 49702 (July 28, 2016) (SR-BATS-2015-100) (Order Approving Generic Listing Standards for Managed Fund Shares); and 78397 (July 22, 2016), 81 FR 49320, 49324-25 (July 27, 2016) (SR-NYSEArca-2015-110) (Order Approving

Exchange agrees with the Commission when it stated that this principle holds true for Commodity-Based Trust Shares as well,³¹ and believes that the proposed amendments to the GLS to permit actively-managed Commodity-Based Trust Shares are therefore consistent with the Act.

As discussed above, the Exchange is adopting safeguards around trading halts and material-non public information that are already in place for other actively-managed products listed and trading on the Exchange today.³² Further, these actively-managed Commodity-Based Trust Shares would be subject to the same requirements under the GLS that are currently applicable to passively-managed strategies, including requirements related to portfolio transparency, valuation, and dissemination. As the Commission stated in the GLS Approval Order, consistently applying listing standards across products with economic exposures to the same underlying commodities levels the playing field between issuers, which should promote competition and would more readily afford investors greater investment options.³³ The Exchange believes that extending the GLS to accommodate actively-managed strategies would further this objective by enabling additional issuers to bring innovative products to market through a transparent, regulated framework.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed rule change would facilitate the listing and trading of additional types of Commodity-Based Trust Shares pursuant to generic listing standards, provided that the applicable requirements are satisfied. Accordingly, the proposal is designed to facilitate product innovation and efficient listing processes, thereby enhancing competition among issuers and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Notice of Designation of a Longer Period for Commission Action

Section 19(b)(2) of the Act³⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is June 12, 2026. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,³⁵ designates July 27, 2026, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change, as modified by Amendment No. 1.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NASDAQ-2026-032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NASDAQ-2026-032. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NASDAQ-2026-032 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12037 Filed 6-15-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105660; File No. SR-NYSEAMER-2026-49]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Partial Cabinet Solution Bundles

June 11, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 ("Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on June 1, 2026, NYSE American LLC ("NYSE American" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

Generic Listing Standards for Managed Fund Shares)).

³¹ See iShares Approval Order at 33253.

³² See *supra* notes 18 and 20.

³³ See GLS Approval Order at 45419.

³⁴ 15 U.S.C. 78s(b)(2).

³⁵ 15 U.S.C. 78s(b)(2).

³⁶ 17 CFR 200.30-3(a)(12) and (31).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. The description of the Partial Cabinet Solution bundles and related fees in the Connectivity Fee Schedule ("Fee Schedule") would be updated accordingly. The proposed rule change is available on the Exchange's website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Partial Cabinet Solution bundles offered

as part of its co-location services. Specifically, the Exchange proposes to delete the current 1 kW Partial Cabinet Solution ("PCS") bundle and change the fee charged for the 2 kW PCS bundle. The description of the PCS bundles and related fees in the Fee Schedule would be updated accordingly.

The Exchange expects that the proposed rule change would become operative no later than October 31, 2026. The Exchange will announce the date through a customer notice.

Background

Currently, there are two PCS bundles available to Users,⁴ each of which includes a partial cabinet; access to the Liquidity Center Network ("LCN") and internet protocol ("IP") network, the local area networks available in the data center; two NMS network⁵ connections, two fiber cross connections; and connectivity to one of two time feeds.⁶ Option A has a 1 kW partial cabinet, and Option B has a 2 kW partial cabinet. In addition to other requirements, a User and its Affiliates⁷ must have an Aggregate Cabinet Footprint⁸ of 2 kW or less to qualify for either Option A or Option B.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.⁹ That has not changed. But as hardware and

other infrastructure has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may find the 1 kW PCS bundle inadequate to meet their needs.

At the same time, the monthly recurring fees that Users pay for IP and LCN ports (also referred to as "connections" and "network access") increased¹⁰ but the fees for the 2 kW PCS bundle did not.

Proposed Changes

The Exchange proposes to make the following changes. First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle and therefore proposes to delete it from the Fee Schedule as obsolete.

Second, the Exchange proposes to change the monthly recurring charge for the 2 kW PCS bundle. With this proposal, the Exchange proposes to increase the monthly recurring fees by 10.0% (the initial charge would not change). Because it would be the only PCS bundle that remained, the Exchange also proposes to delete "Option B".

To implement the changes, the Exchange would amend the Fee Schedule as follows (proposed deletions bracketed, proposed addition italicized):

Type of service	Description	Amount of charge
Partial Cabinet Solution bundles	[<i>Option A:</i>] 1 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol].	[10,000 initial charge per bundle plus \$14,000 monthly charge per bundle].
Note: A User and its Affiliates are limited to one Partial Cabinet Solution bundle at a time. A User and its Affiliates must have an Aggregate Cabinet Footprint of 2 kW or less to qualify for a Partial Cabinet Solution bundle. See Note 1 under "Colocation Notes".		

⁴ For purposes of the Exchange's colocation services, a "User" means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR-NYSEMKT-2015-67). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the New York Stock Exchange LLC, NYSE Arca, Inc., NYSE National, Inc. and NYSE Texas, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the change described herein.

⁵ The NMS Network is an alternate dedicated network connection that Users use to access the NMS feeds for which the Securities Industry Automation Corporation is engaged as the securities information processor. Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR-NYSE-2019-46, SR-NYSEAMER-2019-34, SR-NYSEArca-2019-61, SR-NYSENAT-2019-19).

⁶ See Securities Exchange Act Release No. 97748 (June 16, 2023), 88 FR 41164 (June 23, 2023) (SR-NYSEAMER-2023-32).

⁷ An "Affiliate" of a User is any other User or Hosted Customer that is under 50% or greater

common ownership or control of the first User. Fee Schedule, p. 1.

⁸ The "Aggregate Cabinet Footprint" of a User is the total kW of the User's cabinets, including both partial and dedicated cabinets. Fee Schedule, p. 1.

⁹ See Securities Exchange Act No. 77071 (February 5, 2016), 81 FR 7382 (February 11, 2016) (SR-NYSEMKT-2015-89).

¹⁰ See Securities Exchange Act No. 104062 (September 25, 2025), 90 FR 46950 (September 30, 2025) (SR-NYSEArca-2025-60) (increasing the monthly recurring fees for IP and LCN ports by between 9.1% and 11.1%) (the "2025 Price Change").

Type of service	Description	Amount of charge
A purchaser of a Partial Cabinet Solution bundle must select NMS Network connections of the same size (i.e. 10 Gb or 40 Gb) as the related LCN and IP network connections.	[Option B:] 2 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.	\$10,000 initial charge per bundle plus \$[15,000]16,500 monthly charge per bundle.

The proposed fee increase would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity products, services, and facilities for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing colocation facility to offer customers additional space and power.¹¹

Nevertheless, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016¹² while inflation has been 15.98% since February 2016 as measured using the "Data PPI" metric described below¹³ and the monthly recurring fees that Users pay for IP and LCN ports recently increased.¹⁴

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees for the 2 kW PCS bundle frozen at 2016 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increase the Exchange proposes is based on an industry-specific Producer Price Index ("PPI"), which is a tailored measure of inflation.¹⁵ As a general matter, the PPI is a family of indexes that measures the

average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index ("CPI"), that measure price change from the purchaser's perspective.¹⁶ About 10,000 PPIs for individual products and groups of products are tracked and released each month.¹⁷ PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI ("Data PPI"), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics ("BLS") as part of an ongoing effort to expand PPI coverage of the services sector of the U.S. economy and is identified as NAICS 518210 in the North American Industry Classification System.¹⁸ According to the BLS,

[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The

transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.¹⁹

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the monthly fee for the 2 kW PCS bundle because the Exchange uses its "own computer systems" and "proprietary software," i.e., its own data center, including the hardware and equipment that it uses to bring customers' orders, transactions, and other data into the data center for processing, routing, and execution. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from February 2016 through December 2025 (the last month for which finalized data is available).²⁰ The Data PPI had a starting value of 106.6 in February 2016 and an ending value of 123.64 in December 2025, a 15.98% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 15.98% during this period. Based on that percentage change, the Exchange proposes to increase its monthly recurring fees for the 2 kW PCS bundle by 10.0%—below the Data PPI increase of 15.98%—which reflects an increase covering the entire period since the last price adjustment to these fees was made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 3.3% increase for any one calendar year period since it was introduced. The average calendar year

¹¹ In addition, in 2020, the Exchange began providing Users, at no additional charge, one port on the new NMS Network for each 10 Gb or 40 Gb IP Network port or LCN port that Users purchased. The Exchange did not increase the underlying IP Network or LCN port fees at the time. See note 5, *supra*.

¹² The price was originally reduced for PCS bundles for 24 months so long as the User ordered its PCS bundle by a given date. If the PCS bundle was ordered after that date, it paid the full fee. See note 9, *supra*.

¹³ See <https://fred.stlouisfed.org/series/PCU51825182#0>.

¹⁴ See 2025 Price Change, note 10, *supra*.

¹⁵ See note 13, *supra*.

¹⁶ See <https://www.bls.gov/ppi/overview.htm>.

¹⁷ *Id.*

¹⁸ NAICS appears in table 5 of the PPI Detailed Report and is available at <https://data.bls.gov/timeseries/PCU518210518210>.

¹⁹ See <https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm>.

²⁰ See note 18, *supra*.

change from 2002 to 2025 was 0.8%, with a cumulative increase of 19.7% over this period.²¹ The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar year increases averaging 2.5%, and a cumulative increase of 83.0% during the same period.²²

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increase.²³

Application and Impact of the Proposed Change

The proposed change would apply to all PCS bundles. The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally.

Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List is applied uniformly to all Users.

As no Users have the 1 kW PCS bundle, none would be impacted by its deletion. The Exchange expects to obtain no new Users as a result of changing the fees for 2 kW PCS bundles.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and

coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,²⁶ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees for the 2 kW PCS bundle do not properly reflect the quality of the services and products, as fees for the 2 kW PCS bundle have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems has increased the performance of these ports.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefited, while the Exchange's ability to recoup its investments has been hampered.

Between February 2016 and December 2025, the total inflation rate was 36.7%.²⁷ Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 15.98%. The Exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees for the 2 kW PCS bundle for more than eight years. The price change would be commensurate with the 2025 fee changes to the LCN and IP network and below the amount of the increase in the Data PPI. The proposed fee change

therefore represents a modest increase from the current fees.

The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing several aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities. The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize its technology so that it may benefit its members in offering connectivity products and services.

Additional Considerations

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be reasonable.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increase is equitably allocated and not unfairly discriminatory because it would apply to all market participants that choose to purchase the 2 kW PCS bundle from the Exchange. Any participant that chooses to purchase the 2 kW PCS bundle would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the products and services. Additionally, the fee increases would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities.

²¹ See *id.*

²² See <https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/>.

²³ See *supra* discussion of system performance advancements. Additionally, other exchanges, including the Affiliate SROs, have filed for increases in certain fees, based in part on comparisons to inflation. See, e.g., Securities Exchange Act Release Nos. 102073 (January 2, 2025), 90 FR 1558 (January 8, 2025) (SR-BOX-2024-30); 102103 (January 3, 2025), 90 FR 2045 (January 10, 2025) (SR-NASDAQ-2024-087); 102574 (March 11, 2025), 90 FR 12439 (March 17, 2025) (SR-NYSEARCA-2025-20); 104061 (September 25, 2025), 90 FR 47009 (September 30, 2025) (SR-NYSE-2025-37); 104063 (September 25, 2025), 90 FR 47038 (September 30, 2025) (SR-NYSEArca-2025-71); 104064 (September 25, 2025), 90 FR 46960 (September 30, 2025) (SR-NYSEArca-2025-23); 104065 (September 25, 2025), 90 FR 46966 (September 30, 2025) (SR-NYSEArca-2025-35); and 100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR-NYSEARCA-2024-79).

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78f(b)(4).

²⁷ See note 22, *supra*.

The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.²⁸

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the Fee Schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today, albeit at inflation-adjusted rates for the 2 kW PCS bundle, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the deletion of the 1 kW PCS bundle and the level of the proposed fees neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition.

Intermarket Competition. The Exchange believes that the removal of the 1 kW PCS bundle and the proposed fees for the 2 kW PCS bundle do not impose a burden on competition or on

other SROs that is not necessary or appropriate.

First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle, and so no Users would be impacted by its deletion.

Second, in determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and facilities would not impose a burden on competition.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁹ and Rule 19b-4(f)(6) thereunder.³⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³¹ and Rule 19b-4(f)(6)³² thereunder.

²⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁰ 17 CFR 240.19b-4(f)(6).

³¹ 15 U.S.C. 78s(b)(3)(A).

³² Rule 19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEAMER-2026-49 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEAMER-2026-49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-NYSEAMER-2026-49 and should be submitted on or before July 7, 2026.

proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 15 U.S.C. 78s(b)(2)(B).

²⁸ 15 U.S.C. 78f(b)(8).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12025 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105673; File No. SR-24X-2026-19]

Self-Regulatory Organizations; 24X National Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Transaction Rebates Applicable to Members of the Exchange

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder, ² notice is hereby given that, on May 29, 2026, 24X National Exchange LLC (“24X” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the transaction rebates applicable to Members ³ of the Exchange, as described below. The proposed rule change is available on the Exchange’s website at <https://equities.24exchange.com/regulation> and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the transaction rebates applicable to Members of the Exchange. Specifically, the Exchange proposes the following: (i) to decrease the rebate for executions of non-retail ⁴ orders that are displayed on the 24X Book ⁵ and add liquidity to the Exchange (“Added Displayed Volume”) in all securities traded on the Exchange priced at or above \$1.00 per share from \$0.0034 per share to \$0.00295 per share, and (ii) to increase the rebate for executions of retail ⁶ and non-retail ⁷ orders that are not displayed on the 24X Book and add liquidity to the Exchange (“Added Non-Displayed Volume”) in all securities traded on the Exchange priced at or above \$1.00 per share from \$0.0025 per share to \$0.0027 per share. The Exchange proposes to implement the rule change on June 1, 2026.

The proposed decreased rebate for Added Displayed Volume transactions and increased rebates for Added Non-Displayed Volume transactions are consistent with or higher than the rebates provided by other exchanges for similar executions,⁸ and are intended to incentivize Members to increase the liquidity-providing orders they submit to the Exchange, which would support price discovery on the Exchange and provide additional liquidity for incoming orders.

The proposed rule change does not include different rebates depending on the number of orders submitted to, or transactions executed on or through, the Exchange. Accordingly, the rebates described above are applicable to all

Members, regardless of the overall volume of a Member’s trading activities on the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) ⁹ of the Act in general, and furthers the objectives of Section 6(b)(4) ¹⁰ of the Act in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed amended rebates are consistent with the objectives of Section 6(b)(5) ¹¹ of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that the proposed amended rebates reflect a simple and competitive pricing structure designed to incentivize market participants to add aggressively priced displayed liquidity and direct their order flow to the Exchange, which the Exchange believes would promote price discovery and price formation and deepen liquidity that is subject to the Exchange’s transparency, regulation, and oversight as an exchange, thereby enhancing market quality to the benefit of all Members and investors.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and self-regulatory organization revenues, and also recognized that current regulation

³⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78a.

² 17 CFR 240.19b-4.

³ See Exchange Rule 1.5(u).

⁴ Such executions correspond to fee codes “1,” “53,” “54,” and “62” in the Exchange’s fee schedule.

⁵ “24X Book” refers to the Exchange system’s electronic file of orders. See Exchange Rule 1.5(a).

⁶ Such executions correspond to fee codes “151,” “152,” and “163” in the Exchange’s fee schedule.

⁷ Such executions correspond to fee codes “51,” “52,” and “63” in the Exchange’s fee schedule.

⁸ See Choe EDGX Exchange, Inc. (“Choe EDGX”) fee schedule, available at: https://www.choe.com/us/equities/membership/fee_schedule/edgx/; MIAx PEARL, LLC (“MIAx Pearl”) fee schedule, available at: https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAx_Pearl_Equities_Fee_Schedule_05012026_0.pdf; and NYSE Texas, Inc. (“NYSE Texas”) fee schedule, available at: https://www.nyse.com/publicdocs/nyse/markets/nyse-texas/NYSE_Texas_Fee_Schedule.pdf; MEMX LLC (“MEMX”) fee schedule, available at: <https://info.memxtrading.com/equities-trading-resources/us-equities-fee-schedule/>.

⁹ 15 U.S.C. 78f.

¹⁰ 15 U.S.C. 78f(b)(4).

¹¹ 15 U.S.C. 78f(b)(5).

of the market system “has been remarkably successful in promoting market competition in its broader forms

that are most important to investors and listed companies.”¹²

As illustrated in the following table, the Exchange notes that the proposed

amended rebates are comparable to or higher than those in place on other exchanges:¹³

Exchange	Rebate for added displayed volume ≥\$1.00 (non-retail)	Rebate for added non-displayed volume ≥\$1.00 (non-retail)	Rebate for added non-displayed volume ≥\$1.00 (retail)
24X	(\$0.00295)	(\$0.0027)	(\$0.0027)
Cboe EDGX	(\$0.0034)	(\$0.0026)	* (\$0.0037)
MIAX Pearl	(\$0.00335)	(\$0.0020)	(\$0.0020)
NYSE Texas	(\$0.0029)	(\$0.0014)	N/A
MEMX	(\$0.0033)	(\$0.0028)	** (\$0.0037)

* The Cboe EDGX fee schedule does not specify a rebate for non-displayed retail orders that add liquidity, so the table includes Cboe EDGX's general, highest-tier rebate for retail orders that add liquidity.

** The MEMX fee schedule does not specify a rebate for non-displayed retail orders that add liquidity, so the table includes MEMX's general, highest-tier rebate for retail orders that add liquidity.

The Exchange believes that it is appropriate, reasonable, and consistent with the Act to provide a rebate of \$0.00295 for Added Displayed Volume non-retail transactions because it is comparable to or higher than the rebates provided by other exchanges for similar transactions.¹⁴ The Exchange further believes that this rebate is equitably allocated and not unfairly discriminatory because it applies equally to all Members, and is designed to facilitate increased activity on the Exchange to the benefit of all Members by providing more trading opportunities and promoting price discovery.

The Exchange believes that it is appropriate, reasonable, and consistent with the Act to provide a rebate of \$0.0027 for Added Non-Displayed Volume retail and non-retail transactions in securities priced at or above \$1.00 per share because those rebates are also comparable to or higher than rebates provided by other exchanges for similar transactions.¹⁵ The Exchange further believes that this rebate structure is equitably allocated and not unfairly discriminatory because it applies equally to all Members.

The Exchange notes that under the proposed amended rebate structure, it will pay an equal rebate for non-retail Added Displayed Volume as the fee it charges for removing such volume, and as such the Exchange will have zero net capture with respect to such transactions. As noted above, the Exchange operates in a highly competitive market, and the Exchange believes this pricing structure will enable it to effectively compete with other exchanges by attracting Members and order flow to the Exchange, which

will help the Exchange to gain market share for executions. The Exchange may determine to modify its pricing structure after it has gained sufficient participation from market participants to instead be profitable with respect to such transactions. The Exchange believes this pricing structure, including the zero net capture for non-retail Added Displayed Volume transactions, is designed to incentivize market participants to add aggressively priced displayed liquidity and direct their order flow to the Exchange, which the Exchange believes would promote price discovery, price formation, and narrower spreads, and deepen liquidity that is subject to the Exchange's transparency, regulation, and oversight as an exchange, thereby enhancing market quality to the benefit of all Members and investors. The Exchange does not believe that the zero net capture with respect to non-retail Added Displayed Volume transactions will materially impact the capitalization of the Exchange or otherwise impair the Exchange's ability to operate or regulate itself. The Exchange is well-capitalized and the Exchange's parent company, 24X US Holdings LLC, has agreed to provide adequate funding for the Exchange's operations, including the regulation of the Exchange.

In conclusion, the Exchange submits that its proposed amended rebate structure satisfies the requirements of Sections 6(b)(4)¹⁶ and 6(b)(5)¹⁷ of the Act for the reasons discussed above in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities, does not permit unfair discrimination

between customers, issuers, brokers, or dealers, and is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and in general to protect investors and the public interest, particularly as the proposal neither targets nor will it have a disparate impact on any particular category of market participant. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange is subject to significant competitive forces, and believes that its proposed amended rebate structure is an appropriate effort to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of order flow to a public exchange, thereby promoting market depth, execution incentives, and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes “more efficient pricing of individual stocks for all types of orders, large and small.”¹⁸

The Exchange does not believe that the proposed rule change will impose

¹² Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

¹³ See *supra* note 9. If a particular exchange provides different rebates depending on transaction

volume, the highest available rebate is included in the table.

¹⁴ See *supra* note 9.

¹⁵ *Id.*

¹⁶ 15 U.S.C. 78f(b)(4).

¹⁷ 15 U.S.C. 78f(b)(5).

¹⁸ Regulation NMS Adopting Release at 37499.

any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed amended pricing structure will increase competition and is intended to draw volume to the Exchange. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or reduce use of certain categories of products in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. As a new exchange, the Exchange faces intense competition from existing exchanges and other non-exchange venues that provide markets for equities trading. With respect to the Exchange's proposal to operate with zero net capture for non-retail transactions involving Added Displayed Volume, the Exchange is proposing this pricing in an effort to encourage market participants to join, connect to, and participate on the Exchange. The Exchange may modify its pricing structure after it has gained sufficient participation from market participants to eliminate the zero net capture and instead be profitable with respect to such transactions.

Although these pricing incentives are intended to attract liquidity to the Exchange, most other exchanges in operation today already offer multiple incentives to their participants, including tiered pricing that provides higher rebates or discounted executions, and other exchanges will be able to modify such incentives in order to compete with the Exchange. As discussed above, the Exchange notes that the proposed amended rebates are comparable to or higher than those in place on other exchanges. Accordingly, with respect to a market participant deciding to submit an order to add liquidity, there are multiple exchanges that will continue to be competitively priced for such orders when compared to the Exchange's pricing. Further, while pricing incentives do cause shifts of liquidity between trading centers, market participants make determinations on where to provide liquidity or route orders to take liquidity based on factors other than pricing, including technology, functionality, and other considerations. Consequently, the Exchange believes that the degree to

which its proposed amended rebates could impose any burden on competition is extremely limited, and does not believe that such pricing structure would burden competition of Members or competing venues in a manner that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed amended rebates apply equally to all Members. The proposed pricing structure is intended to encourage market participants to add displayed liquidity on the Exchange by providing rebates that are comparable to or higher than those offered by other exchanges, which the Exchange believes will help to encourage Members to send orders to the Exchange to the benefit of all Exchange participants. As the proposed rates are equally applicable to all Members, regardless of the overall volume of a Member's trading activities on the Exchange, the Exchange does not believe there is any burden on intramarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) ¹⁹ of the Act and subparagraph (f)(2) of Rule 19b-4 thereunder,²⁰ because it establishes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) ²¹ of the Act to determine whether the proposed rule change should be approved or disapproved.

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(2).

²¹ 15 U.S.C. 78s(b)(2)(B).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-24X-2026-19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-24X-2026-19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-24X-2026-19 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12038 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

²² 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105669; File No. SR–CBOE–2026–052]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on May 29, 2026, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) proposes to amend certain standard transaction fees, amend Floor Broker permit fees, amend the SPX and VIX Floor Broker trading surcharges, amend the Floor Broker ADV discount, adopt two floor jacket stipends, and adopt SPXW excessive complex instrument creation charges. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission’s website (<https://www.sec.gov/rules/sro.shtml>), the Exchange’s website (https://www.cboe.com/us/options/regulation/rule_filings/cone/), and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule.³

Standard Transaction Fee Changes

XSP, MRUT, and DJX

The Exchange proposes to apply certain fee codes currently applicable to transactions in Mini-SPX Index options (“XSP”) to transactions in each of Mini-Russell 2000 Index options (“MRUT”) and options on the Dow Jones Industrial Average (“DJX”). Specifically, the proposed rule change amends certain fees for XSP in the Rate Table for All Products Excluding Underlying Symbol List A, as follows:⁴

- Amends fee code XC, appended to all Customer (capacity “C”) orders in XSP that are for less than 10 contracts and provides a rebate of \$0.30 per contract, to apply to all Customer (capacity “C”) orders in XSP, MRUT, or DJX that are for less than 10 contracts.
- Amends fee code CC, appended to all Customer (capacity “C”) orders in XSP that are for greater than or equal to 10 contracts and assesses a fee of \$0.07 per contract, to apply to all Customer (capacity “C”) orders in XSP, MRUT, or DJX that are for greater than or equal to 10 contracts.
- Amends fee code XN, appended to all Clearing Trading Permit Holders (“TPHs”) (capacity “F”), Non-Clearing TPH Affiliates (capacity “L”), Broker-Dealer (capacity “B”), Joint Back-Office (capacity “J”), Non-TPH Market-Maker (capacity “N”), and Professional (capacity “U”) (collectively, “Non-Market Maker, Non-Customer”) orders in XSP that are executed manually (*i.e.*, open outcry) and assesses a fee of \$0.30 per contract, to apply to all Non-Market Maker, Non-Customer orders in XSP, MRUT, or DJX that are executed manually (*i.e.*, open outcry).
- Amends fee code XF, appended to all Non-Market Maker, Non-Customer

orders in XSP contra to a customer or contra to a non-customer that add liquidity and that are executed electronically and assesses a fee of \$0.30 per contract, to apply to all Non-Market Maker, Non-Customer orders in XSP, MRUT, or DJX contra to a customer or contra to a non-customer that add liquidity and that are executed electronically.

- Amends fee code XB, appended to all Non-Market Maker, Non-Customer orders in XSP contra to a non-customer that remove liquidity and assesses a fee of \$0.50 per contract, to apply to all Non-Market Maker, Non-Customer orders in XSP, MRUT, or DJX contra to a non-customer that remove liquidity.
 - Amends fee code MP, appended to all Market-Maker (capacity “M”) orders in XSP that are executed manually (*i.e.*, open outcry) and assesses a fee of \$0.15 per contract, to apply to all Market-Maker (capacity “M”) orders in XSP, MRUT, or DJX that are executed manually (*i.e.*, open outcry).
 - Amends fee code MC, appended to all Market-Maker (capacity “M”) orders in XSP that are contra customer and that are executed electronically and assesses a fee of \$0.15 per contract, to apply to all Market-Maker (capacity “M”) orders in XSP, MRUT, or DJX that are contra customer and that are executed electronically.
 - Amends fee code MX, appended to all Market-Maker (capacity “M”) orders in XSP contra to non-customers that add liquidity and that are executed electronically and assesses a fee of \$0.09 per contract, to apply to all Market-Maker (capacity “M”) orders in XSP, MRUT, or DJX contra to non-customers that add liquidity and that are executed electronically.
 - Amends fee code MY, appended to all Market-Maker (capacity “M”) in XSP contra to non-customers that remove liquidity and assesses a fee of \$0.50 per contract, to apply to all Market-Maker (capacity “M”) in XSP, MRUT, or DJX contra to non-customers that remove liquidity.
- As part of the proposed changes, the Exchange proposes to delete the following fee codes, which are currently appended to MRUT orders. Specifically, the Exchange proposes to delete:
- Fee code CQ, appended to Customer orders in MRUT and assesses a fee of \$0.02 per contract.
 - Fee code FM, appended to Clearing TPH (capacity “F”) and Non-Clearing TPH Affiliates (capacity “L”) orders in MRUT and assesses a fee of \$0.02 per contract.
 - Fee code MM, appended to Market-Maker (capacity “M”) orders in MRUT and assesses a fee of \$0.03 per contract.

³ The Exchange initially filed the proposed fee change, among other changes, on April 1, 2026 (SR–CBOE–2026–031) (the “Original Filing”). On May 29, 2026, the Exchange withdrew that filing and submitted this proposal. The Exchange notes that subsequent to the Original Filing that proposed these changes, the Exchange amended its Fees Schedule to make changes in connection with the fees related to certain orders executed in Automated Improvement Mechanism (“AIM”) Auctions and to amend the Customer Volume Incentive Program and Affiliated Volume Plan; such changes are incorporated Exhibit 5 to this filing.

⁴ As part of the proposed changes, the Exchange proposes to amend Footnote 9 to reflect the changes to fee code XC and CC described herein.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

- Fee code BM, appended to Broker-Dealer (capacity “B”), Joint Back-Office (capacity “J”), Non-TPH Market-Maker (capacity “N”), and Professional (capacity “U”) orders in MRUT and assesses a fee of \$0.04 per contract.

As part of the proposed changes, the Exchange proposes to add DJX to Liquidity Provider Sliding Scale⁵ and Liquidity Provider Sliding Scale Adjustment Program (as described within Footnote 44).

SPESG and SPEQX

The Exchange proposes to adopt certain fees related to transactions in S&P 500 Scored & Screened Index options (“SPESG”) and S&P 500 Equal Weight Index options (SPEQX). Specifically, the proposed rule change adopts certain fees for SPESG and SPEQX in the Rate Table for All Products Excluding Underlying Symbol List A, as follows:

- Adopts fee code G1, appended to Customer (capacity “C”) orders in SPESG and SPEQX options and assesses a fee of \$0.10 per contract.
- Adopts fee code G2, appended to all Market-Maker (capacity “M”) orders in SPESG and SPEQX that are executed manually (*i.e.*, open outcry) and assesses a fee of \$0.15 per contract.
- Adopts fee code G3, appended to Market-Maker (capacity “M”) orders in SPESG and SPEQX contra to non-customers that remove liquidity and that are executed electronically and assesses a fee of \$0.50 per contract.
- Adopts fee code G4, appended to all Market-Maker (capacity “M”) orders in SPESG and SPEQX contra to non-customers that add liquidity and that are executed electronically and provides a rebate of \$0.25 per contract.
- Adopts fee code G5, appended to all Market-Maker (capacity “M”) orders in SPESG and SPEQX contra to customers and that are executed electronically and assesses a fee of \$0.15 per contract.
- Adopts fee code G6, appended to Non-Market Maker, Non-Customer orders in SPESG and SPEQX that are executed manually (*i.e.*, in open outcry) and assesses a fee of \$0.20 per contract.
- Adopts fee code G7, appended to Non-Market Maker, Non-Customer orders in SPESG and SPEQX contra to a customer or contra to a non-customer that add liquidity, and that are executed electronically, and assesses a fee of \$0.20 per contract.

As part of the proposed changes, the Exchange proposes to delete the below fee codes, which are currently appended

to certain SPEQX orders. Specifically, the Exchange proposes to delete:

- Fee code E1, appended to Customer orders in SPEQX and assesses a fee of \$0.05 per contract.
- Fee code E2, appended to Non-Customer orders in SPEQX and assesses a fee of \$0.25.

As part of the proposed changes, the Exchange also proposes to amend the below fee codes, which are currently appended to certain SPESG orders. Specifically, the Exchange proposes to amend:

- Fee code CS, appended to Customer (capacity “C”) premium orders for less than \$1.00 in SPW (including SPXW) and SPESG and assesses a fee of \$0.36 per contract, to apply to Customer (capacity “C”) premium orders for less than \$1.00 in SPW (including SPXW).
- Fee code CT, appended to Customer (capacity “C”) premium orders for greater than or equal to \$1.00 in SPX (including SPXW) and SPESG and assesses a fee of \$0.40 per contract, to apply to Customer (capacity “C”) premium orders for greater than or equal to \$1.00 in SPX (including SPXW).
- Fee code BT, appended to Broker-Dealer (capacity “B”), Joint Back-Office (capacity “J”), Non-TPH Market-Maker (capacity “N”), and Professional (capacity “U”) orders in SPX (including SPXW) and SPESG and assesses a fee of \$0.42 per contract, to apply only to Broker-Dealer (capacity “B”), Joint Back-Office (capacity “J”), Non-TPH Market-Maker (capacity “N”), and Professional (capacity “U”) orders in SPX (including SPXW).
- Fee code MS, appended to Market-Maker (capacity “M”) orders in SPX (including SPXW) and SPESG and assesses a fee of \$0.28 per contract, to apply only to Market-Maker (capacity “M”) orders in SPX (including SPXW).
- Fee code FH, assesses a fee of \$0.26 per contract and is appended to Broker-Dealer (capacity “B”), Joint Back-Office (capacity “J”), Non-TPH Market-Maker (capacity “N”), and Professional (capacity “U”) orders in Underlying Symbol List A, under which SPESG is currently listed and to which the Exchange proposes to remove SPESG.⁶

The Exchange also proposes to exclude SPESG from certain surcharges applicable to certain Non-Market-Maker orders. Specifically, the Exchange proposes to exclude SPESG from the Execution Surcharge (\$0.21 per contract), AIM Response Surcharge (\$0.05 per contract), AIM Contra

Surcharge (\$0.10 per contract), and the AIM Agency/Primary Surcharge (\$0.10 per contract).⁷ The Exchange proposes to list SPESG to the FLEX Surcharge Fee under “Rate Table—All Products Excluding Underlying Symbol List A”, which assesses a charge of \$0.10 per contract (capped at \$250 per trade).⁸

As a result of the removal of SPESG from Underlying Symbol List A, the Exchange also proposes to update certain fee program descriptions set forth within the Fees Schedule to specifically reference SPESG. Specifically, the Exchange proposes to amend the SPX/SPXW Liquidity Provider Sliding Scale,⁹ Liquidity Provider Sliding Scale, Liquidity Provider Sliding Scale Adjustment Table, Volume Incentive Program, Break-up Credits, Marketing Fees, Floor Broker Sliding Scale Rebate Program, Floor Broker Slide Scale Supplemental Rebate Program, Order Router Subsidy Program (“ORS”), Complex Order Router Subsidy Program (“CORS”), Floor Brokerage Fees, and the Floor Brokerage Fees Discount Scale to list SPESG as program exclusions.¹⁰ These are not substantive changes, as SPESG was previously excluded via its inclusion in Underlying Symbol List A.

LMM Program Updates

The Exchange propose to eliminate the MRUT, RTH SPESG, RTH MBTX/MBTXW, RTH CBTX/CBTXW, and RTH SPEQX LMM Incentive Programs (the “LMM Incentive Programs”), set forth in the Fees Schedule. By way of background, each LMM Incentive Program provides a rebate to TPHs with LMM appointments to the respective incentive program that meet certain quoting standards in the applicable series in a month. Meeting or exceeding the quoting standards in each of the

⁷ The Exchange also proposes to amend Footnote 12 appended to the Execution Surcharge, AIM Response Surcharge, AIM Contra Surcharge, and the AIM Agency/Primary Surcharge, to remove reference to SPESG, and to amend Footnote 21 appended to the Execution Surcharge to remove reference to SPESG.

⁸ Currently, SPESG falls under the FLEX Surcharge Fee under Rate Table—Underlying Symbol List A, which assesses the same charge of \$0.10 per contract (capped at \$250 per trade); thus there is no substantive change to the fee assessed as a result of this change.

⁹ As part of the proposed change, the Exchange proposes to amend Footnote 33 to reflect the changes to the SPX/SPXW Liquidity Provider Sliding Scale.

¹⁰ As part of the proposed changes, the Exchange proposes to amend Footnotes 6, 10, 11, 22, 29, 30, 35, 36, and 44, to include SPESG. The Exchange notes that SPESG was previously included in such footnotes via inclusion in Underlying Symbol List A; as a result of the change to remove SPESG from Underlying Symbol List A, the Exchange now proposes to separately list SPESG within these footnotes.

⁵ The Exchange also proposes to amend Footnote 10 to reflect inclusion of DJX in the Liquidity Provider Sliding Scale program.

⁶ As part of the proposed change, the Exchange also proposes to amend Footnote 34 to remove SPESG from Underlying Symbol List A.

LMM Incentive Program products to receive the applicable rebate is optional for an LMM appointed to a program. Rather, an LMM appointed to an incentive program is eligible to receive the corresponding rebate if it satisfies the applicable quoting standards.

The Exchange is not required to offer these LMM Incentive Programs and no longer desires to do so, as of April 1, 2026. As such, the Exchange proposes deleting each of the LMM Incentive Program details set forth in the Fees Schedule.

Floor Fee Changes

Floor Broker Permit Fee Change

By way of background, a Floor Broker Permit ("FB Permit") entitles the holder to act as a Floor Broker on the floor of the exchange. The Exchange currently maintains a Floor Trading Permit Sliding Scale, which allows Floor Brokers to pay reduced rates for a higher

quantity of FB Permits. Particularly, Floor Brokers pay \$7,500 for the first FB Permit, \$5,700 per permit for the 2nd and 3rd FB Permits, \$4,500 per permit for the 4th and 5th FB permits and \$3,200 for each additional FB Permit thereafter. The Exchange now proposes to eliminate the current fee structure and introduce a flat per-permit FB Permit fee structure. Specifically, the Exchange proposes to assess a fee of \$750 per FB Permit.¹¹ The Exchange believes the proposed change may incentivize new market participants to become Floor Brokers on the Exchange and help offset initial costs of operation as Floor Brokers. The Exchange also notes the proposed structure is consistent with the flat per-permit rates charged by another Exchange to Floor Broker participants.¹²

Floor Broker Trading Surcharge

The Exchange proposes to amend its Floor Broker Trading Surcharge Program

for SPX and VIX. Currently, the Exchange assesses a monthly fee of \$3,000 per month for any Floor Broker TPH that executes more than 20,000 SPX (including SPXW) contracts during the month ("FB SPX Surcharge") and a monthly fee of \$3,000 per month for any Floor Broker TPH that executes more than 20,000 VIX contracts during the month ("FB VIX Surcharge"). First, the Exchange proposes to amend the Floor Broker Trading Surcharge Program to assess a monthly fee for any Floor Broker TPH that executes more than 1,000 SPX (including SPXW) or 1,000 VIX contracts during the month. Further, the Exchange proposes to amend its Floor Broker Trading Surcharge Program to establish a tiered structure, wherein Floor Broker TPHs will be assessed applicable FB SPX and VIX Surcharges based on their quantity of FB Permits. The proposed structure is as follows for SPX/SPXW:

Criteria	Floor trading permit quantity	Monthly fee
FB Trading Permit Holder executes $\geq 1,000$ contracts in SPX/SPXW	1	\$7,500
	2 to 3	6,750
	4 to 5	4,000
	6 to 10	2,500
	>10	2,000

The proposed structure is as follows for VIX:

Criteria	Floor trading permit quantity	Monthly fee
FB Trading Permit Holder executes $\geq 1,000$ contracts in VIX	1	\$3,000
	2 to 5	2,500
	>5	2,000

For each of the FB SPX Surcharge and the FB VIX Surcharge, the volume executed by all Floor Brokers associated with a particular Floor Broker Trading Permit in a given month, will be aggregated for purposes of determining if the Floor Broker Trading Surcharge will be charged.

Floor Broker ADV Discount Change

Next, the Exchange proposes to modify¹³ its discount for Floor Broker Trading Permit fees. Currently, as set forth in the Floor Broker ADV Discount table, any Floor Broker that executes a certain average of Customer (capacity "C") open-outcry contracts per day over

the course of a calendar month in all underlying symbols, will receive a rebate on that TPH's Floor Broker Trading Permit Fees.¹⁴ Such rebate amount is a percentage of the TPH's FB Permit total costs; the criteria and corresponding percentage rebates are noted below.

Floor broker ADV discount tier	ADV	Floor broker permit rebate (%)
1	0 to 99,999	0
2	100,000 to 174,999	15
3	>174,999	25

¹¹ As part of the proposed changes, the Exchange proposes to remove language regarding reduced Floor Broker Permit fees for any new TPH or existing TPH that has not held an active Floor Broker Permit in at least 12 months, as such discount will no longer be available.

¹² See NYSE American Options Fees Schedule, Section III (Monthly Trading Permit, Rights, Floor Access and Premium Product Fees).

¹³ As part of the proposed change, the Exchange proposes to remove outdated language referring to discounts applicable in June 2020.

¹⁴ The Floor Broker ADV Discount will be available for all Floor Broker Trading Permits held by affiliated TPHs and TPH organizations.

The Exchange proposes to modify the discount so TPHs will also receive the applicable discount on their Floor Broker Trading Surcharge fees (both SPX and VIX).

Floor Jacket Stipends

The Exchange proposes to adopt two stipends to assist with the cost of floor jackets. Specifically, the Exchange proposes to adopt a \$275 stipend for new trading floor jackets, to be issued every three years, and a \$100 stipend for the cleaning of trading jackets, to be issued annually. The Exchange will provide the initial stipends to all active

floor badge holders as of April 1, 2026, with subsequent stipends issued according to the established issuance schedule, based on applicable frequency. Floor participants who receive their badge after a scheduled issuance date will receive both stipends upon badge activation and will then follow the established issuance schedule for subsequent stipends.

SPXW Excessive Complex Instrument Creation Charges

Next, the Exchange proposes to amend its Fees Schedule to adopt SPXW

Excessive Complex Instrument Creation Charges (the “Excessive CIC Fee”).

The proposed Excessive CIC Fee is calculated as follows: (i) a TPH’s (and its Affiliate’s, if applicable) daily number of complex instrument¹⁵ creations¹⁶ are added together to determine the Daily Charge based on the below Table 1 and (ii) the Daily Charge is then multiplied by the Daily Multiplier, based on the ratio of the TPH’s SPXW Complex Instruments Traded to SPXW Complex Instruments Created in SPXW, shown in the below Table 2.

TABLE 1

Tier	SPXW complex instrument creations	Daily charge
Tier 1	<20,000	\$0
Tier 2	≥20,000 <29,999	500
Tier 3	≥30,000 <34,999	2,000
Tier 4	≥35,000	4,000

TABLE 2

Tier	SPXW complex instruments traded/ SPXW complex instruments created	Daily multiplier
Tier 1	≥0% <15%	2.00
Tier 2	≥15% <30%	1.50
Tier 3	≥30% <50%	1.00
Tier 4	≥50% <70%	0.50
Tier 5	≥70%	0.00

The proposed Excessive CIC Fee will apply during all Exchange trading sessions.¹⁷ A TPH’s volume in its complex instrument creation activity as well as its complex executed volume will be combined with any of its Affiliates.¹⁸ The Excessive CIC Fee will be calculated on a daily basis and will be assessed to TPHs at the end of the month.

The Exchange notes that market participants with incrementally higher numbers of complex instrument creations have the potential residual effect of exhausting System resources, bandwidth, and capacity. Higher numbers of complex instrument creations may therefore, in turn, create latency and impact other market participants’ ability to receive timely executions.

In fact, the Exchange has recently seen an unprecedented increase in complex instruments creations in SPXW, specifically. The potential for significant price improvement through Legging has created incentives for market participants, particularly Professional and Public Customers, to routinely rest complex orders across thousands of instrument combinations in the Complex Order Book (“COB”) with minimal genuine trading intent. Rather, these participants seek to trade in an opportunistic manner with a Customer order that is received inside the best bid or offer (“BBO”), exploiting the Legging process with speculative behavior. For example, year-to-date, there have been an average of 570 predatory (*i.e.*, sell orders executed above intrinsic value) legged-in contracts in SPXW per day, 91% of

which are box spreads. This behavior does not contribute meaningfully to price discovery or liquidity provision, but instead creates operational burdens, reduces system latency, and degrades market quality. As a result, the Exchange has noticed increased strain on its System, particularly, as it relates to activity in SPXW. With this in mind, the Exchange has proposed this fee specifically for activity in SPXW in order to encourage more efficient behavior among its TPHs as it relates to their complex instrument creation activity.

The proposed fee structure has multiple thresholds, and the proposed fees are incrementally greater at complex instrument creation amounts because the potential impact on Exchange Systems, bandwidth and capacity becomes greater with increased

¹⁵ For purposes of the SPXW Excessive Complex Instrument Creation Charges, a “complex instrument” shall have the same meaning as “complex strategy” as defined in Cboe Options Rule 5.33. See proposed Footnote 54, which the Exchange proposes to append to the Excessive CIC Fee table.

¹⁶ Complex instruments created through the daily reloading of Good-til-Cancel (“GTC”) orders are included in a TPH’s complex instrument creation

total for that trading day. See proposed Footnote 54. For example, if a TPH’s GTC reload produces 13,000 complex instrument creations and the TPH creates an additional 19,000 complex instruments during the same session, the TPH’s total for that day would be 32,000 complex instrument creations.

¹⁷ The Exchange proposes to append reference to Footnotes 37 and 42 to the Excessive CIC Fee table, to denote that, in addition to Regular Trading

Hours, the fee applies during Global Trading Hours (“GTH”) and Curb, respectively.

¹⁸ See proposed Footnote 54, which provides in relevant part, that the Exchange will aggregate the complex instrument creations and executed SPXW complex volume of affiliated TPHs for purposes of the determining SPXW Excessive Complex Instrument Creation Charges if there is at least 75% common ownership between the firms as reflected on each firm’s Form BD, Schedule A.

complex instrument creations. The proposal contemplates that a TPH would have to exceed 20,000 complex instrument creations before that market participant would be charged a fee under the proposed respective tiers. The Exchange believes that it is in the interests of all market participants who access the Exchange to not allow other market participants to exhaust System resources, but to encourage efficient usage of network and System capacity. The Exchange also believes this proposal (and in particular the proposed fee amounts associated with higher complex instrument creation amounts without adequate executed volume) will reduce the incentive for market participants to engage in excessive complex instrument creation activity that will encourage such activity to be submitted in good faith for legitimate purposes.

The Exchange also represents that the proposed fees are not intended to raise revenue; rather, as noted above, it is intended to encourage efficient behavior so that market participants do not exhaust System resources. This is demonstrated by the Exchange (i) targeting the offending behavior and (ii) limiting this to only be for SPXW (where the Exchange is noticing inefficient use of the System).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁰ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,²² which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its TPHs and other persons using its facilities.

Standard Transaction Fee Changes XSP, MRUT, and DJX

The Exchange believes that the proposal to apply certain XSP transaction fee codes to transactions in MRUT and DJX is reasonable, equitable and not unfairly discriminatory. Similar to XSP, MRUT and DJX are index options traded on the Exchange, based on a broad-market index, and they attract a similar mix of market participants and order types. Applying a unified fee structure across these products aligns the fee structure for similar products and simplifies the Fees Schedule. The proposal will result in slightly different fees for MRUT and DJX orders. For example, the current MRUT codes assess fees ranging from \$0.02 to \$0.04 per contract and current DJX codes (assessed under “All Other Index Products”) assess fees ranging from \$0.07 to \$1.05, whereas the corresponding XSP codes assess fees generally ranging from \$0.07 to \$0.50 per contract, and include a customer rebate of \$0.30 per contract for orders under 10 contracts. However, aligning MRUT and DJX with XSP fees creates a fee structure in which the fees assessed for MRUT and DJX transactions are consistent with the rates applicable to a comparable, similarly situated product, and better reflect the value of the Exchange’s services and the costs associated with facilitating such transactions.

The Exchange believes that the proposed fees for orders in MRUT and DJX are equitable and not unfairly discriminatory because the proposed fees will apply automatically and uniformly to all orders in MRUT and DJX, as applicable by capacity. All fee amounts applicable to Customers will be applied equally to all Customers, *i.e.*, all Customer orders will be assessed the same amount. All fee amounts applicable to Market-Makers will be applied equally to all Market-Makers, *i.e.*, all Market Maker orders will be assessed the same amount. Similarly, the Exchange notes that the fee amounts for each separate type of other market participant will be assessed equally to all such market participants, *i.e.*, all Non-Customer and Non-Market-Maker

orders will be assessed the same amount.

The Exchange further believes it is reasonable to delete fee codes which currently apply to MRUT orders, as such codes are inapplicable as a result of the proposed fee change. Additionally, the addition of DJX to the Liquidity Provider Sliding Scale and Liquidity Provider Sliding Scale Adjustment tables extends to DJX the same incentive structure already available to MRUT and XSP, further aligning the fee structure for the three index products and providing Market-Makers in DJX the opportunity to benefit from the same tiered pricing framework as those in MRUT and XSP.

SPESG and SPEQX

The Exchange believes that the proposal to amend fee codes for transactions in SPEQX and SPESG is reasonable, equitable and not unfairly discriminatory. The proposed fees, in general, have minor distinctions based on execution method, capacity of the contra-party, and orders that add liquidity and those that remove liquidity, similar to other fees with the Fees Schedule.²³ Further, other exchanges offer varying fees based on whether an order adds or removes liquidity.²⁴

The Exchange believes it is reasonable to provide a rebate for Market-Maker orders in SPESG and SPEQX that are contra to a non-customer and add liquidity, and are executed electronically, as such changes are designed to incentivize an increase in non-customer liquidity-adding volume in SPESG and SPEQX on the Exchange. The Exchange believes that incentivizing more non-customer orders in SPESG and SPEQX will create more trading opportunities, which, in turn attracts Market-Makers. A resulting increase in Market-Maker activity facilitates tighter spreads, which may lead to additional increase of order flow in SPESG and SPEQX from other market participants, further contributing to a deeper, more liquid market to the benefit of all market participants by creating a more robust and well-balanced market ecosystem.

Additionally, the Exchange believes that it is equitable and not unfairly discriminatory to assess lower fees to Market-Makers (*i.e.*, for all manual Market-Maker orders in SPESG and SPEQX and for all Market-Maker orders in SPESG and SPEQX contra to

¹⁹ 15 U.S.C. 78f(b).

²⁰ 15 U.S.C. 78f(b)(5).

²¹ *Id.*

²² 15 U.S.C. 78f(b)(4).

²³ See Cboe Fees Schedule, “Rate Table—All Products Excluding Underlying Symbol List A.”

²⁴ See EDGX Options Fees Schedule and BZX Options Fees Schedule.

customers and that are executed electronically) as compared to other market participants other than Customers because Market-Makers, unlike other market participants, take on a number of obligations, including quoting obligations, that other market participants do not have. Further, these lower fees offered to Market-Makers are intended to incent Market-Makers to quote and trade more on the Exchange, thereby providing more trading opportunities for all market participants.

The Exchange believes assessing a higher fee for SPESG and SPEQX orders contra a non-customer that remove liquidity and are executed electronically is reasonable because it provides an incentive to maintain non-customer liquidity at the Exchange, thereby promoting price discovery and enhancing order execution opportunities for all TPHs.

The Exchange also believes the proposed changes to the fee structure for Non-Customer, Non-Market Maker orders in SPESG and SPEQX are reasonable. As noted above, it is not novel to charge different fees based on capacity of contra-party, and other exchanges offer varying fees based on whether an order adds or removes liquidity.²⁵ The Exchange believes assessing higher fees in general for Non-Customer, Non-Market Maker orders is reasonable, equitable, and non-discriminatory because, as noted above, the obligations and circumstances between market participants differ. The Exchange believes assessing a lower fee for Non-Customer, Non-Market Maker SPESG and SPEQX orders contra to a customer or contra to a non-customer that add liquidity and are executed electronically is reasonable because it provides an incentive to add liquidity at the Exchange, including in customer volume, thereby promoting price discovery and enhancing order execution opportunities for all TPHs.

The Exchange believes the proposed fee for Customer SPESG and SPEQX orders is reasonable, as it is slightly higher than the fee currently assessed for SPEQX orders yet lower than the proposed Non-Customer, Non-Market Maker SPESG and SPEQX orders. Further, the fee is within the range of similar market participant fees associated with other index products.²⁶

The Exchange believes that the proposed fees for Customer, Market-Maker, and Non-Customer, Non-Market

Maker orders in SPESG and SPEQX are equitable and not unfairly discriminatory because the proposed fees will apply automatically and uniformly to all Customer, Market-Maker, and Non-Customer, Non-Market Maker orders in SPESG and SPEQX, as applicable, based on capacity.

The Exchange further believes it is reasonable to delete fee codes which currently apply to SPEQX orders, as such codes are inapplicable as a result of the proposed fee change. Additionally, the Exchange believes it is reasonable to amend the fee codes that are currently appended to certain SPESG orders, to remove SPESG from such fee codes, as such fee codes will no longer be applicable to SPESG orders as a result of the proposed fee change.

The Exchange believes it is reasonable to exclude SPESG from the Execution Surcharge, AIM Response Surcharge, AIM Contra Surcharge, and AIM Agency/Primary Surcharge applicable to certain Non-Market-Maker orders. As part of the proposed changes. These changes are designed to further align the fee structure of SPESG with the fee structure of SPEQX. The Exchange also believes it is reasonable to exclude volume in SPESG from the SPX/SPXW Liquidity Provider Sliding Scale, Liquidity Provider Sliding Scale, Liquidity Provider Sliding Scale Adjustment Table, Volume Incentive Program, Break-up Credits, Marketing Fees, Floor Broker Sliding Scale Rebate Program, Floor Broker Slide Scale Supplemental Rebate Program, ORS/CORS, Floor Brokerage Fees, and the Floor Brokerage Fees Discount Scale. As noted above, these are not substantive changes, as SPESG was previously excluded via its inclusion in Underlying Symbol List A. Further, the Exchange believes it is reasonable to list SPESG in the FLEX Surcharge fee under Rate Table—Excluding Symbol List A, as SPESG is no longer listed within Underlying Symbol List A.

LMM Program Updates

Finally, the Exchange believes the proposed change to eliminate the LMM Incentive Programs is reasonable, equitable and not unfairly discriminatory. As noted above, the Exchange is not required to offer these LMM Incentive Programs and no longer desires to do so. The proposed change is reasonable, as the Exchange wishes to reallocate resources to its other pricing programs, as well as to developing other pricing programs that may benefit market participants.

The Exchange believes the proposed change is equitable and is not unfairly discriminatory, as the proposed change

applies to all Market-Makers equally. While no Market-Maker will be or continue to be eligible for the eliminated LMM Incentive Programs, all Market-Makers remain eligible to participate in the Exchange's other pricing programs, including other LMM Incentive Programs offered by the Exchange.

Floor Fee Changes

Floor Broker Permit Fee Change

The Exchange believes that the proposed fee change related to FB Permits is reasonable, equitable and not unfairly discriminatory. As noted above, the proposed structure is consistent with the flat per-permit rates charged by another Exchange to Floor Broker participants.²⁷ The Exchange believes the proposed change is reasonable as it may incentivize new market participants to become Floor Brokers on the Exchange and help offset initial costs associated with becoming a Floor Broker. The Exchange believes the proposed discount is equitable and not unfairly discriminatory because the change will apply to all Floor Brokers who currently hold a FB Permit or any new Floor Brokers who will hold a FB Permit. The Exchange further believes the lower rate is reasonable, as Floor Brokers serve an important function in facilitating the execution of orders via open outcry, which as a price-improvement mechanism, the Exchange wishes to encourage and support. Further, the proposed change is designed to further encourage the execution of orders via open outcry, which should increase volume, which would benefit all market participants.

Floor Broker Trading Surcharge

The Exchange believes its proposed change to amend its Floor Broker Trading Surcharge Program for SPX and VIX is reasonable, equitable and not unfairly discriminatory. First, the Exchange believes it is reasonable to lower the volume threshold at which the FB SPX Surcharge and FB VIX Surcharge are triggered, from 20,000 contracts per month to 1,000 contracts per month for each surcharge, as the Exchange believes the revised threshold better aligns the surcharge with the Exchange's costs of supporting floor-based trading activity across a broader range of active Floor Broker TPHs.

The Exchange further believes it is reasonable to establish a tiered fee structure for the FB SPX Surcharge and FB VIX Surcharge based on the number

²⁵ See EDGX Options Fees Schedule and BZX Options Fees Schedule.

²⁶ See Cboe Fees Schedule, "Rate Table—All Products Excluding Underlying Symbol List A."

²⁷ See NYSE American Options Fees Schedule, Section III (Monthly Trading Permit, Rights, Floor Access and Premium Product Fees).

of Floor Broker Trading Permits held by a TPH. Under the proposed structure, Floor Broker TPHs holding a greater number of permits are assessed a lower per-permit monthly surcharge, while those holding fewer permits are assessed a higher surcharge. The Exchange believes this tiered approach is reasonable because Floor Broker TPHs that hold more permits have a larger presence and potential related costs in the floor-based trading operations on the Exchange. Further, the changes may incentivize expanded participation in the Exchange's floor trading environment, which promotes liquidity to the benefit of all participants.

The Exchange believes the proposed tiered structure is equitable and not unfairly discriminatory. All Floor Broker TPHs are subject to the same tiered schedule and are assessed fees based on the number of permits they hold and their trading volume in VIX or SPX. The Exchange also notes that the proposed rates for SPX and VIX reflect the trading characteristics of each product, with SPX and SPXW generally having greater volumes and therefore utilizing greater floor resources.

Floor Broker ADV Discount Change

The Exchange believes its proposal to modify its discount for Floor Broker Trading Permit fees is reasonable, equitable, and not unfairly discriminatory. The Exchange believes it is reasonable to extend the Floor Broker ADV Discount to apply to the FB SPX Surcharge and the FB VIX Surcharge as well as Floor Broker Trading Permit fees. The ADV Discount is designed to encourage the execution of Customer orders in all classes via open outcry, which may increase volume, which would benefit all market participants (including Floor Brokers who do not hit the ADV thresholds) trading via open outcry. TPHs that meet the applicable ADV thresholds and thus qualify for the 15% or 25% rebate are among the most active participants on the Exchange's trading floor. The Exchange believes it is equitable and consistent with the purpose of the discount program to extend its benefits to the FB SPX Surcharge and FB VIX Surcharge, as these surcharges represent part of the overall fees assessed to Floor Broker TPHs in connection with their floor-based trading activity.

The Exchange believes the proposed changes are equitable and not unfairly discriminatory. The ADV Discount tiers and applicable rebate percentages remain unchanged; the proposed modification simply broadens the scope of fees to which the existing discount applies. All Floor Broker TPHs are

eligible to receive the Floor Broker Trading Permit and FB SPX and VIX Trading Surcharges fees rebates under Program.

Floor Jacket Stipends

The Exchange believes the proposed change to adopt two stipends to assist with the cost of floor jackets is reasonable, equitable, and not unfairly discriminatory.

The Exchange believes such change is reasonable, as trading floor jackets are now required to be worn by floor participants at all times when on the Exchange's floor trading. The Exchange believes that providing financial assistance for the purchase and maintenance of these required jackets is a reasonable way of off-setting costs incurred by its floor trading community.

The Exchange believes the proposed stipends are equitable and not unfairly discriminatory. Both stipends will be provided to all active floor badge holders on a uniform basis. Further, floor participants who receive their badge after a scheduled issuance date will receive both stipends upon badge activation and will thereafter follow the established issuance schedule for subsequent stipends, ensuring that all floor participants, whether existing or new, are treated similarly. Further, the Exchange believes the proposed stipend amounts are reasonable. The \$275 jacket stipend and \$100 cleaning stipend are modest in amount and designed to provide meaningful assistance with the actual costs floor participants incur in connection with these required items.

Excessive CIC Fee Change

The Exchange believes the proposed Excessive CIC Fee will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange notes that the proposed fee structure is designed to protect the Exchange's matching engines from being adversely impacted from excessive complex instrument creations. The Exchange believes it is reasonable, equitable and not unfairly discriminatory to assess higher fees when a TPH has higher complex instrument creation activity relative to the ratio of the TPH's SPXW Complex Instruments Traded to SPXW Complex Instruments Created in SPXW because the potential impact on Exchange Systems, bandwidth and capacity becomes greater with increased complex instrument creations. The Exchange believes the proposed fee amounts are reasonable as the Exchange believes them to be commensurate with the

proposed thresholds. Particularly, the proposed fee amounts that correspond to higher complex instrument creation amounts are designed to incentivize TPHs to reduce excessive complex instrument creation activity that the Exchange believes can be detrimental to all market participants at the levels outlined and encourage such activity to be made in good faith and for legitimate purposes.

The Exchange believes the proposed fees are reasonable as TPHs that do not exceed the high SPXW complex instrument creation amount of 20,000 will not be charged any fee under the proposed tiers. As noted above, the Exchange believes that it is in the interests of all TPHs and market participants who access the Exchange to not allow TPHs to exhaust System resources, but to encourage efficient usage of network and System capacity. The Exchange therefore also believes that the proposed fees appropriately reflect the benefits to different firms of being able to engage in complex instrument creation and also believes the proposed fee is one method of facilitating the Commission's goal of ensuring that critical market infrastructure has "levels of capacity, integrity, resiliency, availability, and security adequate to maintain their operational capability and promote the maintenance of fair and orderly markets."²⁸

The Exchange believes adopting the proposed Excessive CIC Fee is reasonable as unfettered usage of System capacity and network resource consumption can have a detrimental effect on all market participants who access and use the Exchange. As discussed above, high complex instrument creations may adversely impact System resources, bandwidth, and capacity which may, in turn, create latency and impact other market participants' ability to receive timely executions. The Exchange believes the proposed fee is therefore reasonable as they are designed to focus on activity that is truly disproportionate while fairly allocating fees to disincentivize the adverse behavior.

Further, the Exchange believes that the proposed Excessive CIC Fee is equitable and not unfairly discriminatory because it will be assessed uniformly to similarly situated users in that all TPHs that exceed the thresholds in connection with the Excessive CIC Fee will be assessed the

²⁸ See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (File No. S7-01-13) (Regulation SCI Adopting Release).

proposed rates. As noted above, the Exchange believes the proposed thresholds are appropriately high rates and have been set out given market behaviors recently observed. The Exchange also believes it is equitable and not unfairly discriminatory to aggregate a TPH's order flow with its Affiliate to prevent TPHs from shifting their order flow and trading activity to their Affiliate in order to circumvent the proposed fees.

The Exchange believes it is equitable and not unfairly discriminatory to assess incrementally higher fees to TPHs that have higher complex instrument creation activity relative to the ratio of the TPH's SPXW Complex Instruments Traded to SPXW Complex Instruments Created in SPXW because the potential impact on Exchange Systems, bandwidth and capacity becomes greater higher complex instrument creation activity.

The Exchange lastly believes that its proposal is reasonable, equitably allocated and not unfairly discriminatory because it is not intended to raise revenue for the Exchange; rather, it is intended to encourage efficient behavior so that TPHs do not exhaust System resources. Specifically, the Exchange is limiting this to the offending behavior and to the specific asset class effected.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Standard Transaction Fee Changes

The Exchange does not believe that the proposed rule changes related to standard transaction fees for XSP, MRUT, DJX, SPESG, or SPEQX will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the fee amounts for each separate type of market participants will be assessed equally to all such market participants. While different fees are assessed to different market participants in some circumstances, the obligations and circumstances between these market participants differ, as discussed above. For example, Market-Makers have quoting obligations that are not applicable to other market participants. Further, the proposed fees structures are intended to encourage more trading of XSP, MRUT, DJX, SPESG, and SPEQX, which bring liquidity to the Exchange and benefits all market participants.

The Exchange does not believe that the proposed rule changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed fees assessed apply to Exchange proprietary products, which are traded exclusively on the Exchange.

LMM Program Updates

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change to eliminate the LMM Incentive Programs applies to all Market-Makers equally. While no Market-Maker will be or continue to be eligible for the eliminated LMM Incentive Programs, all Market-Makers remain eligible to participate in the Exchange's other pricing programs, including other LMM Incentive Programs offered by the Exchange.

The Exchange also does not believe that the proposed changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Further, in regard to the proposed changes to the LMM Incentive Programs, the Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as the proposed changes apply only to programs applicable to transactions in products that are currently exclusively listed on the Exchange.

Floor Fee Changes

The Exchange does not believe that the proposed rule change related to Floor Broker Permit fees will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while it is limited to Floor Brokers, Floor Brokers serve an important function in facilitating the execution of orders via open outcry, which as a price-improvement mechanism, the Exchange wishes to encourage and support. Further, the proposed change is designed to encourage more Floor Brokers which may further encourage more execution of orders via open outcry, which should increase volume, which would benefit all market participants trading via open outcry.

Further, the Exchange does not believe the proposed changes related to the Floor Broker Trading Surcharge will impose any burden on intramarket competition that is not necessary or

appropriate in furtherance of the purposes of the Act. The proposed amendments apply uniformly to all Floor Broker TPHs that meet the applicable criteria. Further, while the tiered structure provides lower permit surcharge rates to TPHs holding a greater number of permits, the Exchange believes this tiered approach is reasonable because Floor Broker TPHs that hold more permits have a larger presence and potential related costs in the floor-based trading operations on the Exchange. Further, the changes may incentivize expanded participation in the Exchange's floor trading environment, which promotes liquidity to the benefit of all participants.

The Exchange does not believe the proposed changes related to the Floor Broker ADV Discount will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Floor Broker TPHs are eligible to receive the Floor Broker Trading Permit and FB SPX and VIX Trading Surcharges fees rebates under Program As noted above, the ADV Discount is designed to encourage the execution of Customer orders in all classes via open outcry, which may increase volume, which would benefit all market participants (including Floor Brokers who do not hit the ADV thresholds) trading via open outcry, and TPHs that meet the applicable ADV thresholds and thus qualify for the 15% or 25% rebate are active participants on the Exchange's trading floor. Thus, the Exchange believes that it is consistent with the purpose of the discount program to extend its benefits to the FB SPX Surcharge and FB VIX Surcharge, as these surcharges represent part of the overall fees assessed to Floor Broker TPHs in connection with their floor-based trading activity.

The Exchange does not believe the proposed changes to adopt two stipends to assist with the cost of floor jackets will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Both stipends will be provided to all active floor badge holders on a uniform basis. Further, floor participants who receive their badge after a scheduled issuance date will receive both stipends upon badge activation and will thereafter follow the established issuance schedule for subsequent stipends, ensuring that all floor participants are treated similarly.

The Exchange does not believe that the proposed floor fee changes will impose an unnecessary or inappropriate burden on intermarket competition because they only apply to Cboe

Options. To the extent that the changes prove attractive to market participants on other options exchanges, or its results prove attractive to market participants on other exchanges, such market participants may elect to become Floor Brokers or market participants at the Exchange.

Excessive CIC Fee Change

The Exchange does not believe that the proposed rule change to adopt the Excessive CIC Fee will impose any burden on intramarket competition that is not necessary in furtherance of the purposes of the Act because such fees will apply equally to all similarly situated TPHs. Particularly, the proposed Excessive CIC Fee applies uniformly to all TPH, in that any TPH who exceeds the thresholds will be subject to a fee under the proposed corresponding tiers. The Exchange believes that the proposed change neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition. Rather, the proposal seeks to reduce incentives for market participants to rest speculative SPXW complex orders in the COB. The Exchange expects such a reduction in non-bona fide order activity would decrease the total number of complex instruments the Exchange's matching engines must track and process, enhancing overall system performance. Such improved system efficiency benefits all market participants through more efficient order handling and reduced latency. Accordingly, the Exchange believes that the proposed Excessive CIC Fee does not favor certain categories of market participants in a manner that would impose a burden on competition.

Finally, the Exchange believes the proposed rule change to adopt the Excessive CIC Fee does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change applies only to a product exclusively listed on the Exchange. As noted above, the Exchange is limiting this to the offending behavior and to the specific asset class effected. The fee is not intended to raise revenue for the Exchange; rather, it is intended to encourage efficient behavior so that TPHs do not exhaust System resources. The Exchange, along with other exchanges, have adopted various fee programs intended to disincentivize trading behaviors that may exhaust

system resources, bandwidth, and capacity.²⁹

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³⁰ and paragraph (f) of Rule 19b-4³¹ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or

²⁹ See, e.g., Exchange Fees Schedule, "SPXW Excessive Mass Cancellations and Purge Charges." See also Securities Exchange Act Release No. 60102 (June 11, 2009), 74 FR 29251 (June 19, 2009) (SR-NYSEArca-2009-50) (adopting fees applicable to Members based on the number of orders entered compared to the number of executions received in a calendar month). It appears that Nasdaq assesses a penalty charge to its members that exceed certain "weighted order-to-trade ratios". See *Price List—Trading Connectivity*, NASDAQ, available at <https://www.nasdaqtrader.com/trader.aspx?id=pricelisttrading2>; and Securities Exchange Act Release No. 91406 (March 25, 2021), 86 FR 16795 (March 31, 2023) (SR-EMERALD-2021-10) (adopting an "Excessive Quoting Fee" to ensure that Market Makers do not over utilize the exchange's System by sending messages to the MIAAX Emerald, to the detriment of all other Members of the exchange); and Securities Exchange Act Release No. 97262 (March 29, 2023), 88 FR 22509 (April 13, 2023) (SR-ChoeEDGX-2023-023) (adopting fees applicable to Market Makers based on the number of orders (including modification messages) entered compared to the number of orders traded in a calendar month).

³⁰ 15 U.S.C. 78s(b)(3)(A).

³¹ 17 CFR 240.19b-4(f).

- Send an email to rule-comments@sec.gov. Please include file number SR-CBOE-2026-052 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CBOE-2026-052. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CBOE-2026-052 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12034 Filed 6-15-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105671; File No. SR-MRX-2026-28]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Rename "Outcome-Related Options" as "Nasdaq Event Options"

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on June 8, 2026, Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is

³² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the name of its Outcome-Related Options or "OROs."

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/mrx/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

MRX received approval to list and trade standardized, cash-settled, European-style binary options on broad-based security indexes referred to as Outcome-Related Options or "OROs."³ Specifically, the Exchange received approval⁴ to list and trade OROs on the Nasdaq-100[®] Index⁵ and on the Nasdaq-

100 Micro Index[®].⁶ The Exchange has not yet listed these products.

At this time, the Exchange proposes to rename "Outcome-Related Options" or "OROs" as "Nasdaq Event Options" throughout Options 3B. The name change is a non-substantive amendment.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁸ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange's proposal to rename "Outcome-Related Options" or "OROs" as "Nasdaq Event Options" throughout Options 3B is consistent with the Act as the proposed amendment is non-substantive.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange's proposal to rename Outcome-Related Options or OROs as Nasdaq Event Options does not impose an undue burden on intra-market or inter-market competition because the proposed amendment is non-substantive.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section

19(b)(3)(A) of the Act⁹ and Rule 19b-4(f)(6) thereunder.¹⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MRX-2026-28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-MRX-2026-28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-MRX-2026-28 and

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³ See Securities Exchange Act Release No. 105342 (April 30, 2026), 91 FR 24299 (May 5, 2026) (SR-MRX-2026-05).

⁴ See *id.*

⁵ The Nasdaq-100 Index ("NDX") is a modified market capitalization-weighted index that includes 100 of the largest non-financial companies listed on The Nasdaq Stock Market LLC, based on market capitalization. It does not contain securities of financial companies, including investment companies. Security types generally eligible for the Nasdaq-100 Index include common stocks, ordinary shares, American Depositary Receipts, and tracking stocks. Security or company types not included in the Nasdaq-100 Index are closed-end funds, convertible debentures, exchange traded funds, limited liability companies, limited partnership interests, preferred stocks, rights, shares or units of beneficial interest, warrants, units and other derivative securities. A description of the Nasdaq-100 Index is available on Nasdaq's website at https://indexes.nasdaqomx.com/docs/methodology_NDX.pdf. The Nasdaq-100 Index is a broad-based index, as defined in Options 4A, Section 3. See also: https://www.nasdaq.com/NDX-NDXP_Factsheet.

⁶ The Nasdaq-100 Micro Index or XND is designed to reflect 1/100th the value of the Nasdaq-100 Index. See https://www.nasdaq.com/docs/2023/08/14/XND_FactSheet.pdf.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026–12036 Filed 6–15–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105659; File No. SR–NYSEARCA–2026–62]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Partial Cabinet Solution Bundles

June 11, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on June 1, 2026, NYSE Arca, Inc. (“NYSE Arca” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. The description of the Partial Cabinet Solution bundles and related fees in the Connectivity Fee Schedule (“Fee Schedule”) would be updated accordingly. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. Specifically, the Exchange proposes to delete the current 1 kW Partial Cabinet Solution (“PCS”) bundle and change the fee charged for the 2 kW PCS bundle. The description of the PCS bundles and related fees in the Fee Schedule would be updated accordingly.

The Exchange expects that the proposed rule change would become operative no later than October 31, 2026. The Exchange will announce the date through a customer notice.

Background

Currently, there are two PCS bundles available to Users,⁴ each of which includes a partial cabinet; access to the Liquidity Center Network (“LCN”) and internet protocol (“IP”) network, the local area networks available in the data center; two NMS network⁵ connections, two fiber cross connections; and connectivity to one of two time feeds.⁶ Option A has a 1 kW partial cabinet, and Option B has a 2 kW partial cabinet. In addition to other requirements, a

User and its Affiliates⁷ must have an Aggregate Cabinet Footprint⁸ of 2 kW or less to qualify for either Option A or Option B.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.⁹ That has not changed. But as hardware and other infrastructure has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may find the 1 kW PCS bundle inadequate to meet their needs.

At the same time, the monthly recurring fees that Users pay for IP and LCN ports (also referred to as “connections” and “network access”) increased¹⁰ but the fees for the 2 kW PCS bundle did not.

Proposed Changes

The Exchange proposes to make the following changes. First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle and therefore proposes to delete it from the Fee Schedule as obsolete.

Second, the Exchange proposes to change the monthly recurring charge for the 2 kW PCS bundle. With this proposal, the Exchange proposes to increase the monthly recurring fees by 10.0% (the initial charge would not change). Because it would be the only PCS bundle that remained, the Exchange also proposes to delete “Option B”.

To implement the changes, the Exchange would amend the Fee Schedule as follows (proposed deletions bracketed, proposed addition italicized):

¹¹ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ For purposes of the Exchange’s colocation services, a “User” means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the New York Stock Exchange LLC, NYSE American LLC, NYSE National, Inc. and NYSE Texas, Inc.

(together, the “Affiliate SROs”). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the change described herein.

⁵ The NMS Network is an alternate dedicated network connection that Users use to access the NMS feeds for which the Securities Industry Automation Corporation is engaged as the securities information processor. See Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19).

⁶ See Securities Exchange Act Release No. 97749 (June 16, 2023), 88 FR 41164 (June 23, 2023) (SR–NYSEArca–2023–42).

⁷ An “Affiliate” of a User is any other User or Hosted Customer that is under 50% or greater common ownership or control of the first User. See Schedule, p. 1.

⁸ The “Aggregate Cabinet Footprint” of a User is the total kW of the User’s cabinets, including both partial and dedicated cabinets. Fee Schedule, p. 1.

⁹ See Securities Exchange Act No. 77070 (February 5, 2016), 81 FR 7401 (February 11, 2016) (SR–NYSEArca–2015–102).

¹⁰ See Securities Exchange Act No. 104063 (September 25, 2025), 90 FR 47038 (September 30, 2025) (SR–NYSEArca–2025–71) (increasing the monthly recurring fees for IP and LCN ports by between 9.1% and 11.1%) (the “2025 Price Change”).

Type of service	Description	Amount of charge
Partial Cabinet Solution bundles	[Option A: 1 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol]. [Option B: 2 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.	[10,000 initial charge per bundle plus \$14,000 monthly charge per bundle]. \$10,000 initial charge per bundle plus \$[15,000]16,500 monthly charge per bundle.

Note: A User and its Affiliates are limited to one Partial Cabinet Solution bundle at a time. A User and its Affiliates must have an Aggregate Cabinet Footprint of 2 kW or less to qualify for a Partial Cabinet Solution bundle. See Note 1 under "Colocation Notes."

A purchaser of a Partial Cabinet Solution bundle must select NMS Network connections of the same size (i.e. 10 Gb or 40 Gb) as the related LCN and IP network connections.

The proposed fee increase would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity products, services, and facilities for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing colocation facility to offer customers additional space and power.¹¹

Nevertheless, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016¹² while inflation has been 15.98% since February 2016 as measured using the "Data PPI" metric described below¹³ and the monthly recurring fees that Users pay for IP and LCN ports recently increased.¹⁴

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees.

¹¹ In addition, in 2020, the Exchange began providing Users, at no additional charge, one port on the new NMS Network for each 10 Gb or 40 Gb IP Network port or LCN port that Users purchased. The Exchange did not increase the underlying IP Network or LCN port fees at the time. See note 5, *supra*.

¹² The price was originally reduced for PCS bundles for 24 months so long as the User ordered its PCS bundle by a given date. If the PCS bundle was ordered after that date, it paid the full fee. See note 9, *supra*.

¹³ See <https://fred.stlouisfed.org/series/PCU51825182#0>.

¹⁴ See 2025 Price Change, note 10, *supra*.

Continuing to operate at fees for the 2 kW PCS bundle frozen at 2016 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increase the Exchange proposes is based on an industry-specific Producer Price Index ("PPI"), which is a tailored measure of inflation.¹⁵ As a general matter, the PPI is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index ("CPI"), that measure price change from the purchaser's perspective.¹⁶ About 10,000 PPIs for individual products and groups of products are tracked and released each month.¹⁷ PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI ("Data PPI"), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor

Statistics ("BLS") as part of an ongoing effort to expand PPI coverage of the services sector of the U.S. economy and is identified as NAICS 518210 in the North American Industry Classification System.¹⁸ According to the BLS,

[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.¹⁹

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the monthly fee for the 2 kW PCS bundle because the Exchange uses its "own computer systems" and "proprietary software," i.e., its own data center, including the hardware and equipment that it uses to bring customers' orders, transactions, and other data into the data center for processing, routing, and execution. In other words, the Exchange is in the

¹⁸ NAICS appears in table 5 of the PPI Detailed Report and is available at <https://data.bls.gov/timeseries/PCU518210518210>.

¹⁹ See <https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm>.

¹⁵ See note 13, *supra*.

¹⁶ See <https://www.bls.gov/ppi/overview.htm>.

¹⁷ *Id.*

business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from February 2016 through December 2025 (the last month for which finalized data is available).²⁰ The Data PPI had a starting value of 106.6 in February 2016 and an ending value of 123.64 in December 2025, a 15.98% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 15.98% during this period. Based on that percentage change, the Exchange proposes to increase its monthly recurring fees for the 2 kW PCS bundle by 10.0%—below the Data PPI increase of 15.98%—which reflects an increase covering the entire period since the last price adjustment to these fees was made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 3.3% increase for any one calendar year period since it was introduced. The average calendar year change from 2002 to 2025 was 0.8%, with a cumulative increase of 19.7% over this period.²¹ The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar year increases averaging 2.5%, and a cumulative increase of 83.0% during the same period.²²

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increase.²³

Application and Impact of the Proposed Change

The proposed change would apply to all PCS bundles. The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally.

Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List is applied uniformly to all Users.

As no Users have the 1 kW PCS bundle, none would be impacted by its deletion. The Exchange expects to obtain no new Users as a result of changing the fees for 2 kW PCS bundles.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,²⁶ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees for the 2 kW PCS bundle do not properly reflect the quality of the services and products, as fees for the 2 kW PCS bundle have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems has increased the performance of these ports.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefited, while the Exchange's ability to recoup its investments has been hampered.

Between February 2016 and December 2025, the total inflation rate was 36.7%.²⁷ Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 15.98%. The Exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees for the 2 kW PCS bundle for more than eight years. The price change would be commensurate with the 2025 fee changes to the LCN and IP network and below the amount of the increase in the Data PPI. The proposed fee change therefore represents a modest increase from the current fees.

The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing several aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities. The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize its technology so that it may benefit its members in offering connectivity products and services.

Additional Considerations

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated

²⁰ See note 18, *supra*.

²¹ See *id.*

²² See <https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/>.

²³ See *supra* discussion of system performance advancements. Additionally, other exchanges, including the Affiliate SROs, have filed for increases in certain fees, based in part on comparisons to inflation. See, e.g., Securities Exchange Act Release Nos. 102073 (January 2, 2025), 90 FR 1558 (January 8, 2025) (SR-BOX-2024-30); 102103 (January 3, 2025), 90 FR 2045 (January 10, 2025) (SR-NASDAQ-2024-087); 104061 (September 25, 2025), 90 FR 47009 (September 30, 2025) (SR-NYSE-2025-37); 104062 (September 25, 2025), 90 FR 46950 (September 30, 2025) (SR-NYSEAmex-2025-60); 104064 (September 25, 2025), 90 FR 46960 (September 30, 2025) (SR-NYSEAT-2025-23); and 104065 (September 25, 2025), 90 FR 46966 (September 30, 2025) (SR-NYSETEX-2025-35).

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78f(b)(4).

²⁷ See note 22, *supra*.

cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be reasonable.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increase is equitably allocated and not unfairly discriminatory because it would apply to all market participants that choose to purchase the 2 kW PCS bundle from the Exchange. Any participant that chooses to purchase the 2 kW PCS bundle would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the products and services. Additionally, the fee increases would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities.

The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.²⁸

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the Fee Schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today, albeit at inflation-adjusted rates for the 2 kW PCS bundle, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the deletion of the 1 kW PCS bundle and the level of the proposed fees neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition.

Intermarket Competition. The Exchange believes that the removal of the 1 kW PCS bundle and the proposed fees for the 2 kW PCS bundle do not impose a burden on competition or on other SROs that is not necessary or appropriate.

First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle, and so no Users would be impacted by its deletion.

Second, in determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and facilities would not impose a burden on competition.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

²⁸ 15 U.S.C. 78f(b)(8).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁹ and Rule 19b-4(f)(6) thereunder.³⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³¹ and Rule 19b-4(f)(6)³² thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

²⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁰ 17 CFR 240.19b-4(f)(6).

³¹ 15 U.S.C. 78s(b)(3)(A).

³² Rule 19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2026-62 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-NYSEARCA-2026-62. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-NYSEARCA-2026-62 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12024 Filed 6-15-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105666; File No. SR-NYSEAMER-2025-72]

Self-Regulatory Organizations; NYSE American LLC; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 3, To Amend Section 1003 of the NYSE American Company Guide

June 11, 2026.

On December 3, 2025, NYSE American LLC ("NYSE American" or the "Exchange") filed with the

Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Section 1003 of the NYSE American Company Guide ("Company Guide"). The proposed rule change was published for comment in the **Federal Register** on December 17, 2025.³ On January 22, 2026, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original proposed rule change in its entirety.⁴ On January 28, 2026, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designated a longer period within which to take action on the proposed rule change.⁶

On February 25, 2026, the Exchange filed Amendment No. 2 to the proposed rule change, which superseded the original proposed rule change, as modified by Amendment No. 1, in its entirety.⁷ On March 6, 2026, the Exchange filed Amendment No. 3 to the proposed rule change, which superseded the original proposed rule change, as modified by Amendment No. 2, in its entirety.⁸ On March 17, 2026,

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 104386 (Dec. 12, 2025), 90 FR 58648. Comments received on the proposed rule change are available at: <https://www.sec.gov/rules-regulations/public-comments/sr-nyseamer-2025-72>.

⁴ In Amendment No. 1, the Exchange: (1) clarified the Exchange's authority to suspend or delist a security; (2) specified that an issuer subject to delisting under the proposal, and under Sections 1003(f)(vi) and (vii) of the Company Guide, would not be eligible to follow the procedures in Section 1009 of the Company Guide; (3) provided additional description of certain aspects of the proposal; and (4) made other technical and non-substantive changes. The full text of Amendment No. 1 can be found on the Commission's website at <https://www.sec.gov/comments/sr-nyseamer-2025-72/srnyseamer202572-696287-2176995.pdf> ("Amendment No. 1").

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 104704, 91 FR 4696 (Feb. 2, 2026). The Commission designated March 17, 2026, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁷ In Amendment No. 2, the Exchange: (1) provided additional explanation of certain aspects of the proposal; and (2) made other technical and non-substantive changes. The full text of Amendment No. 2 can be found on the Commission's website at <https://www.sec.gov/comments/sr-nyseamer-2025-72/srnyseamer202572-715787-2239694.pdf> ("Amendment No. 2").

⁸ In Amendment No. 3, the Exchange: (1) removed the proposed addition of Section 1003(b)(i)(D) of the Company Guide by which an issuer that is determined to have an average market capitalization over a consecutive 30 trading-day period of less than \$5,000,000 would be subject to immediate suspension and delisting ("Minimum Market Capitalization"); (2) removed a proposed modification to Section 1009 of the Company Guide with regard to the Minimum Market Capitalization

the Commission published notice of Amendment No. 3 and instituted proceedings under Section 19(b)(2)(B) of the Act⁹ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 3.¹⁰

Section 19(b)(2) of the Act¹¹ provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on December 17, 2025.¹² The 180th day after publication of the proposed rule change is June 15, 2026. The Commission is extending the time period for approving or disapproving the proposed rule change, as modified by Amendment No. 3, for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Amendment No. 3, so that it has sufficient time to consider the proposed rule change, as modified by Amendment No. 3, and the issues raised therein, as well as the comments received. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,¹³ designates August 14, 2026, as the date by which the Commission shall either approve or disapprove the proposed rule change, as modified by Amendment No. 3 (File No. SR-NYSEAMER-2025-72).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Vanessa A. Countryman,
Secretary.

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criteria; and (3) made other technical and nonsubstantive changes. The full text of Amendment No. 3 can be found on the Commission's website at <https://www.sec.gov/comments/sr-nyseamer-2025-72/srnyseamer202572-719747-2253335.pdf> ("Amendment No. 3").

⁹ 15 U.S.C. 78s(b)(2)(B).

¹⁰ See Securities Exchange Act Release No. 105034, 91 FR 13648 (Mar. 20, 2026).

¹¹ 15 U.S.C. 78s(b)(2).

¹² See *supra* note 3 and accompanying text.

¹³ 15 U.S.C. 78s(b)(2).

¹⁴ 17 CFR 200.30-3(a)(57).

³⁴ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105662; File No. SR–NYSENAT–2026–17]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Partial Cabinet Solution Bundles

June 11, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that on June 1, 2026, NYSE National, Inc. (“NYSE National” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. The description of the Partial Cabinet Solution bundles and related fees in the Connectivity Fee Schedule (“Fee Schedule”) would be updated accordingly. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Partial Cabinet Solution bundles offered as part of its co-location services. Specifically, the Exchange proposes to delete the current 1 kW Partial Cabinet Solution (“PCS”) bundle and change the fee charged for the 2 kW PCS bundle. The description of the PCS bundles and related fees in the Fee Schedule would be updated accordingly.

The Exchange expects that the proposed rule change would become operative no later than October 31, 2026. The Exchange will announce the date through a customer notice.

Background

Currently, there are two PCS bundles available to Users, ⁴ each of which includes a partial cabinet; access to the Liquidity Center Network (“LCN”) and internet protocol (“IP”) network, the local area networks available in the data center; two NMS network ⁵ connections, two fiber cross connections; and connectivity to one of two time feeds. ⁶ Option A has a 1 kW partial cabinet, and Option B has a 2 kW partial cabinet. In addition to other requirements, a User and its Affiliates ⁷ must have an

⁴ For purposes of the Exchange’s colocation services, a “User” means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 at n.9 (June 6, 2018) (SR–NYSENAT–2018–07). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Texas, Inc. (together, the “Affiliate SROs”). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the change described herein.

⁵ The NMS Network is an alternate dedicated network connection that Users use to access the NMS feeds for which the Securities Industry Automation Corporation is engaged as the securities information processor. See Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19).

⁶ See Securities Exchange Act Release No. 97752 (June 16, 2023), 88 FR 41134 (June 23, 2023) (SR–NYSENAT–2023–10).

⁷ An “Affiliate” of a User is any other User or Hosted Customer that is under 50% or greater common ownership or control of the first User. Fee Schedule, p 1.

Aggregate Cabinet Footprint ⁸ of 2 kW or less to qualify for either Option A or Option B.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. ⁹ That has not changed. But as hardware and other infrastructure has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may find the 1 kW PCS bundle inadequate to meet their needs.

At the same time, the monthly recurring fees that Users pay for IP and LCN ports (also referred to as “connections” and “network access”) increased ¹⁰ but the fees for the 2 kW PCS bundle did not.

Proposed Changes

The Exchange proposes to make the following changes. First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle and therefore proposes to delete it from the Fee Schedule as obsolete.

Second, the Exchange proposes to change the monthly recurring charge for the 2 kW PCS bundle. With this proposal, the Exchange proposes to increase the monthly recurring fees by 10.0% (the initial charge would not change). Because it would be the only PCS bundle that remained, the Exchange also proposes to delete “Option B”.

To implement the changes, the Exchange would amend the Fee Schedule as follows (proposed deletions bracketed, proposed addition italicized):

⁸ The “Aggregate Cabinet Footprint” of a User is the total kW of the User’s cabinets, including both partial and dedicated cabinets. Fee Schedule, p 1.

⁹ See 83 FR 26314, *supra* note 4, at 26317. See also Securities Exchange Act No. 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR–NYSE–2015–53).

¹⁰ See Securities Exchange Act No. 104064 (September 25, 2025), 90 FR 46960 (September 30, 2025) (SR–NYSENAT–2025–23) (increasing the monthly recurring fees for IP and LCN ports by between 9.1% and 11.1%) (the “2025 Price Change”).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

Type of service	Description	Amount of charge
Partial Cabinet Solution bundles	[Option A: 1 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol].	[10,000 initial charge per bundle plus \$14,000 monthly charge per bundle].
Note: A User and its Affiliates are limited to one Partial Cabinet Solution bundle at a time. A User and its Affiliates must have an Aggregate Cabinet Footprint of 2 kW or less to qualify for a Partial Cabinet Solution bundle. See Note 1 under "Colocation Notes". A purchaser of a Partial Cabinet Solution bundle must select NMS Network connections of the same size (i.e. 10 Gb or 40 Gb) as the related LCN and IP network connections.	[Option B: 2 kW partial cabinet, 1 LCN connection (10 Gb LX or 40 Gb), 1 IP network connection (10 Gb or 40 Gb), 2 NMS Network connections (10 Gb or 40 Gb each), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.	\$10,000 initial charge per bundle plus \$[15,000]16,500 monthly charge per bundle.

The proposed fee increase would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity products, services, and facilities for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing colocation facility to offer customers additional space and power.¹¹

Nevertheless, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016¹² while inflation has been 15.98% since February 2016 as measured using the "Data PPI" metric described below¹³ and the monthly recurring fees that Users pay for IP and LCN ports recently increased.¹⁴

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees.

¹¹ In addition, in 2020, the Exchange began providing Users, at no additional charge, one port on the new NMS Network for each 10 Gb or 40 Gb IP Network port or LCN port that Users purchased. The Exchange did not increase the underlying IP Network or LCN port fees at the time. See note 5, *supra*.

¹² The price was originally reduced for PCS bundles for 24 months so long as the User ordered its PCS bundle by a given date. If the PCS bundle was ordered after that date, it paid the full fee. See note 9, *supra*.

¹³ See <https://fred.stlouisfed.org/series/PCU51825182#0>.

¹⁴ See 2025 Price Change, note 10, *supra*.

Continuing to operate at fees for the 2 kW PCS bundle frozen at 2016 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increase the Exchange proposes is based on an industry-specific Producer Price Index ("PPI"), which is a tailored measure of inflation.¹⁵ As a general matter, the PPI is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index ("CPI"), that measure price change from the purchaser's perspective.¹⁶ About 10,000 PPIs for individual products and groups of products are tracked and released each month.¹⁷ PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI ("Data PPI"), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor

Statistics ("BLS") as part of an ongoing effort to expand PPI coverage of the services sector of the U.S. economy and is identified as NAICS 518210 in the North American Industry Classification System.¹⁸ According to the BLS,

[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.¹⁹

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the monthly fee for the 2 kW PCS bundle because the Exchange uses its "own computer systems" and "proprietary software," i.e., its own data center, including the hardware and equipment that it uses to bring customers' orders, transactions, and other data into the data center for processing, routing, and execution. In other words, the Exchange is in the

¹⁸ NAICS appears in table 5 of the PPI Detailed Report and is available at <https://data.bls.gov/timeseries/PCU518210518210>.

¹⁹ See <https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm>.

¹⁵ See note 13, *supra*.

¹⁶ See <https://www.bls.gov/ppi/overview.htm>.

¹⁷ *Id.*

business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from February 2016 through December 2025 (the last month for which finalized data is available).²⁰ The Data PPI had a starting value of 106.6 in February 2016 and an ending value of 123.64 in December 2025, a 15.98% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 15.98% during this period. Based on that percentage change, the Exchange proposes to increase its monthly recurring fees for the 2 kW PCS bundle by 10.0%—below the Data PPI increase of 15.98%—which reflects an increase covering the entire period since the last price adjustment to these fees was made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 3.3% increase for any one calendar year period since it was introduced. The average calendar year change from 2002 to 2025 was 0.8%, with a cumulative increase of 19.7% over this period.²¹ The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar year increases averaging 2.5%, and a cumulative increase of 83.0% during the same period.²²

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increase.²³

Application and Impact of the Proposed Change

The proposed change would apply to all PCS bundles. The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally.

Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List is applied uniformly to all Users.

As no Users have the 1 kW PCS bundle, none would be impacted by its deletion. The Exchange expects to obtain no new Users as a result of changing the fees for 2 kW PCS bundles.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,²⁶ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees for the 2 kW PCS bundle do not properly reflect the quality of the services and products, as fees for the 2 kW PCS bundle have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems

has increased the performance of these ports.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased the fees for the 2 kW PCS bundle since 2016. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefited, while the Exchange's ability to recoup its investments has been hampered.

Between February 2016 and December 2025, the total inflation rate was 36.7%.²⁷ Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 15.98%. The Exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees for the 2 kW PCS bundle for more than eight years. The price change would be commensurate with the 2025 fee changes to the LCN and IP network and below the amount of the increase in the Data PPI. The proposed fee change therefore represents a modest increase from the current fees.

The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing several aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities. The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize its technology so that it may benefit its members in offering connectivity products and services.

Additional Considerations

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space

²⁰ See note 18, *supra*.

²¹ See *id.*

²² See <https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/>.

²³ See *supra* discussion of system performance advancements. Additionally, other exchanges, including the Affiliate SROs, have filed for increases in certain fees, based in part on comparisons to inflation. See, e.g., Securities Exchange Act Release Nos. 102073 (January 2, 2025), 90 FR 1558 (January 8, 2025) (SR-BOX-2024-30); 102103 (January 3, 2025), 90 FR 2045 (January 10, 2025) (SR-NASDAQ-2024-087); 102574 (March 11, 2025), 90 FR 12439 (March 17, 2025) (SR-NYSEARCA-2025-20); 104061 (September 25, 2025), 90 FR 47009 (September 30, 2025) (SR-NYSE-2025-37); 104062 (September 25, 2025), 90 FR 46950 (September 30, 2025) (SR-NYSEAmex-2025-60); 104063 (September 25, 2025), 90 FR 47038 (September 30, 2025) (SR-NYSEArca-2025-71); 104065 (September 25, 2025), 90 FR 46966 (September 30, 2025) (SR-NYSETEX-2025-

35); and 100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR-NYSEARCA-2024-79).

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78f(b)(4).

²⁷ See note 22, *supra*.

demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be reasonable.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increase is equitably allocated and not unfairly discriminatory because it would apply to all market participants that choose to purchase the 2 kW PCS bundle from the Exchange. Any participant that chooses to purchase the 2 kW PCS bundle would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the products and services. Additionally, the fee increases would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities.

The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome. As equipment has evolved, even those with minimal demands need more power to meet the requirements of their hardware, such that even smaller Users may not find the 1 kW PCS bundle meets their needs adequately. As a consequence, there are no Users with a 1 kW PCS bundle and accordingly the Exchange believes that to delete the 1 kW PCS bundle would be equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.²⁸

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the Fee Schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today, albeit at inflation-adjusted rates for the 2 kW PCS bundle, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the deletion of the 1 kW PCS bundle and the level of the proposed fees neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition.

Intermarket Competition. The Exchange believes that the removal of the 1 kW PCS bundle and the proposed fees for the 2 kW PCS bundle do not impose a burden on competition or on other SROs that is not necessary or appropriate.

First, presumably as a result of the increased power needs of newer hardware, there are no Users with a 1 kW PCS bundle. The Exchange believes that there is no remaining User demand for the 1 kW PCS bundle, and so no Users would be impacted by its deletion.

Second, in determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and facilities would not impose a burden on competition.

For the reasons described above, the Exchange believes that the proposed rule changes reflect this competitive environment.

²⁸ 15 U.S.C. 78f(b)(8).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁹ and Rule 19b-4(f)(6) thereunder.³⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)³¹ of the Act and Rule 19b-4(f)(6)³² thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

²⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁰ 17 CFR 240.19b-4(f)(6).

³¹ 15 U.S.C. 78s(b)(3)(A).

³² Rule 19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSENAT-2026-17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSENAT-2026-17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-NYSENAT-2026-17 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12027 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105668; File No. SR-CboeBZX-2026-052]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule by Removing the Note Appended to the Member Quoting Tier and MPID Quoting Tier

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on June 1,

2026, Cboe BZX Exchange, Inc. ("Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the "Exchange" or "BZX") proposes to amend its Fee Schedule by removing the note appended to the Member Quoting Tier and MPID Quoting Tier. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/equities/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform ("BZX Equities") by removing the note appended to the Member Quoting Tier and MPID Quoting Tier. The Exchange proposes to implement these changes effective June 1, 2026.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 17 registered equities exchanges, as well

as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Securities Exchange Act of 1934 (the "Act"), to which market participants may direct their order flow. Based on publicly available information,³ no single registered equities exchange has more than 15% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a "maker-taker" model whereby it pays rebates to members that add liquidity and assesses fees to those that remove liquidity.

The Exchange's Fee Schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above \$1.00, the Exchange provides a standard rebate of \$0.00160 per share for orders that add liquidity and assesses a fee of \$0.0030 per share for orders that remove liquidity.⁴ For orders in securities priced below \$1.00, the Exchange does not provide a rebate for orders that add liquidity and assesses a fee of 0.30% of the total dollar value for orders that remove liquidity.⁵ The Exchange offers various fee codes applicable to orders that add or remove liquidity on BZX.

Under footnote 1 of the Fee Schedule, the Exchange offers various Add/Remove Volume Tiers. In particular, the Exchange offers a Member Quoting Tier and an MPID Quoting Tier that each provide an enhanced rebate for orders yielding fee code B,⁶ V⁷ and Y⁸ that satisfy certain add volume-based criteria. Additionally, the Member Quoting Tier and MPID Quoting Tier each contain a note, which provided that for May 2026, the respective tier is only available for qualification and shall utilize quoting and trading activity from May 2026 for its volume calculations. Payment for each tier shall not begin until June 2026 for those Members that satisfy the criteria during May 2026. The Exchange now proposes to remove the note appended to the Member Quoting

³ See Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (May 26, 2026), available at <https://www.cboe.com/us/equities/statistics/>.

⁴ See BZX Equities Fee Schedule, Standard Rates.

⁵ *Id.*

⁶ Fee code B is appended to displayed orders that add liquidity to BZX in Tape B securities.

⁷ Fee code V is appended to displayed orders that add liquidity to BZX in Tape A securities.

⁸ Fee code Y is appended to displayed orders that add liquidity to BZX in Tape C securities.

³⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Tier and the MPID Quoting Tier as each tier will utilize the prior month's quoting and trading activity to derive volume figures, in accordance with the General Notes section of the Fee Schedule.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4)¹² as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

The Exchange believes removing the text accompanying the Member Quoting Tier and the MPID Quoting Tier promotes just and equitable principles of trade, provides for the equitable allocation of reasonable dues, fees and other charges, and is not unfairly discriminatory because it applies to all Members equally, in that any Member seeking to achieve the criteria of the Member Quoting Tier and the MPID Quoting Tier will be utilizing quoting and trading activity from the prior month, in accordance with the General Notes section of the Fee Schedule. No Member shall be permitted to use quoting and trading activity from the current month when seeking to achieve the criteria of the Member Quoting Tier and the MPID Quoting Tier. Providing this additional clarity on the Exchange's Fee Schedule ensures that all market participants have information regarding

the quoting and trading activity being utilized to determine qualification for the Member Quoting Tier and the MPID Quoting Tier, which provides for the equitable allocation of reasonable fees among the Exchange's Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes will encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed removal of the note associated with the Member Quoting Tier and the MPID Quoting Tier is not being made for competitive reasons, but rather to appropriately define the applicable time period for which the Exchange will utilize quoting and trading activity for the tiers' volume calculations.

Next, the Exchange believes the proposed rule changes do not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 15% of the market share.¹³ Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels

at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."¹⁴ The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated as follows: "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . ."¹⁵ Accordingly, the Exchange does not believe its proposed fee changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁶ and paragraph (f) of Rule 19b-4¹⁷ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

¹⁴ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

¹⁵ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782-83 (December 9, 2008) (SR-NYSEArca-2006-21)).

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ *Id.*

¹² 15 U.S.C. 78f(b)(4).

¹³ *Supra* note 4.

investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2026-052 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CboeBZX-2026-052. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBZX-2026-052 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12033 Filed 6-15-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105664; File No. SR-CBOE-2026-050]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Market-Maker Tier Appointment Fees

June 11, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 29, 2026, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend Market-Maker tier appointment fees. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/options/regulation/rule_filings/cone/), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule.³

By way of background, Exchange Rule 5.50(g)(2) provides that the Exchange may establish one or more types of tier appointments and Exchange Rule 5.50(g)(2)(B) provides such tier appointments are subject to such fees and charges the Exchange may establish. In 2011, the Exchange established the VIX Floor Tier Appointment and adopted an initial fee of \$1,000 per Market-Maker trading permit, per month,⁴ and later increased this fee to from \$1,000 to \$2,000 per month.⁵ In 2016, the Exchange established the RUT Floor Tier Appointment and adopted an initial fee of \$1,000 per Market-Maker trading permit, per month.⁶ In 2020, the Exchange established the separate VIX and RUT Electronic Access Permit ("EAP") Tier Appointment fees, which align with the respective Floor Tier Appointment fees.⁷

Currently, these fees are assessed to any Market-Maker TPH that has the respective VIX or RUT appointment at any time during a calendar month and trades a specified number of contracts. The Exchange assesses separate Tier Appointment Fees for each type of Market-Maker Trading Permit (*i.e.*, Market-Maker Floor Permit and Market-Maker Electronic Access Permit ("EAP")). Specifically, as it relates to Market-Maker Floor Permits, the \$2,000 per month VIX Tier Appointment is assessed to any Market-Maker TPH that executes at least 1,000 contracts in VIX, and the \$1,000 per month RUT Tier Appointment is assessed to any Market-Maker TPH that executes at least 1,000 contracts in RUT; both are applied per Market-Maker Floor Permit. As it relates to Market-Maker EAP, the \$2,000 per month VIX Tier Appointment is assessed to any Market-Maker TPH that executes at least 1,000 contracts in VIX

³ The Exchange initially filed the proposed fee change, among other changes, on April 1, 2026 (SR-CBOE-2026-031). On May 29, 2026, the Exchange withdrew that filing and submitted this proposal.

⁴ See Securities Exchange Act Release No. 63706 (January 12, 2011), 76 FR 3184 (January 19, 2011) (SR-CBOE-2011-004).

⁵ See Securities Exchange Act Release No. 66277 (January 30, 2012), 77 FR 5595 (February 3, 2012) (SR-CBOE-2012-008).

⁶ See Securities Exchange Act Release No. 76923 (January 15, 2016), 81 FR 3841 (January 22, 2016) (SR-CBOE-2016-002).

⁷ See Securities Exchange Act Release No. 90333 (November 4, 2020), 85 FR 71666 (November 10, 2020) (SR-CBOE-2020-105).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁸ 17 CFR 200.30-3(a)(12).

and the \$1,000 per month RUT Tier Appointment is assessed to any Market-Maker TPH that executes at least 1,000 contracts in RUT; both are applied per TPH.

The Exchange proposes to amend the Tier Appointment Fee amounts. Specifically, the Exchange proposes to increase the VIX Tier Appointment fee to \$2,500 (for both Market-Maker Floor Permits and Market-Maker EAP) and to increase the RUT Tier Appointment Fee to \$1,500 (for both Market-Maker Floor Permits and Market-Maker EAP).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁹ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its TPHs and other persons using its facilities.

The Exchange believes its proposal to amend its Market-Maker Tier Appointment Fees for VIX and RUT is reasonable, equitable, and not unfairly discriminatory.

The Exchange believes the proposed fees are reasonable as the Exchange believes it remains commensurate with the value of operating as a Market-Maker at the Exchange.

First, in regard to the floor tier appointments, in 2022, the Exchange transitioned from its previous trading floor, which it had occupied since the 1980s, to a brand new, modern and upgraded trading floor facility. The Exchange believes customers continue to find value in open outcry trading and rely on the floor for price discovery and the deep liquidity provided by floor Market-Makers, particularly for more complicated strategies and larger-sized orders. The build out of a new modern trading floor reflects the Exchange’s commitment to open outcry trading and focus on providing the best possible trading experience for its customers, including Market-Makers. For example, the current trading floor provides a state-of-the-art environment and technology and more efficient use of physical space, which the Exchange believes better reflects and supports the current trading environment. The Exchange also believes the infrastructure provides a cost-effective, streamlined, and modernized approach to floor connectivity. For example, the new trading floor has more than 330 individual kiosks, equipped with top-of-the-line technology that enables floor participants to plug in and use their devices with greater ease and flexibility. The new trading floor provided by the Exchange also provides floor Market-Makers with more space and increased capacity to support additional floor-based traders on the trading floor. The Exchange believes the new location, which was also home to the Exchange’s original trading floor in the 1970s and early 1980s, is also able to support robust trading floor infrastructure as it currently hosts several banks, trading firms and even trading floors (*i.e.*, trading floors for the Chicago Mercantile Exchange and BOX Options Market). The Exchange also believes the relocation to the new trading floor resulted in a streamlined and simplified trading floor and facility fee structure, as further described in the Exchange’s proposal to amend certain facility fees in connection with the new trading floor.¹² The Exchange also notes that it has not sought to pass through a number of costs incurred in connection with the new trading floor, including design, construction and other on-going maintenance costs.¹³ The Exchange also

offers free coffee and beverages on the new trading floor, along with occasional breakfast events. Moreover, the Exchange has not modified many of its facilities fees in several years. The Exchange therefore believes the proposed increase to the VIX and RUT Floor Market-Maker Tier Appointment fees is reasonable because the Exchange’s investment in its new modern cutting-edge trading floor has improved the quality of the trading floor.

Additionally, the Exchange further believes the proposal to increase the fees is reasonable as the Exchange has provided further value to Market-Makers by expanding the suite of RUT and VIX products available to Market-Makers since the RUT and VIX Market-Maker Tier Appointment fees were first adopted. For example, in 2016, the Exchange began listing RUT Weekly options with Monday and Wednesday expirations;¹⁴ in 2024, the Exchange began listing RUT options that expire on Tuesday or Thursday;¹⁵ in 2024, the Exchange began listing RUT P.M.-settled options that expire on the standard third Friday-of-the-month;¹⁶ and in 2015, the Exchange began listing VIX Weekly options with Wednesday expirations.¹⁷ The introduction of these products provides Market-Makers with additional opportunities to trade RUT and VIX and greater trading flexibility as compared to when the tier appointment fees were first established. Moreover, overall average daily volume (ADV) in VIX options has increased nearly 144% from 2011, while overall average ADV in RUT options has increased nearly 5% from 2016. Further, increased ADV in VIX and RUT options provides increased trading opportunities for VIX and RUT Market-Makers which the Exchange believes is commensurate with the value of the proposed increase of the tier appointment fees.

Moreover, the Exchange also believes its proposal to increase the VIX and RUT Market-Maker Tier Appointment fees is reasonable as each respective fee amount has not been increased since the

(September 15, 2023), 88 FR 65218 (September 21, 2023) (SR-CBOE-2023-047).

¹⁴ See Securities Exchange Act Release No. 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (SR-CBOE-2015-106). See also Securities Exchange Act Release No. 78531 (August 10, 2016), 81 FR 54643 (August 16, 2016) (SR-CBOE-2016-146).

¹⁵ See Securities Exchange Act Release No. 98957 (November 15, 2023), 88 FR 81130 (November 21, 2023) (SR-CBOE-2023-054).

¹⁶ See Securities Exchange Act Release No. 101197 (September 26, 2024), 89 FR 80291 (October 2, 2024) (SR-CBOE-2024-034).

¹⁷ See Securities Exchange Act Release No. 75501 (July 21, 2015), 80 FR 44403 (July 27, 2015) (SR-CBOE-2015-050).

¹² See Securities Exchange Act Release No. 96001 (October 6, 2022), 87 FR 62129 (October 13, 2022) (SR-CBOE-2022-049).

¹³ The Exchanges notes that in 2023, the Exchange increased the SPX (and SPXW) Floor Market-Maker Tier Appointment Fee (from \$3,000 per Market-Maker Floor Trading Permit to \$5,000 per Market-Maker Floor Trading Permit). See Securities Exchange Act Release No. 98406

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

¹⁰ *Id.*

¹¹ 15 U.S.C. 78f(b)(4).

VIX fee was last changed in 2012 and the RUT fee was adopted in 2016. Particularly, since the time that the VIX Market-Maker Tier Appointment fee was last changed in 2012 and the RUT Market-Maker Tier Appointment fee was adopted in 2016, respectively, there has been notable inflation.

Indeed, the dollar has had an average inflation rate of 2.7% per year between 2012 and today, thus producing a cumulative price increase of approximately 46% inflation since 2012, when the VIX Market-Maker Tier Appointment was last changed.¹⁸ For nearly fourteen years with respect to the VIX Market-Maker Tier Appointment fee, Market-Makers were only subject to the rate that was adopted in 2012 (*i.e.*, \$2,000) notwithstanding an average inflation rate of 2.7% per year. The Exchange acknowledges its proposed fee is an increase of 25%. However, the Exchange believes such increase is reasonable given many Market-Makers for nearly 14 years did not have to pay increased fees notwithstanding yearly inflation.

The dollar has had an average inflation rate of 3.38% per year between 2016 and today, thus producing a cumulative price increase of approximately 40% inflation since 2016 when the RUT Market-Maker Tier Appointment was first adopted.¹⁹ For nearly ten years with respect to the RUT Market-Maker Tier Appointment fee, Market-Makers were only subject to the rate that was adopted in 2016 (*i.e.*, \$1,000) notwithstanding an average inflation rate of 3.38% per year. The Exchange acknowledges its proposed fee is an increase of 50%. However, the Exchange believes such increase is reasonable given many Market-Makers for nearly 10 years did not have to pay increased fees notwithstanding yearly inflation. Moreover, the Exchange historically does not increase fees every year, notwithstanding inflation. The Exchange therefore believes that proposing a fee in excess of the cumulative 40% inflation rate is still reasonable, especially when considered in conjunction with all of the additional and further rationale discussed above. The Exchange is also unaware of any standard that suggests any fee proposal that exceeds a yearly or cumulative inflation rate is unreasonable.

Further, the Exchange believes the proposed changes are equitable and not unfairly discriminatory. The increased Market-Maker Tier Appointment Fees

apply uniformly to all Market-Maker TPHs with a VIX or RUT appointment who meet the 1,000-contract execution threshold.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe the proposed changes related to the Market-Maker Tier Appointment Fees for VIX and RUT will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The increased Market-Maker Tier Appointment Fees apply uniformly to all Market-Maker TPHs with a VIX or RUT appointment who meet the 1,000-contract execution threshold. The Exchange believes the fee increases are modest and proportionate relative to the current rates and notes that it operates in a competitive environment in which Market-Maker TPHs may evaluate the costs and benefits of maintaining appointments in particular products.

The Exchange does not believe that the proposed floor fee changes will impose an unnecessary or inappropriate burden on intermarket competition because they only apply to Cboe Options. To the extent that the changes prove attractive to market participants on other options exchanges, or its results prove attractive to market participants on other exchanges, such market participants may elect to become Floor Brokers or market participants at the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act²⁰ and paragraph (f) of Rule 19b-4²¹ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CBOE-2026-050 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CBOE-2026-050. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-CBOE-2026-050 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12029 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

¹⁸ See https://www.bls.gov/data/inflation_calculator.htm.

¹⁹ See https://www.bls.gov/data/inflation_calculator.htm.

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 17 CFR 240.19b-4(f).

²² 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105657; File No. SR–NYSEARCA–2026–61]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges

June 11, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that on June 1, 2026, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (“Fee Schedule”) to modify the application of the Ratio Threshold Fee. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to modify the application of the Ratio Threshold Fee, which applies to Auction-Only Orders during

the period when auction imbalance information is being disseminated for a Core Open Auction or Closing Auction. ⁴

The Exchange proposes to implement the fee changes effective June 1, 2026.

Background

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.” ⁵

While Regulation NMS has enhanced competition, it has also fostered a “fragmented” market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that “such competition can lead to the fragmentation of order flow in that stock.” ⁶ Indeed, equity trading is currently dispersed across 17 exchanges, ⁷ numerous alternative trading systems, ⁸ and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly available information, no single exchange currently has more than 20% market share. ⁹ Therefore, no exchange possesses significant pricing power in

the execution of equity order flow. More specifically, the Exchange currently has less than 15% market share of executed volume of equities trading. ¹⁰

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, based on transaction fees and credits. Accordingly, the Exchange’s fees, including the proposed modification to the Ratio Threshold Fee, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

Proposed Rule Change

The Ratio Threshold Fee currently applies to shares of Auction-Only Orders ¹¹ during the period when Auction Imbalance information is being disseminated for a Core Open Auction or Closing Auction (“RT—Auction Fee”).

The purpose of the RT—Auction Fee is the same as it was since it was originally adopted, *e.g.*, to disincentivize the cancellation of shares close to the commencement of the Opening Auction and the Closing Auction. Under the current formula, shares cancelled nearer to the Opening Auction and the Closing Auction are weighted more heavily than those cancelled earlier. ¹² The RT—Auction Fee is currently calculated based on the number of shares cancelled by an ETP Holder. An ETP Holder is charged the fee if its average daily cancelled shares reach 500,000 shares and its Weighted Ratio Shares Threshold reaches 25. However, the current calculation produces distorted results in certain

¹⁰ See *id.*

¹¹ An Auction-Only Order is a Limit or Market Order that is to be traded only within an auction pursuant to Rule 7.35–E or routed pursuant to Rule 7.34–E. See Rule 7.31–E(c). Auction-Only Orders are orders submitted by an ETP Holder during the Early Open Auction, Core Open Auction, Closing Auction and Trading Halt Auction. See Rule 7.35–E.

¹² The current fee focuses on Auction-Only Orders because a disproportionate amount of such orders that are not executed use more system resources, including updates to the Auction Imbalance Information as such orders are entered and cancelled, than other order entry and cancellation practices of ETP Holders. Accordingly, for Auction-Only Orders, Ratio Shares would include shares of Auction-Only Orders cancelled during the period when Auction Imbalance Information is being disseminated for the Core Open Auction and Closing Auction. The proposed modification to the calculation method would maintain the same focus and is intended to disincentivize the activity noted above.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ See Securities Exchange Act Release No. 103938 (September 10, 2025), 90 FR 44442 (September 15, 2025) (SR–NYSEARCA–2025–69). The Ratio Threshold Fee was originally adopted in 2020. See Securities Exchange Act Release No. 88930 (May 21, 2020), 85 FR 32068 (May 28, 2020) (SR–NYSEARCA–2020–45). The Ratio Threshold Fee was subsequently modified in 2023. See Securities Exchange Act Release No. 97681 (June 9, 2023), 88 FR 39275 (June 15, 2023) (SR–NYSEARCA–2023–39).

⁵ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (“Regulation NMS”).

⁶ See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

⁷ See Choe U.S. Equities Market Volume Summary, available at https://markets.cboe.com/us/equities/market_share. See generally <https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html>.

⁸ See FINRA ATS Transparency Data, available at <https://otctransparency.finra.org/otctransparency/AtsIssueData>. A list of alternative trading systems registered with the Commission is available at <https://www.sec.gov/foia/docs/atlist.htm>.

⁹ See Choe Global Markets U.S. Equities Market Volume Summary, available at http://markets.cboe.com/us/equities/market_share/.

cases, as described below. To address such edge cases, the Exchange proposes to modify how the RT—Auction Fee is calculated.

More specifically, the Exchange proposes to add a second threshold: an ETP Holder would be charged a fee only if both its average daily cancelled shares and its average daily weighted cancelled shares each equal or exceed 500,000. As proposed, an ETP Holder would be charged an RT—Auction Fee if the ETP Holder has an average daily number of cancelled shares of 500,000 or more and an average daily number of weighted cancelled shares of 500,000 or more for each auction.

The current formula can produce a distorted result when an ETP Holder cancels a large number of shares but executes very few. For example, an ETP Holder that cancels 1,000,000 shares—yielding only 100 weighted shares under the formula—but executes just 1 share would have a Weighted Ratio Shares Threshold of 100, triggering the fee even though its actual market impact is minimal. The proposed dual threshold addresses this distortion by ensuring the fee applies only when both raw and weighted cancellation activity are substantial.

In revising how the RT—Auction Fee would be calculated, the Exchange also proposes to modify the definition of “Weighted Ratio Shares Threshold” to address a gap in the current formula. The current definition does not account for an ETP Holder that does not execute any shares during the billing month. Currently, the threshold is calculated by dividing an ETP Holder’s total Weighted Ratio Shares by its total executed shared, which leaves the ratio undefined when an ETP Holder executes zero shares (division by zero). To address this, the Exchange proposes to add the following sentence to the current definition: “If no shares are executed in an auction by the ETP Holder, a value of 1 will be used in the denominator.” For example, an ETP Holder with 1,000,000 Weighted Ratio Shares and 0 shares executed would have a threshold of 1,000,000 rather than an undefined value.

The Exchange’s proposed modifications are intended to more precisely target the order entry practices that impose costs on other market participants. The Exchange believes the proposed modification to the calculation of the RT—Auction Fee will continue to strengthen the Exchange’s goal of providing a more efficient marketplace and enhance the trading experience of all ETP Holders by encouraging them to more efficiently participate on the Exchange.

The purpose of the Ratio Threshold Fee is not to create revenue, but rather to provide an incentive for a small number of ETP Holders to change their order entry practices. Based on an analysis of order entry practices by ETP Holders between January 2026 and April 2026, only 4 ETP Holders would have incurred the RT—Auction Fee, as modified by this proposed rule change. The Exchange does not anticipate the proposed recalibration would subject any additional ETP Holders to the RT—Auction Fee.

The Ratio Threshold Fee is intended to encourage efficient usage of Exchange systems by ETP Holders. The Exchange believes that it is in the best interests of all ETP Holders and investors who access the Exchange to encourage efficient systems usage. Unproductive share entry and cancellation practices, such as when ETP Holders flood the market with orders that are frequently and/or rapidly cancelled, do little to support meaningful price discovery, may create investor confusion about the extent of trading interest in a security. The Exchange further believes that inefficient order entry practices of a small number of ETP Holders may place excessive burdens on Exchange systems and to the systems of other ETP Holders that are ingesting market data, while also negatively impacting the usefulness of market data feeds that transmit each order and subsequent cancellation.¹³ ETP Holders with an excessive amount of cancelled shares relative to executed shares do little to support meaningful price discovery.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁴ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,¹⁵ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly

¹³ See generally Recommendations Regarding Regulatory Responses to the Market Events of May 6, 2010, Joint CFTC—SEC Advisory Committee on Emerging Regulatory Issues, at 11 (February 18, 2011) (“The SEC and CFTC should also consider addressing the disproportionate impact that [high frequency trading] has on Exchange message traffic and market surveillance costs. . . . The Committee recognizes that there are valid reasons for algorithmic strategies to drive high cancellation rates, but we believe that this is an area that deserves further study. At a minimum, we believe that the participants of those strategies should properly absorb the externalized costs of their activity.”).

¹⁴ 15 U.S.C. 78f(b).

¹⁵ 15 U.S.C. 78f(b)(4) and (5).

discriminate between customers, issuers, brokers or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹⁶

The proposed modification to the RT—Auction Fee is reasonable for two reasons. First, it is designed to improve liquidity quality in advance of auctions for the benefit of all market participants. Second, it more precisely identifies the unproductive order entry behavior the fee was designed to target, ensuring the fee falls only on ETP Holders whose cancellation activity—measured both in raw and weighted terms—is genuinely disruptive. Any affected ETP Holder can avoid the fee by adjusting its order entry and/or cancellation practices, which would itself advance the fee’s purpose.

As a general principle, the Exchange believes that greater participation on the Exchange by ETP Holders improves market quality for all market participants. Thus, in modifying the current fee, the Exchange balanced the desire to improve market quality against the need to discourage inefficient order entry and/or cancellation practices.

The Exchange believes that the proposed change to the RT—Auction Fee is equitably allocated among its market participants because it applies equally to all similarly situated ETP Holders. Although only a small number of ETP Holders may be subject to the RT—Auction Fee based on their current trading practices, any ETP Holder could decide to change its order entry practices at any time and thus avoid the fee. The fee is therefore designed to encourage better order entry practices by all ETP Holders for the benefit of all market participants.

¹⁶ See Regulation NMS, *supra* note 5, 70 FR at 37499.

The Exchange believes that the proposed change to the RT—Auction Fee is not unfairly discriminatory. In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value and are free to transact on competitor markets to avoid being subject to the Exchange's fees that are the subject of this proposed rule change. The Exchange believes that the proposed fee changes neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because it would be applied to all similarly situated ETP Holders, who would all be subject to the fee on an equal basis. All ETP Holders would continue to be subject to the same fee structure, and access to the Exchange's market would continue to be offered on fair and non-discriminatory terms.

For the foregoing reasons, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) and (5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹⁷ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition. The Exchange believes the proposed change to the RT—Auction Fee would not place any undue burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed fee change is designed to encourage ETP Holders to submit shares into the market that are actionable. Further, the proposal would apply to all ETP Holders on an equal basis, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange. To the extent that these purposes are achieved, the Exchange believes that the proposal would serve as an incentive for ETP Holders to modify their order entry practices, thus enhancing the quality of the market and increasing the volume of orders directed to, and shares executed on, the Exchange. In turn, all the Exchange's market participants would benefit from the improved market liquidity.

Intermarket Competition. The Exchange operates in a highly

competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As noted above, the Exchange's market share of intraday trading (*i.e.*, excluding auctions) is currently less than 15%. In such an environment, the Exchange must continually review, and consider adjusting its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act,¹⁸ and Rule 19b-4(f)(2) thereunder,¹⁹ the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-

NYSEARCA-2026-61 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEARCA-2026-61. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2026-61 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12022 Filed 6-15-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105670; File No. SR-NYSEARCA-2026-60]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To amend Rule 7.35-E

June 11, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 ("Act") ² and Rule 19b-4 thereunder,³ notice is hereby given that on May 29, 2026, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

¹⁷ 15 U.S.C. 78f(b)(8).

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁹ 17 CFR 240.19b-4.

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.35–E (Auctions) to introduce an option for an exchange-traded products (“ETP”) eligible to participate in an initial public offering (“IPO”) auction to elect to commence trading in the NYSE Arca Early Trading Session. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.35–E(f) to provide an option for an “ETP IPO Security” as defined therein to commence trading in the Early Trading Session. The proposal is substantively identical to Cboe BZX Exchange, Inc. (“Cboe BZX”) functionality that allows similarly defined ETP IPO Securities the option to commence trading at 4:00 a.m. Eastern Time (“ET”) or in the IPO Auction at 9:30 a.m. ET on the first day of trading.⁴

⁴ See Cboe BZX Rule 11.23(a)(24) & 11.23(d)(2)(E)(i)(a). See Securities Exchange Act Release No. 104037 (Sept. 29, 2025), 90 FR 46690 (Sept. 29, 2025) (SR–CboeBZX–2025–130) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.23 To Introduce an Option for an Exchange-Traded Product (“ETP”) Eligible To Participate in an Initial Public Offering (“IPO”) Auction To Elect to Commence Trading in the BZX Early Trading Session) (“Cboe BZX Notice”). Nasdaq Stock Market LLC (“Nasdaq”) also offers substantially similar functionality. See Nasdaq Rule 4120; see generally Securities Exchange Act Release No. 103085 (May 20, 2025), 90 FR 22424 (May 27, 2025) (SR–Nasdaq–2025–011) (Notice of Filing of Amendment No. 1, and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Introduce Functionality To Initiate a Trading Halt

Given the current competitive landscape, the Exchange respectfully requests that the Commission waive the five business day notice of the Exchange’s intent to file this proposed rule change as well as the 30-day operative delay, so that the proposed rule change may become effective and operative upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act⁵ and paragraph (f)(6) of Rule 19b–4 thereunder.⁶

Background and Proposed Rule Change

Currently, IPO Auctions for any security, including Derivative Securities Products,⁷ for which NYSE Arca is the primary listing market, excluding transfers, commence trading at the start of the Core Trading Session, which begins for each security at 9:30 a.m. ET.⁸ IPO Auctions follow the processing rules of a Core Open Auction subject to Rule 7.35(f).

The Exchange proposes to provide that an ETP IPO Security, defined as a Derivative Securities Product that is eligible to participate in an IPO Auction pursuant Rule 7.35–E(f), may elect to begin trading in the Early Trading Session, which begins at 4:00 a.m. ET,⁹ as an alternative to the IPO Auction. As proposed, an ETP IPO Security that elects to commence trading during the Early Trading Session would follow the processing rules of an Early Open Auction set forth in Rule 7.35–E(b).

To effectuate these changes, the Exchange would add the following text to Rule 7.35–E(f):

An “ETP IPO Security” as defined herein may elect to commence trading in the Early Trading Session. An ETP IPO Security that elects to commence trading during the Early Trading Session will follow the processing rules of an Early Open Auction. An “ETP IPO Security” means a Derivative Securities Product that is eligible to participate in an IPO Auction pursuant to this Rule.

The proposed rule text is substantially the same as Cboe BZX Rule 11.23(a)(24) and Rule 11.23(d)(2)(E)(i)(a).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹¹ in particular, in that it is

for Exchange-Traded Products on Launch Day) (“Nasdaq Approval Order”).

⁵ 15 U.S.C. 78s(b)(3)(A).

⁶ 17 CFR 240.19b–4(f)(6).

⁷ Rule 1 defines “Derivative Securities Product” as a security that meets the definition of “derivative securities product” in Rule 19b–4(e) under the Act.

⁸ See Rule 7.34–E(a)(2).

⁹ See Rule 7.34–E(a)(1).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest by strengthening the Exchange’s ability to oversee and police its marketplace. In addition, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.¹²

The Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and national market system and will benefit investors by providing market participants with additional opportunities to source and access liquidity for their orders in new issue ETPs on the Exchange. The proposed option to permit issuers to begin trading an ETP IPO Security during the Early Trading Session would provide for earlier trading opportunities in highly anticipated new issue ETPs, functionality that is already in place on other marketplaces.¹³ The Exchange believes that the issuer is best situated to determine whether to commence trading in its ETP IPO Security during the Early Trading Session or pursuant to the IPO Auction.

The proposed amendments will have no impact on the operation of trading in the Early Trading Session and would simply allow for an ETP IPO Security to begin trading on the Exchange at 4 a.m. ET at the issuer’s option in the same manner that an ETP transferred from another securities exchange begins trading on the Exchange. The Exchange believes that amending its rules to extend trading hours for ETP IPO Securities will benefit investors in that they will now be able to trade ETP IPO Securities earlier in the day on the Exchange in the same manner as currently available on other marketplaces, thereby providing additional access to liquidity in securities that an ETP issuer deems appropriate for trading in the Early Trading Session. The Exchange also believes that offering the IPO Auction as a default for ETP IPO Securities with the option to participate in the Early Trading Session will allow issuers an

¹² 15 U.S.C. 78f(b)(5).

¹³ See note 4, *supra*.

alternative option if such issuer is concerned about unexpected volatility in ETP pricing during the Early Trading Session.¹⁴

The Exchange believes that proposed rule changes raise no novel issues as the proposed rules are consistent with early trading for ETPs already in place under the rules of other exchanges.¹⁵

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the Exchange does not believe that the proposed rule change will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of purposes of the Act because all ETP IPO Securities may commence trading in the Exchange's Early Trading Session if requested by the issuer. The Exchange also does not believe that the proposed rule change will impose any burden on intermarket competition but instead may promote competition because the proposed early trading hours for ETP IPO Securities are identical to those on Cboe and Nasdaq.¹⁶ Market participants are free to trade on the Exchange if they determine that this proposed rule change has made the Exchange a more attractive or favorable venue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act¹⁷ and Rule 19b-4(f)(6)¹⁸ thereunder, the Exchange has designated this proposal as one that effects a change that: (i) does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate

if consistent with the protection of investors and the public interest.¹⁹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)²⁰ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal can become effective upon filing. The Exchange states that the proposal would benefit ETP issuers by providing similar flexibility and an additional source of liquidity for ETP IPO securities on an exchange. Further, the Exchange states that the proposal will provide the same treatment of ETP IPOs as allowed on other exchanges. For these reasons, and because the proposal does not raise any novel legal or regulatory issues, the Commission finds that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.²¹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or

¹⁹ In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange requested waiver of the five-day pre-filing requirement for this proposal for the reasons stated in its filing, which the Commission hereby grants.

²⁰ 17 CFR 240.19b-4(f)(6)(iii).

²¹ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2026-60 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEARCA-2026-60. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2026-60 and should be submitted on or before July 7, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2026-12035 Filed 6-15-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, June 18, 2026.

PLACE: The meeting will be held via remote means and at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the

¹⁴ See Cboe BZX Notice, 90 FR at 46691 (citing Nasdaq Approval Order, 90 FR at 24430).

¹⁵ See note 4, *supra*.

¹⁶ See *id.*

¹⁷ 15 U.S.C. 78s(b)(3)(A).

¹⁸ 17 CFR 240.19b-4(f)(6).

²² 17 CFR 200.30-3(a)(12), (59).

meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

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

Dated: June 12, 2026.

Stephanie J. Fouse,

Assistant Secretary.

[FR Doc. 2026-12098 Filed 6-12-26; 4:15 pm]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 13042]

Notice of Determinations; Culturally Significant Object Being Imported for Scientific Research and Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary scientific research and display at the J. Paul Getty Museum at the Getty Center, Los Angeles, California, and in the exhibition "Faces of Fame: Inventing Celebrity in Europe, 1750-1800" at the National Gallery of Art, Washington, District of Columbia; the J. Paul Getty Museum at the Getty Center; and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary scientific research and exhibition or display within the United States as aforementioned is in the national interest. I have ordered that

Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA-5), Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Sherry C. Keneson-Hall,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2026-12049 Filed 6-15-26; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 13044]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: "Photography's First Century: Masterworks from the Bibliothèque nationale de France" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition "Photography's First Century: Masterworks from the Bibliothèque nationale de France" at the Kimbell Art Museum, Fort Worth, Texas, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov)

state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW, (SA-5), Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Sherry C. Keneson-Hall,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2026-12082 Filed 6-15-26; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 13045]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: "Will These Words Reach You? The Underground Archive of the Warsaw Ghetto" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition "Will These Words Reach You? The Underground Archive of the Warsaw Ghetto" at the Museum of Jewish Heritage, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA-5), Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me

by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Sherry C. Keneson-Hall,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2026–12095 Filed 6–15–26; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 13043]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Nguni: Migrant Nations of Southeast Africa” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition “Nguni: Migrant Nations of Southeast Africa” at the Yale University Art Gallery, New Haven, Connecticut, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/DP, 2200 C Street NW, (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of

Authority No. 523 of December 22, 2021.

Sherry C. Keneson-Hall,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2026–12081 Filed 6–15–26; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 13046]

Notice of Charter Renewal for the Cultural Property Advisory Committee

AGENCY: Department of State.

ACTION: Charter renewal for the Cultural Property Advisory Committee; notice.

The Department of State has renewed the Charter of the Cultural Property Advisory Committee. The Committee was established by the Convention on Cultural Property Implementation Act of 1983, 19 U.S.C. 2601 *et seq.*, to provide recommendations regarding requests for assistance from foreign governments under the 1970 Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property. The Presidentially appointed members include individuals representing the interests of museums; experts in the fields of archaeology, anthropology, or related areas; experts in the international sale of archaeological, ethnological, and other cultural property; and individuals who represent the interests of the general public. The renewed Charter was filed with Congress on April 29, 2026.

FOR FURTHER INFORMATION CONTACT:

Cultural Heritage Center, U.S. Department of State, Bureau of Educational and Cultural Affairs, 2200 C Street NW, Washington, DC 20522. Telephone: (771) 204–6071; Email: culprop@state.gov.

Authority: 5 U.S.C. 1001 *et seq.*; 19 U.S.C. 2601 *et seq.*

Andrew L. Zonderman,

Designated Federal Officer, Cultural Property Advisory Committee, Bureau of Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 2026–12080 Filed 6–15–26; 8:45 am]

BILLING CODE 4710–26–P

DEPARTMENT OF STATE

[Public Notice: 13041]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Krasner and Pollock: Past Continuous” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition “Krasner and Pollock: Past Continuous” at The Metropolitan Museum of Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/DP, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Sherry C. Keneson-Hall,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2026–12115 Filed 6–15–26; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36938]

Delaware and South Branch Railroad, LLC—Lease and Change of Operator Exemption—Black River & Western Corp. d/b/a Black River & Western Railroad, and Belvidere & Delaware River Railway Company, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice; correction.

SUMMARY: The Surface Transportation Board published a document in the **Federal Register** of June 12, 2026, concerning a notice of exemption filed by Delaware and South Branch Railroad, LLC (DSBR). The document included an inadvertent blank footnote.

SUPPLEMENTARY INFORMATION:**Correction**

In the **Federal Register** of June 12, 2026, in FR Doc. 2026–11833, page 35782, in the second column, strike the footnote.

Dated: June 12, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Jeffrey Herzig,
Clearance Clerk.

[FR Doc. 2026–12047 Filed 6–15–26; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Docket No.: FAA–2025–2167; Summary Notice No. –2026–15]

Petition for Exemption; Summary of Petition Received; Amor Fati Industries Corp

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before July 6, 2026.

ADDRESSES: Send comments identified by docket number FAA–2025–2167 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

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

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Liam Andrews, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, at 202–267–8181.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan A. Ngo,

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2025–2167.

Petitioner: Amor Fati Industries Corp. d/b/a Seneca.

Section(s) of 14 CFR Affected:

§§ 61.3(a)(1)(i), 61.3(c)(1), 61.23(a)(2), 91.7(a), 91.119(c), 91.121, 91.151(b), 91.209(a)(1), 91.403(b), 91.405(a), 91.407(a)(1), 91.409(a)(1), 91.409(a)(2), 91.417(a), 91.417(b), 137.19(c), 137.19(d), 137.19(e)(2)(ii),

137.19(e)(2)(iii), 137.19(e)(2)(v), 137.31(a), 137.31(b), 137.33(a), 137.33(b), 137.41(c), and 137.42.

Description of Relief Sought: Amor Fati Industries Corp. d/b/a/Seneca (Seneca) is seeking to amend existing Grant of Exemption No. 25122 which provides relief necessary to enable Part 137 fire management and suppression operations with the Seneca Argo-1 unmanned aircraft system (UAS). The proposed amendments would allow for the operation of the Argo-3 UAS, which is a modified version of the Argo-1 UA with a maximum takeoff weight of 450 pounds, and to allow for the operation of up to five UAS simultaneously by a single pilot-in-command and enable Seneca beyond visual line of sight (BVLOS) operations without visual observers and without requiring the pilot in command to maintain visual line of sight, using shielding mitigations and ADS–B In.

[FR Doc. 2026–12042 Filed 6–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

[Docket No. VA–2025–VACO–0001]

Privacy Act of 1974; System of Records

AGENCY: Office of Inspector General (OIG), Department of Veterans Affairs (VA).

ACTION: Notice of a modified system of records.

SUMMARY: As required by the Privacy Act of 1974, notice is hereby given that VA is modifying the system of records titled “Inspector General Hotline (Complaint Center) Records” (66VA53). This system is used to store records and information related to official complaints made to the OIG about impropriety and wrongdoing related to VA programs and operations.

DATES: Comments on this modified system of records must be received no later than 30 days after publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through www.regulations.gov

under docket number VA–2025–VACO–0001 or mailed to VA Privacy Service (005X6F), 810 Vermont Avenue NW, Washington, DC 20420. Comments should indicate that they are submitted in response to “Inspector General Hotline (Complaint Center) Records” (66VA53). Comments received will be available at www.regulations.gov for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Chris Wilber, Counselor to the Inspector General (50C), Office of Inspector General, Chris.Wilber@va.gov.

SUPPLEMENTARY INFORMATION: OIG has reviewed its system of records notices and has determined its record system, “Inspector General Hotline (Complaint Center) Records” (66VA53), should be amended to reflect evolving technology and procedures, to conform to current practice, and to reflect current authorities. VA is amending the system of records by revising the Security Classification, Routine Uses, Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records, Retention and Disposal, Record Access Procedures, and Contesting Record Procedures.

The Security Classification is being updated to state “Unclassified”. Routine Uses 1–10 are being updated in accordance with OMB recommendations.

The Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records within the system are being modified to state current practices and systems.

The Retention and Disposal section is being amended to include “Records Control Schedule DAA–0015-2013-0004”.

The Record Access Procedures section is being amended to state that record access should be requested from the system manager and requests should include proof of identity and a sufficient description of the records sought.

The Contesting Record Procedures section is being amended to state that requests to contest or amend records should be directed to the system manager, should specify what is being contested, and that most records in this system are exempt from relevant portions of the Privacy Act.

The Report of Intent to Amend a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Signing Authority: The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Eddie Pool, Assistant Secretary for Information and Technology and Chief Information Officer, Department of Veterans Affairs approved this document on September 25, 2025 for publication.

Dated: June 11, 2026.

Saurav Devkota,

Government Information Specialist, VA Privacy Service, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME AND NUMBER:

“Inspector General Hotline (Complaint Center) Records” (66VA53).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Department of Veterans Affairs (VA), Office of Inspector General (OIG), Office of Assistant Inspector General for Management and Administration (53), 810 Vermont Avenue NW, Washington, DC 20420.

SYSTEM MANAGER(S):

Assistant Inspector General for Management and Administration (53), Department of Veterans Affairs, Office of Inspector General, 810 Vermont Avenue NW, Washington, DC 20420.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law (Pub. L.) 95–452, as amended; 5 U.S.C. 401, *et. seq.*

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to compile and store records and information related to official complaints made to the VA OIG. The Hotline Division is the OIG’s complaint center and serves as the recipient of all types of complaints about impropriety and wrongdoing related to VA programs and operations. The specific information about each complaint, including name of complainant, name of subject, and allegations of improper conduct, is recorded and then forwarded to the appropriate VA OIG division or external entity for investigation, review, or resolution. The information is also used to provide prompt, responsive, and accurate information regarding the status of Hotline complaints and to provide a record of complaint disposition and statistical information about complaints.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The following categories of individuals will be covered by the system: Individuals who are subjects of complaints, complainants, and witnesses. Subjects, complainants, and witnesses may be VA employees or third parties (e.g., a veteran, VA beneficiary, contractor, or private citizen). Subjects are those alleged to have engaged in wrongdoing or impropriety, criminal, civil, or administrative, either in performance of their official VA duties or related to the programs and operations of VA. Subjects include those identified during the investigation of a complaint. The allegations are made to the OIG Hotline by complainants or developed by the OIG based on complaints. Complainants are individuals who have reported the possible existence of an activity constituting a violation of law, rule, regulation, or mismanagement, gross waste of funds, abuse of authority or a substantial and specific danger to the public health and safety. Complaints may also be made anonymously. Witnesses are individuals who have witnessed or may have information regarding the possible existence of an activity constituting a violation of law, rule, regulation, or mismanagement, gross waste of funds, abuse of authority or a substantial and specific danger to the public health and safety.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records and information in this system include (1) the name, home and work address, email address, and home, work and cellular phone numbers of the complainant and witnesses; (2) the name, title, date of birth, Social Security Number and home and work address of the subject of the complaint; and (3) the location and nature of the alleged wrongdoing. The records maintained in this system may also include: (1) documentation and other evidence from the complainant and witnesses; (2) correspondence between the VA OIG Office of Management and Administration (53) and other components of the Office of Inspector General, agency departments, and the complainant and witnesses; and (3) reports based on the investigation of the allegations.

RECORD SOURCE CATEGORIES:

Information is obtained from VA employees, third parties (e.g., a veteran, VA beneficiary, VA contractor, or private party), the Government Accountability Office, VA records, Congressional, Federal, state, and local offices, or agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. *Congress*: To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. *Data Breach Response and Remediation, for VA*: To appropriate agencies, entities, and persons when (a) VA suspects or has confirmed that there has been a breach of the system of records, (b) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

3. *Data Breach Response and Remediation, for Another Federal Agency*: To another Federal agency or Federal entity, when VA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

4. *Law Enforcement Authorities, for Reporting Violations of Law*: To a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting a violation or potential violation of law, whether civil, criminal, or regulatory in nature, or charged with enforcing or implementing such law, provided that the disclosure is limited to information that, either alone or in conjunction with other information, indicates such a violation or potential violation. A disclosure of information about veterans or their dependents from VA claims files under this routine use must also comply with the requirements of 38 U.S.C. 5701(f).

5. *Department of Justice (DoJ), Litigation, Administrative Proceeding*: To the DoJ, or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when any of the following is a party to such proceedings

or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings:

- a. VA or any component thereof;
- b. Any VA employee in their official capacity;
- c. Any VA employee in their individual capacity where DoJ has agreed to represent the employee; or
- d. The United States, where VA determines that litigation is likely to affect the agency or any of its components.

6. *Contractors*: To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

7. *Equal Employment Opportunity Commission (EEOC)*: To the EEOC in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

8. *Federal Labor Relations Authority (FLRA)*: To the FLRA in connection with the investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised, matters before the Federal Service Impasses Panel, and the investigation of representation petitions and the conduct or supervision of representation elections.

9. *Merit Systems Protection Board (MSPB)*: To the MSPB, or the Office of Special Counsel, in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

10. *National Archives and Records Administration (NARA)*: To NARA in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

11. *Background Investigations*: To another Federal, state, or local agency maintaining civil or criminal violation records or other pertinent information such as prior employment history, prior Federal employment background investigations, and/or personal or educational background in order for VA to obtain information relevant to the

hiring, transfer, or retention of an employee, the letting of a contract, the granting of a security clearance, or the issuance of a grant or other benefit. The name and address of a veteran may be disclosed to a Federal agency, but not a state, or local agency, under this routine use if this information has been requested by the Federal agency to enable it respond to the VA inquiry.

12. *Federal Agencies, Courts, Litigants, for Litigation or Administrative Proceedings*: To another Federal agency, court, or party engaged in or in anticipation of litigation before a court or in an administrative proceeding conducted by a Federal agency, when the government is a party to the judicial or administrative proceeding. Any information in this system of records may be disclosed, in the course of presenting evidence to a court, magistrate, administrative tribunal, or grand jury, including disclosures to opposing counsel in the course of such proceedings or in settlement negotiations.

13. *Law Enforcement, for Locating Fugitives*: To any Federal, state, local, territorial, tribal, or foreign law enforcement agency in order to identify, locate, or report a known fugitive felon, in compliance with 38 U.S.C. 5313B(d).

14. *Sources*: To any source or person, either private or governmental, to the extent necessary to secure from such source or person information relevant to, and sought in furtherance of, an investigation, review, or inspection.

15. *State Licensing Boards, Professional Disciplinary Boards*: To Federal, state, or local professional, regulatory, or disciplinary organizations or associations, including but not limited to bar associations, state licensing boards, and similar professional entities, for use in disciplinary proceedings and inquiries preparatory thereto, where VA determines that there is good cause to question the legality or ethical propriety of the conduct of a person employed by VA or a person representing a person in a matter before VA. The name and address of a veteran may be disclosed to a Federal agency under this routine use if this information has been requested by the Federal agency to enable it to respond to the VA inquiry.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records and information are stored electronically in the VA OIG's Enterprise Management System or legacy Master Case Index databases and servers in the office of the VA OIG's Information Technology Division, VA Central Office. Backup records are

stored on electronic media, or on cloud storage, and some files may also be retained in hard copy format in secure file folders. The VA OIG Hotline Division and Office of Investigations are responsible for electronically inputting records and information received from complainants, referrals and correspondence related to the initiation of a case, and final reports. Information input electronically includes all correspondence to and from complainants, correspondence (including email messages) to and among VA OIG organizational elements about complaints, and correspondence to and from any VA component to which a case was referred. Complaints and information about VA employees, including all investigative reports and work papers, are maintained in electronic files with restricted access limited to those with a need to know for their official duties, including personnel in the VA OIG Office of Investigations, VA OIG Human Resources Management Division, VA OIG attorneys, and VA OIG management officials responsible for supervising any VA OIG employee who is the subject of an internal investigation.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the case numbers. In addition, electronic records may be retrieved by the names of the complainants and names of the subjects of the complaints, retrieved by such person's title, or by their Social Security number, if entered. Scanned documents, reports and other uploaded information that are made part of the file cannot be searched or retrieved from the databases as part of a general search. Hard copy paper files are retrieved by the case number only.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are retained and disposed of in accordance with the schedule approved by the Archivist of the United States, Records Control Schedule DAA-0015-2013-0004.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Information in the system is protected from unauthorized access through administrative, physical, and technical safeguards. Administrative safeguards include restricted access to the hard copy and computerized information to authorized OIG personnel on a need-to-know basis. Physical safeguards include the maintenance of hard copy records in offices that are restricted during work hours or are locked after duty hours. Additionally, the headquarters building

is protected by security guards and access is restricted during non-duty hours. Technical safeguards include limited access to the computerized information to VA OIG employees by means of passwords and authorized user identification codes. Computer system documentation is maintained in a secure environment in the Office of Inspector General, VA Central Office.

RECORD ACCESS PROCEDURES:

Individuals seeking information on the existence and content of records in this system pertaining to them should contact the system manager in writing as indicated above. A request for access to records must contain the requester's full name, address, telephone number, be signed by the requester, include proof of identity (*e.g.*, a copy of a state driver's license), and describe the records sought in sufficient detail to enable VA personnel to locate them with a reasonable amount of effort.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records in this system pertaining to them should contact the system manager in writing as indicated above. A request to contest or amend records must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record. Most records in this system are exempt from review and amendment provisions under 5 U.S.C. 552a (j) and (k).

NOTIFICATION PROCEDURES:

Individuals who wish to be notified if a record in this system of records applies to them should submit the request following the procedures described in "Record Access Procedure," above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(j)(2), the head of any agency may exempt any system of records within the agency from certain provisions of the Privacy Act, if the agency or component that maintains the system performs as its principal function any activities pertaining to the enforcement of criminal laws. The Inspector General Act of 1978, Public Law 95-452, as amended, mandates that the Inspector General recommend policies for and to conduct, supervise, and coordinate activities in the Department of Veterans Affairs and between VA and other Federal, State and local governmental agencies with respect to: (1) the prevention and detection of fraud in programs and operations administered or financed by VA and (2) the identification and

prosecution of participants in such fraud. Under the IG Act, whenever the Inspector General has reasonable grounds to believe there has been a violation of Federal criminal law, the Inspector General must report the matter expeditiously to the Attorney General. This system of records has been created in major part to support the criminal law-related activities assigned by the Inspector General to the Assistant Inspector General for Investigations. These activities constitute a principal function of the Inspector General's Hotline and Criminal Investigations staff. In addition to principal functions pertaining to the enforcement of criminal laws, the Inspector General may receive and investigate complaints and allegations from various sources concerning the possible existence of activities constituting non-criminal violations of law, rules, or regulations; mismanagement; gross waste of funds; abuses of authority or substantial and specific danger to the public health and safety. This system of records also exists to support inquiries by the Assistant Inspectors General for Auditing, for Management and Administration, for Administrative Investigations, and for Healthcare Inspections into non-criminal matters. Based upon the foregoing, the Secretary of Veterans Affairs has exempted this system of records, to the extent that it encompasses information pertaining to criminal law-related activities, from the following provisions of the Privacy Act of 1974, as permitted by 5 U.S.C. 552a(j)(2): 5 U.S.C. 552a(c)(3) and (4); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1), (2) and (3); 5 U.S.C. 552a(e)(4)(G), and (H) and (I); 5 U.S.C. 552a(e)(5) and (8); 5 U.S.C. 552a(f); 5 U.S.C. 552a(g). The Secretary of Veterans Affairs has also exempted this system of records to the extent that it does not encompass information pertaining to criminal law related activities under 5 U.S.C. 552a(j)(2) from the following provisions of the Privacy Act of 1974, as permitted by 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1); 5 U.S.C. 552a(e)(4)(G), (H) and (I); 5 U.S.C. 552a(f). These exemptions are codified in 38 CFR 1.582(b). The purpose for exemption of information and material in this system of records is necessary in order to accomplish the law enforcement functions of the Office of Inspector General, *e.g.*, to prevent subjects of investigations from frustrating the investigatory process by discovering the scope and progress of an investigation, to prevent the disclosure of investigative techniques, to fulfill commitments made

to protect the confidentiality of sources, these sources and law enforcement
to maintain access to sources of personnel.
information and to avoid endangering

HISTORY:

73 FR 46708, Aug. 11, 2008; 84 FR
16145, Apr. 17, 2019.

[FR Doc. 2026-12021 Filed 6-15-26; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 429

Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 429

[CMS-4215-P]

RIN 0938-AV90

Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would codify the Medicare Drug Price Negotiation Program (“Negotiation Program”) and would establish certain new policies for the Negotiation Program and the Medicare Prescription Drug Benefit Program as required by the Inflation Reduction Act of 2022. This proposed rule would also propose a modification to the fixed combination drug policy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS-4215-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov/docket/CMS-2026-CMS-2026-2080>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4215-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4215-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Elisabeth Daniel, *IRAREbateand*

Negotiationprogram@cms.hhs.gov, or (667) 290-8793, for issues related to the Medicare Drug Price Negotiation Program.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

A. Executive Summary

1. Purpose

This proposed rule would codify policies related to the implementation of certain provisions of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169, August 16, 2022) and amendments made by the Working Families Tax Cut legislation (Pub. L. 119-21, July 4, 2025).

This proposed rule would also codify policies for the Medicare Drug Price Negotiation Program at part 429 consistent with sections 1191 through 1198 of the Social Security Act (hereinafter “the Act”) and codify policies for the Medicare Prescription Drug Benefit Program at part 423 consistent with section 11001(b) of the IRA, which made certain amendments to the Act, including with respect to Medicare Part D.

2. Summary of the Provisions

We propose to codify policies established in final guidance for the Negotiation Program¹ in regulatory text.

¹ The most recent final guidance published for the Negotiation Program is the Medicare Drug Price

Specifically, we propose to codify, with limited modification, the policies set forth in guidance for the Medicare Drug Price Negotiation Program by adding the new part 429 to title 42, Chapter IV of the Code of Federal Regulations and modifying policies for the Medicare Prescription Drug Benefit Program at part 423 and welcome comments on these proposals.

In addition, we propose new policies for the Medicare Drug Price Negotiation Program as follows:

- Proposed § 429.125(b)(4)(i) would clarify treatment of new formulations where circumstances to emerge where statutory requirements could be in tension with the general fixed combination drug policy proposed at § 429.125(b)(4). To do so, we are proposing a narrow modification to the general fixed combination drug policy for certain fixed combination drugs that are new formulations. Under the modification, if CMS determines that products with the same New Drug Application (NDA)/Biologics License Application (BLA) holder differ in active moiety(ies)/active ingredient(s) due to the inclusion of an active moiety/active ingredient that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies)/active ingredient(s), then CMS will identify the potential qualifying single source drug using all dosage forms and strengths of the shared active moiety(ies)/active ingredient(s) that is offered by the same NDA/BLA holder.

- Proposed § 429.125(c)(3)(i) would clarify how CMS would identify the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the Orphan Drug Exclusion.

- Proposed § 429.130 would codify the process and schedule according to which CMS reviews information to determine if the manufacturer of a generic drug or biosimilar that is approved or licensed, respectively, is engaged in Bona Fide Marketing (as defined in § 429.20) of that generic drug or biosimilar.

- Proposed § 429.210(c) would provide additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity.

Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, available at: <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

- Proposed § 429.415(a)(2) would explain how CMS would calculate the 30-day equivalent supply for a selected drug that is typically administered one time (for example, some vaccines, gene therapies, and cancer therapies).

- Proposed § 429.440 would explain how CMS would implement the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030.

- Proposed §§ 429.605 and 429.610 would clarify when off-label use would be considered for renegotiation eligibility and selection by aligning the renegotiation eligibility and selection policies for off-label use with the initial offer development process. This clarification maintains consistency across CMS processes for negotiation and renegotiation, as required by section 1194(f)(4)(B) of the Act.

Unless otherwise specified, CMS proposes that the provisions herein would apply with respect to all initial price applicability years beginning with initial price applicability year 2029, including, for example, with respect to the selection of drugs and the negotiation or renegotiation of MFPs for initial price applicability year 2029 that will take place during calendar year 2027. In this proposed rule, unless otherwise specified, references hereinafter to “the Negotiation Program Guidance” are to the most recent program guidance published by CMS, which is the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 that was published on September 30, 2025.

CMS anticipates publishing the final version of this rule in Fall 2026, after considering and responding to public comments received on this proposed rule, such that the final requirements will apply to initial price applicability year 2029 and all subsequent years, taking effect beginning with the process of the selection of drugs for negotiation and renegotiation, if applicable, for initial price applicability year 2029.

Given that the identification and selection of drugs for negotiation and renegotiation occurs more than 2 years before the first application of the MFP (that is, before the start of the selected drug’s first initial price applicability year), the processes for drugs that were selected for negotiation for initial price applicability years 2026, 2027, and 2028 and for renegotiation for initial price applicability year 2028 will be at varying stages of implementation when this rule is proposed and finalized.

Consistent with the program instruction requirement at sections 11001(c) and 11002(c) of the IRA, the program guidance issued by CMS for initial price applicability years 2026, 2027, and 2028 remains applicable and is not superseded by this proposed rule with respect to such years. In other words, because sections 11001(c) and 11002(c) of the IRA require CMS to implement the Negotiation Program for initial price applicability years 2026, 2027, and 2028 through program instruction and other forms of program guidance, the requirements for a selected drug that was included on the list of selected drugs with respect to initial price applicability year 2026, 2027, or 2028 are set forth with respect to such years in the applicable program guidance. Revisions to the implementation of policy for 2026, 2027, and 2028 with respect to drugs selected for initial price applicability years 2026, 2027, and 2028 would be addressed by CMS through publication of revised guidance. In accordance with the expiration of the statutory program instruction requirement at the end of 2028, CMS proposes that the provisions herein, as applicable, will apply starting in 2029 with respect to the drugs selected for initial price applicability years of 2026, 2027, or 2028.

Finally, CMS reminds interested parties that the exclusion for small biotech drugs from what is otherwise a negotiation-eligible drug under section 1192(d)(2) of the Act ended in initial price applicability year 2028 and is, therefore, not codified in this rule. However, the definition of an eligible small biotech drug for purposes of the calculation of the temporary floor on the maximum fair price for small biotech drugs under section 1194(d) of the Act is included in this proposed rule (as described in more detail in section II.E.2. of this proposed rule).

3. Summary of Costs and Benefits

We are proposing new policies for the Negotiation Program as follows: a modification to the general fixed combination drug policy to clarify our treatment of certain new formulations; clarification for drugs that formerly qualified for the orphan drug exclusion; revisions regarding process and schedule of CMS review of information in making the determination for Bona Fide Marketing; additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity; calculation of the 30-day equivalent supply for a selected drug that is typically administered one time;

implementation of the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of off-label use in consideration for renegotiation eligibility and selection. In summary, the effects of the IRA are to reduce government expenditures for Part B, to increase expenditures for Part D through 2030, and to decrease Part D expenditures beginning in 2031. For a detailed discussion of the economic impacts, see section V. of this proposed rule.

B. Background

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169), signed into law on August 16, 2022, establish the Medicare Drug Price Negotiation Program (hereinafter the “Negotiation Program”) to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. Specifically, in accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year. The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA and as amended by section 71203 of the “Working Families Tax Cut” legislation (Pub. L. 119–21).

Under the IRA, with respect to each initial price applicability year, CMS shall: (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate MFPs for such selected drugs in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) impose civil monetary penalties (CMPs) in accordance with section 1197 of the Act. With respect to initial price applicability year 2028 and subsequent years, in accordance with section 1194(f) of the Act, CMS shall also: (1) determine renegotiation-eligible drugs; (2) determine whether to select drugs for renegotiation; and (3) renegotiate the MFP for any drug selected for renegotiation. To the extent applicable, any references in this proposed rule to the “MFP” include a renegotiated MFP.

Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

Additionally, on July 4, 2025, the “Working Families Tax Cut” legislation was signed into law. Section 71203(a)(2) of the “Working Families Tax Cut” legislation amended section 1192(e)(1)(3)(A) of the Act to modify the requirements for a drug to qualify for the Orphan Drug Exclusion. Section 71203(a)(3) of the “Working Families Tax Cut” legislation also added new section 1192(e)(4) of the Act, which describes the treatment of former orphan drugs.

For the first year of the Negotiation Program, the Secretary of the U.S. Department of Health and Human Services (“the Secretary”) selected 10 high expenditure, single source drugs covered under Part D for negotiation. The negotiated MFPs for these drugs took effect in initial price applicability year 2026.² The Secretary selected an additional 15 drugs covered under Part D for negotiation for initial price applicability year 2027,³ and 15 drugs covered under Part D and/or payable under Part B for initial price applicability year 2028.⁴ The Secretary will select up to 20 drugs covered under Part D and/or payable under Part B for initial price applicability year 2029 and subsequent initial price applicability years. Beginning with initial price applicability year 2028, the Secretary could also select drugs from initial price applicability year 2026 and subsequent initial price applicability years for renegotiation. The Secretary selected one drug for renegotiation for initial price applicability year 2028.⁵

For initial price applicability years 2026 through 2028 of the Negotiation Program, sections 11001(c) and 11002(c) of the IRA direct CMS to implement the Negotiation Program through program instruction and other forms of program guidance. CMS issued initial or draft versions of program guidance for each initial price applicability year 2026,⁶

2027,⁷ and 2028⁸ and requested public comment on each version. CMS then issued a revised or final version of the guidance for each of these program years.^{9 10 11} This proposed rule proposes to codify these requirements at parts 423 and 429 to title 42, chapter IV of the Code of Federal Regulations to implement sections 11001 and 11002 of the IRA. The effective date of the proposed provisions are discussed in section I.A.2. of this proposed rule.

Consistent with the program instruction requirement of sections 11001(c) and 11002(c) of the IRA, CMS will issue program guidance related to manufacturer effectuation of the MFP for 2028, including with respect to drugs payable under Part B. CMS intends to codify requirements related to MFP effectuation for 2029 and subsequent years in future rulemaking. CMS stated in the Negotiation Program Guidance its intent to codify MFP effectuation policies for 2029 and subsequent years after guidance for 2028 has been finalized.

C. Severability of Provisions

Finally, CMS is clarifying and emphasizing its intent that if any provision of this rule, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, CMS proposes provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

II. Proposed Requirements for the Medicare Drug Price Negotiation Program

A. General Provisions

1. Basis and Scope (§ 429.10)

In proposed § 429.10, we would state that part 429 implements sections 1191 through 1198 of the Act and sections 11001 and 11002 of the IRA, which set forth the requirements of the Medicare Drug Price Negotiation Program. The Medicare Drug Price Negotiation Program requires the Secretary to negotiate and renegotiate, for applicable periods, Medicare prices for certain high expenditure, single source drugs and biological products.

Additionally, in proposed § 429.10(c), we would state that, were any provision of part 429 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provision would be severable from part 429 and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. While the provisions in part 429 are intended to present a comprehensive approach to implementing the Medicare Drug Price Negotiation Program, we intend that each of them is a distinct, severable provision, as proposed. Through this rulemaking, the proposed policies contained herein are intended to operate independently of each other, even if each serves the same general purpose or policy goal. For example, we intend that the proposed policies related to requests for a biosimilar delay (proposed § 429.110) are distinct and severable from the proposals related to the identification of qualifying single source drugs (proposed § 429.125). As another example, we intend that the proposed policy for additional price exchange opportunities for purposes of providing additional flexibility to extend and consider offers and counteroffers (proposed § 429.530) is distinct and severable from the proposals for CMS and Primary Manufacturers (as defined in proposed § 429.20) to submit written initial offers and statutory written counteroffers, respectively, for purposes of determining an agreed-upon maximum fair price (MFP) (proposed § 429.520(a) and 429.525(a), respectively). Even where one provision makes reference to a second provision, § 429.10(c) clarifies the intent of the agency is that the two provisions would be severable if one provision were to be invalidated in whole or in part. For

² See: <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf>.

³ See: <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf>.

⁴ See: <https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip>.

⁵ See: <https://www.cms.gov/files/document/fact-sheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf>.

⁶ See: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>.

⁷ See: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>.

⁸ See: <https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf>.

⁹ See: <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

¹⁰ See: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>.

¹¹ See: <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

example, we would still be able to adjust the preliminary price based on section 1194(e)(1) factors (as defined in proposed § 429.20) as described in proposed § 429.510(f) even if the provision for Primary Manufacturers to submit market data and revenue and sales volume data for the selected drug in the United States is deemed invalid (proposed § 429.505(b)(2)(v)).

2. Definitions (§ 429.20)

In this proposed rule, we would codify the definitions of terms consistent with the meanings given in sections 1191 through 1198 of the Act or established in the Negotiation Program Guidance, as applicable, as well as proposing to codify new definitions based on policies detailed in this proposed rule.

a. Additional Delay Request

We propose to define “Additional Delay Request” as a request to delay the inclusion on the selected drug list of a reference drug for which an initial delay request has been granted for a second initial price applicability year consistent with proposed § 429.110 and section 1192(f)(1)(B)(i)(II) of the Act.

b. Applicable Program Agreement

We propose to define “applicable program agreement” as an agreement under the Manufacturer Discount Program as specified in section 1860D–14C of the Act or a rebate agreement described in section 1927(b) of the Act.

c. Authorized Generic Drug

We propose to define “authorized generic drug” in accordance with the definition of such term at section 1192(e)(2)(B) of the Act. Section 1192(e)(2)(B)(i) of the Act defines an “authorized generic drug” that is a drug as a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic (FD&C) Act. Section 1192(e)(2)(B)(ii) of the Act defines an authorized generic drug that is a biological product as a product that has been licensed under section 351(a) of the Public Health Service (PHS) Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

d. Authorized Representative

We propose to define “authorized representative” as an individual that has the authority or capacity to legally bind the Primary Manufacturer to the terms

and conditions of the Negotiation Program Agreement and meets one of the following criteria:

- Chief Executive Officer of the Primary Manufacturer.
- Chief Financial Officer of the Primary Manufacturer.
- An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Primary Manufacturer.
- An individual that has been granted delegation of signature authority on behalf of one of the individuals specified in paragraphs (1) through (3) of this proposed definition.

We solicit comment on this proposed definition and potential alternative formulations, including whether to adopt a broader definition to account for other contexts within the Negotiation Program, such as an individual making a submission to CMS on behalf of an entity other than a Primary Manufacturer.

e. Average Manufacturer Price (AMP)

We propose to define “average manufacturer price (AMP)” as having the meaning given such term in section 1927(k)(1) of the Act.

f. Average Non-Federal Average Manufacturer Price (non-FAMP)

We propose to define “average non-Federal Average Manufacturer Price (non-FAMP)” as having the meaning set forth in section 1194(c)(6) of the Act.

g. Average Sales Price (ASP)

We propose to define “average sales price (ASP)” as the manufacturer’s price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11) determined under § 414.804 and as reported in section 1927(b)(3) of the Act.

h. Billing Unit

We propose to define “billing unit” as the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a Healthcare Common Procedure Coding System code), as established by CMS.

i. Biologics Licenses Application (BLA)

We propose to define “Biologics License Application (BLA)” as an application submitted under section 351 of the PHS Act.

j. Biosimilar Biological Product or Biosimilar

We propose to define “biosimilar biological product” or “biosimilar” as having the meaning given such term in section 1847A(c)(6) of the Act. For purposes of these regulations, we use

the terms “biosimilar biological product” and “biosimilar” interchangeably when describing the requirements of sections 11001 and 11002 of the IRA. Specifically, section 1192(f)(5) of the Act, as added by section 11002 of the IRA, uses the meaning given to “biosimilar biological product” from section 1847A(c)(6) of the Act. Proposed part 429 uses the term “biosimilar” unless otherwise specified, such as related to the “Biosimilar” included in a Biosimilar Delay Request under section 11002 of the IRA in proposed § 429.20.

k. Biosimilar Delay Request

We propose to define “Biosimilar Delay Request” as either an Initial Delay Request or an Additional Delay Request.

l. Biosimilar Manufacturer

We propose to define “Biosimilar Manufacturer” as one of the following:

- The BLA holder for the Biosimilar.
- If a BLA has been submitted to the U.S. Food and Drug Administration (FDA) for review but the Biosimilar has not been licensed, the sponsor of the BLA submitted for review by the FDA.
- If the Biosimilar has not been licensed and the BLA has not been submitted to the FDA, the organization planning to be the sponsor when the BLA is submitted for review by the FDA.

We believe that this approach is appropriate because: (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay Request for a given Biosimilar, avoiding the possibility that we would receive two such requests naming the same Biosimilar for the same initial price applicability year; and (2) the status of the application for licensure for the Biosimilar is material to CMS’ consideration of a request for a Biosimilar Delay Request, as described in section II.B.3. of this proposed rule.

m. BLA Holder

We propose to define “BLA holder” as the entity that is the holder of the license(s) permitting marketing of a biological product in accordance with section 351 of the PHS Act.

n. Bona Fide Marketing

We propose to define “Bona Fide Marketing” as having the meaning set forth in proposed § 429.130(a). Further discussion of CMS’ review of one or more manufacturers of an approved generic drug or licensed biosimilar engaging in Bona Fide Marketing is included in section II.B.6.d. of this proposed rule.

o. Combined Part B and Part D Amount

We propose to define “combined Part B and Part D amount” as an amount equal to the weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount as determined by CMS under proposed § 429.420(c).

p. CPI–U

We propose to define “CPI–U” as the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

q. Direct and Indirect Remuneration (DIR)

We propose to define “Direct and Indirect Remuneration (DIR)” as having the meaning set forth in 42 CFR 423.308.

r. Drug Covered Under Part D

We propose to define “drug covered under Part D” as a covered part D drug as defined in section 1860D–2(e) of the Act. We acknowledge that section 1860D–2(e) of the Act defines the term “covered part D drug” rather than “drug covered under Part D”. For purposes of this rule, we use the term “drug covered under Part D” for simplicity and intend this term to be synonymous with the statutory term “covered part D drug”.

s. Drug Payable Under Part B

We propose to define “drug payable under Part B” as a drug or biological product for which payment may be made under part B of Title XVIII of the Act.

t. Estimated Remuneration at Point-of-Sale Amounts (ERPOSA)

We propose to define “estimated remuneration at point-of-sale amounts (ERPOSA)” as the estimated amount of rebates or other price concessions that the Part D plan sponsor is required to apply, or has elected to apply, to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale.

u. Extended-Monopoly Drug

We propose to define “extended-monopoly drug” as having the meaning set forth in section 1194(c)(4) of the Act.

v. FDA-Approved Indication

We propose to define “FDA-approved indication” as the information included in drug labeling per 21 CFR 201.57(c)(2) or FDA regulation(s) as applicable.

w. Fixed Combination Drug

We propose to define “fixed combination drug” as having the meaning set forth in 21 CFR 300.50.

x. Generic Drug

We propose to define “generic drug” as a drug approved in an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”).

y. Healthcare Common Procedure Coding System (HCPCS) Code

We propose to define “Healthcare Common Procedure Coding System (HCPCS) code” as a billing and payment code, as established by CMS for payment under Part B, used to describe a drug or biological and for which CMS may publish a payment amount.

z. High Likelihood Deadline

We propose to define “High Likelihood Deadline” as the date that is 2 years after the statutorily defined selected drug publication date for the initial price applicability year for which the reference drug would be included on the selected drug list absent a successful Initial Delay Request. This period of time is consistent with time periods specified in sections 1192(f)(1)(A) and (2)(B)(i)(I) of the Act.

aa. Initial Delay Period

We propose to define “Initial Delay Period” as the time period between: (1) the selected drug publication date for the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request, as proposed in § 429.110(g); and (2) the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request as set forth in section 1192(f)(2) of the Act.

ab. Initial Delay Request

We propose to define “Initial Delay Request” as a request to delay the inclusion of a reference drug on the selected drug list by one initial price applicability year consistent with proposed § 429.110(c) and section 1192(f)(1)(B)(i)(I) of the Act.

ac. Initial Price Applicability Year

We propose to define “initial price applicability year” as having the meaning set forth in section 1191(b)(1) of the Act.

ad. Knowingly

We propose to define “knowingly” as having the meaning set forth in 42 CFR 1003.110.

ae. Long-Monopoly Drug

We propose to define “long-monopoly drug” as having the meaning set forth in section 1194(c)(5) of the Act.

af. Manufacturer

We propose to define “manufacturer” as having the meaning set forth in section 1191(c)(1) of the Act.

ag. Manufacturer Discount Program

We propose to define “Manufacturer Discount Program” to mean the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

ah. Maximum Fair Price (MFP)

We propose to define “maximum fair price (MFP)” as having the meaning set forth in section 1191(c)(3) of the Act.

ai. Medicare Drug Price Negotiation Program (or Negotiation Program)

We propose to define “Medicare Drug Price Negotiation Program (or Negotiation Program)” as the program created by sections 11001 and 11002 of the Inflation Reduction Act and codified in sections 1191 through 1198 of the Act and as amended.

aj. Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement)

We propose to define “Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement)” as the agreement between a Primary Manufacturer and CMS as set forth in proposed § 429.200 of this chapter and section 1193(a) of the Act.

ak. NDA Holder

We propose to define “NDA holder” as the entity that is the holder of the approval(s) to market a drug product in accordance with section 505(c) of the FD&C Act.

al. Negotiation-Eligible Drug

We propose to define “negotiation-eligible drug” as having the meaning set forth in section 1192(d) of the Act. We refer readers to proposed § 429.115 (and related discussion in section II.B.4. of this proposed rule) for CMS’ proposals for identifying drugs that meet this statutory definition.

am. Negotiation Period

We propose to define “negotiation period” as having the meaning set forth in section 1191(b)(4) of the Act.

an. Net Part D Plan Payment and Beneficiary Liability

We propose to define “Net Part D Plan Payment and Beneficiary Liability” as, for purposes of the Medicare Drug Price Negotiation Program, the total gross covered prescription drug cost for a selected drug covered under Part D net of direct and indirect remuneration (DIR) and Manufacturer Discount Program payments and excluding prescription drug event (PDE) records for which a compound code indicates the PDE record is for a compounded drug.

ao. New Drug Application (NDA)

We propose to define “New Drug Application (NDA)” as an application submitted under section 505(b) of the FD&C Act.

ap. Off-Label Use

We propose to define “off-label use” as the use for a condition for a selected drug or therapeutic alternative that is not an FDA-approved indication but is included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration major drug compendia, authoritative medical literature, and accepted standards of medical practice, or some combination thereof.

aq. Orphan Drug Designation

We propose to define “orphan drug designation” as the meaning set forth in 21 CFR 316.3(b)(11).

ar. Outcomes

We propose to define “outcomes” as the impact of an intervention, which may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient’s life.

as. Part B Data

We propose to define “Part B data” as having the meaning of Original Medicare (OM) Part B claims data and Medicare Advantage (MA) encounter data for Part B items or services.

at. Partnership

We propose to define “partnership” as having the meaning set forth in section 1192(f)(1)(C)(ii) of the Act.

au. Personally Identifiable Information (PII)

We propose to define “personally identifiable information (PII)” as having the meaning set forth at 2 CFR 200.1.

av. Plasma-Derived Product

We propose to define “plasma-derived product” as having the meaning set forth in section 1192(e)(3)(C) of the Act.

aw. Preliminary Price

We propose to define “preliminary price” as the numerical dollar amount used by CMS in developing an initial offer in accordance with § 429.510(e) by adjusting the starting point of a selected drug based on section 1194(e)(2) factors.

ax. Price Applicability Period

We propose to define “price applicability period” as having the meaning set forth in section 1191(b)(2) of the Act.

ay. Primary Manufacturer

We propose to define “Primary Manufacturer” as the manufacturer identified by CMS as the NDA holder or the BLA holder for the selected drug.

az. Private Label Distributor

We propose to define “private label distributor” as having the meaning set forth in 21 CFR 207.1.

ba. Protected Health Information (PHI)

We propose to define “protected health information (PHI)” as having the meaning set forth at 45 CFR 160.103.

bb. Qualifying Single Source Drug

We propose to define “qualifying single source drug” as having the meaning set forth in section 1192(e) of the Act. We refer readers to proposed § 429.125 (and related discussion in section II.B.6. of this proposed rule) for CMS’ proposals for identifying drugs that meet this statutory definition.

bc. Rare Disease or Condition

Section 1192(e)(3)(A) of the Act describes “rare disease or condition” as having the definition used for such term in section 526(a)(2) of the FD&C Act. Therefore, we propose to define “rare disease or condition” as having the meaning set forth in section 526(a)(2) of the FD&C Act.

bd. Reference Drug

We propose to define “Reference Drug” as a negotiation-eligible drug that includes the reference product for the biosimilar as described in section 1192(f)(1)(B) of the Act.

be. Reference Manufacturer

We propose to define “Reference Manufacturer” as the Primary Manufacturer of the Reference Drug that is named in a Biosimilar Delay Request.

bf. Reference Product

We propose to define “Reference Product” as having the meaning set forth in section 1191(c)(4) of the Act.

bg. Relabeler

We propose to define “relabeler” as having the meaning set forth in 21 CFR 207.1.

bh. Renegotiation-Eligible Drug

We propose to define “renegotiation-eligible drug” as having the meaning set forth in section 1194(f)(2) of the Act.

bi. Repackager

We propose to define “repackager” as having the meaning given the term “repacker” set forth in 21 CFR 207.1.

bj. Request To Terminate

We propose to define “Request to Terminate” as a written request submitted by a Primary Manufacturer to CMS, that CMS determines meets the conditions described in § 429.205(b)(1)(A) and (B), to request termination of its applicable program agreements in the context of a Primary Manufacturer’s decision not to enter into or to terminate a Negotiation Program Agreement.

bk. Secondary Manufacturer

We propose to define “Secondary Manufacturer” as a manufacturer of a drug product included in the selected drug, that is not the Primary Manufacturer for the selected drug, and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on an NDA or BLA of the selected drug. A Secondary Manufacturer includes any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meet either of these criteria.

bl. Second Delay Period

We propose to define “Second Delay Period” as the time period between (1) the publication date of the selected drug list for initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request and (2) the publication date of the selected drug list for initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay

Request as set forth in section 1192(f)(2) of the Act.

bm. Section 1194(e)(1) Factors

We propose to define “section 1194(e)(1) factors” as the factors described in section 1194(e)(1) of the Act.

bn. Section 1194(e)(2) Factors

We propose to define “section 1194(e)(2) factors” as the factors described in section 1194(e)(2) of the Act.

bo. Selected Drug

We propose to define “selected drug” as having the meaning set forth in section 1192(c) of the Act. We refer readers to proposed § 429.105 (and related discussion in section II.B.2. of this proposed rule) for CMS’ proposals for identifying drugs that meet this statutory definition.

bp. Selected Drug Publication Date

We propose to define “selected drug publication date” as having the meaning set forth in section 1191(b)(3) of the Act.

bq. Self-Administered Drug

We propose to define “self-administered drug” to mean, a drug or biological that is identified by the U.S. Department of Health and Human Services Office of Inspector General (OIG) as a self-administered drug pursuant to section 1847A(g)(1) of the Act.

br. Sequestration Payment Adjustment

We propose to define “sequestration payment adjustment” to mean, when applicable, the amount that is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, merit-based incentive payment adjustments, and any applicable Medicare Secondary Payment adjustments.

bs. Small Biotech Drug

We propose to define “Small Biotech Drug” as meaning a drug that is determined by CMS under the proposed § 429.440(b)(2), in accordance with section 1192(d)(2) of the Act, as eligible for the Temporary Floor for Small Biotech Drugs.

bt. Specified Manufacturer

We propose to define “Specified Manufacturer” as having the meaning set forth in section 1860D–14C(g)(4)(B)(ii) of the Act, as determined by CMS for the purposes of the Manufacturer Discount Program in accordance with §§ 423.2716, 423.2720, and 423.2724.

bu. Starting Point

We propose to define “starting point” as the numerical dollar amount used by CMS in developing an initial offer in accordance with proposed § 429.510(d) that is then adjusted by CMS based on section 1194(e)(2) factors to determine the preliminary price, per the process described in proposed § 429.510(e).

bv. Temporary Floor for Small Biotech Drugs

We propose to define “Temporary Floor for Small Biotech Drugs” as having the meaning set forth in § 429.440(b)(3). We refer readers to proposed § 429.440(b)(1) and (2) (and related discussion in section II.E.9.b. of this proposed rule) for CMS’ proposals for the process for a Primary Manufacturer to request consideration and CMS’ determination of eligibility for the Temporary Floor for Small Biotech Drugs.

bw. Therapeutic Advance

We propose to define “therapeutic advance” as a demonstrated improvement in one or more outcomes or other clinical considerations for each identified condition of a selected drug as compared to its therapeutic alternative(s). For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS would consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

bx. Therapeutic Alternative

We propose to define “therapeutic alternative” as a pharmaceutical product or group of pharmaceutical products other than the selected drug that may be used to treat the same condition or disease state as the selected drug.

by. Total Allowed Charges

We propose to define “total allowed charges” as the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service paid for under part B of Title XVIII of the Act, without a sequestration payment adjustment applied.

bz. Total Expenditures

We propose to define “total expenditures” as having the meaning set forth in section 1191(c)(5) of the Act. We refer readers to § 429.120 and section II.B.5. of this proposed rule for CMS’ proposals for calculating total expenditures under Part D and total

expenditures under Part B that meet this statutory definition.

ca. Total Expenditures Measurement Period

Sections 1192(d)(1)(A) and (d)(1)(B) of the Act require that CMS calculate total expenditures under Part D and Part B, respectively, using data from the most recent 12-month period for which data are available prior to the selected drug publication date with respect to an initial price applicability year, but ending no later than October 31 of the year prior to the year of such drug publication date. To describe this 12-month period, we propose to define “total expenditures measurement period” as the 12-month period ending on October 31 of the year prior to the year of the selected drug publication date with respect to an initial price applicability year.

cb. Total Gross Covered Prescription Drug Costs

Section 1191(c)(5) of the Act specifies that the term “total gross covered prescription drugs costs” is defined at section 1860D–15(b)(3) of the Act. The term “total gross covered prescription drug costs” does not appear at section 1860D–15(b)(3) of the Act, but section 1860D–15(b)(3) of the Act does define the term “gross covered prescription drug costs,” and § 423.308 codifies this term. We therefore propose to define “total gross covered prescription drug costs” as having the meaning given the term “gross covered prescription drug costs” set forth at 42 CFR 423.308.

cc. Unit

We propose to define “unit” as having the meaning set forth in section 1191(c)(6) of the Act.

cd. Unmet Medical Need

We propose to define “unmet medical need” as a circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration.

ce. Wholesale Acquisition Cost (WAC) Unit Price

We propose to define “Wholesale Acquisition Cost (WAC) unit price” as the manufacturer’s list price for the drug or biological product to wholesalers or

direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC–11 level.

3. Limitation on Review (§ 429.30)

Section 1198 of the Act establishes that there shall be no administrative or judicial review of any of the following: (1) the determination of a unit, with respect to a drug or biological product, pursuant to section 1191(c)(6) of the Act; (2) the selection of drugs under section 1192(b) of the Act, the determination of negotiation-eligible drugs under section 1192(d) of the Act, the determination of qualifying single source drugs under section 1192(e) of the Act, and the application of the Biosimilar Delay under section 1192(f) of the Act; (3) the determination of a MFP under subsection (b) or (f) of section 1194 of the Act; and (4) the determination of renegotiation-eligible drugs under section 1194(f)(2) of the Act and the selection of renegotiation-eligible drugs under section 1194(f)(3) of the Act. CMS proposes to codify these limitations on review in proposed § 429.30.

B. Identification of Selected Drugs (§§ 429.100 Through 429.135)

Section 1192 of the Act establishes the requirements governing the publication of the list of selected drugs for an initial price applicability year, the identification of selected drugs, ranking of negotiation-eligible drugs, and the identification of qualifying single source

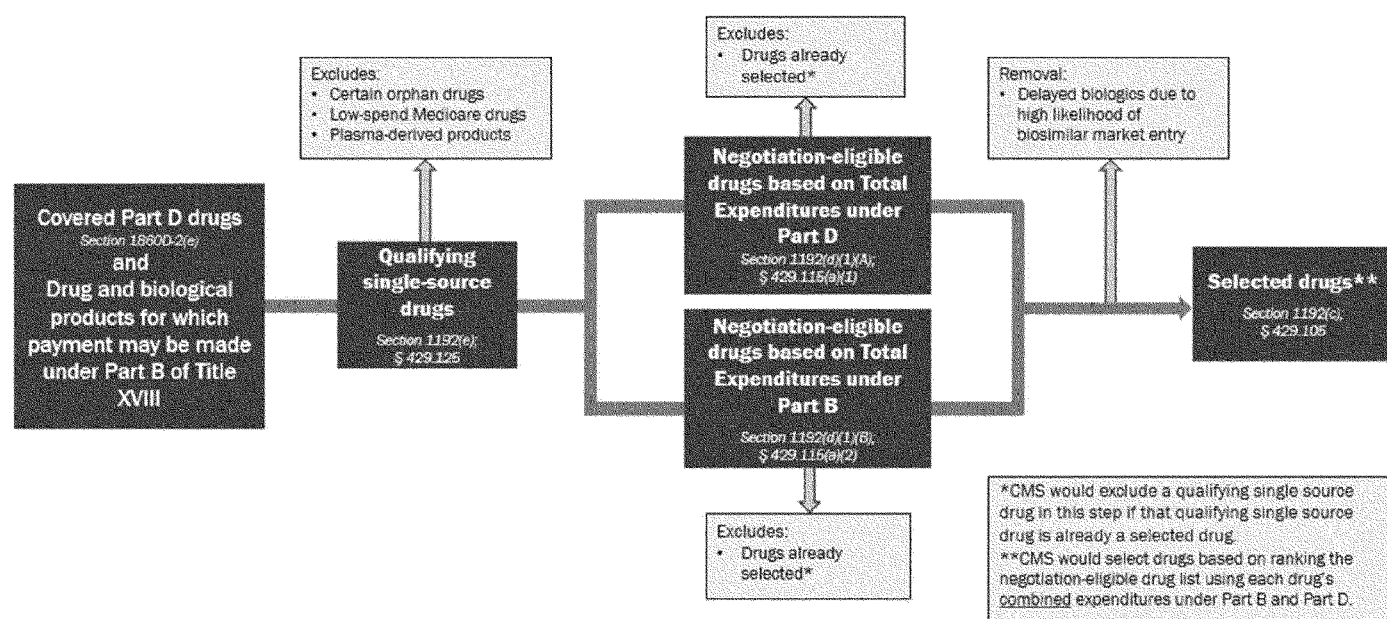
drugs. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example with respect to initial price applicability year 2028, section 30 of the Negotiation Program Guidance. With respect to initial price applicability years beginning with initial price applicability year 2029, we are proposing to codify these steps in an order reflecting the sequence of the statutory provisions which these sections are implementing, with proposed revisions as noted in this section, in proposed §§ 429.100 through 429.135.

Beginning with respect to initial price applicability year 2029 and in accordance with section 1192 of the Act, we propose in §§ 429.100 through 429.135 to codify the policies for identification of selected drugs described in sections 30 and 40.2 of the Negotiation Program Guidance, subject to proposed modifications as noted herein. As a matter of program operations, we would first identify qualifying single source drugs with respect to each initial price applicability year. As a part of this identification process, CMS would exclude certain drugs as proposed in § 429.125(e). Next, we would identify negotiation-eligible drugs using total expenditures under Part B or Part D of Title XVIII of the Act, as applicable and calculated as set forth in proposed § 429.120, to identify qualifying single source drugs that are Part B high spend drugs, Part D high spend drugs, or both, as proposed in § 429.115. (In these steps, we would also exclude drugs that are already selected drugs in accordance with section 1192(d)(3) of the Act.) As proposed in § 429.105(a), we would rank these negotiation-eligible drugs for an initial

price applicability year according to the total expenditures for such drugs. In accordance with section 1192(a) of the Act and subject to the section 1192(f) of the Act (which permits the delay in the selection and negotiation of biological products for biosimilar market entry when certain requirements are met consistent with proposed § 429.110, hereinafter “Biosimilar Delay”), we propose at § 429.105(c) to select up to 20 negotiation-eligible drugs with the highest total expenditures under Part B and Part D of Title XVIII of the Act for negotiation for initial price applicability year 2029 and each initial price applicability year thereafter, and publish the list of selected drugs as proposed at § 429.100. We may also select a drug or drugs for renegotiation based on criteria discussed in detail in section II.G.3. of this proposed rule and in proposed § 429.610.

Finally, as proposed in § 429.100, we would publish the list of drugs selected for negotiation, including the list of drugs selected for renegotiation, if any, not later than the selected drug publication date. We are also proposing to publish a list of the up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D. Detailed descriptions of these proposals for initial price applicability year 2029 and each initial price applicability year thereafter is included later in this section. Figure 1 provides a visual depiction of this proposed process.

Figure 1—Diagram of Proposed Process for Selecting Drugs for Negotiation for Initial Price Applicability Years Beginning With Initial Price Applicability Year 2029



1. Publication of the Selected Drug List (§ 429.100)

Section 1192(a)(4) of the Act requires that, not later than the selected drug publication date with respect to the initial price applicability year, in accordance with section 1192(b) of the Act, the Secretary shall select and publish a list of, with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs, as described in section 1192(d)(1) of the Act, with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year). Proposed § 429.20 defines the term “selected drug publication date” to have the meaning set forth in section 1191(b)(3) of the Act, which provides that the term “selected drug publication date” means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 30.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We are proposing at § 429.100(a) to codify the requirement at section 1192(c)(1) of the Act that each drug included on the selected drug list¹² for an initial price applicability year is a selected drug with respect to such

initial price applicability year and each subsequent year unless and until CMS makes a determination in accordance with proposed § 429.135(a) that such drug will be deselected (as described in further detail in section II.B.6.d. of this proposed rule). We are proposing at § 429.100(b) to codify the requirement that CMS publish the selected drug list and the drugs selected for renegotiation, if any, for each initial price applicability year beginning with initial price applicability year 2029, no later than the selected drug publication date with respect to the initial price applicability year. For example, for initial price applicability year 2029, we would publish this information no later than February 1, 2027. As proposed in § 429.100(b)(1), the selected drug list would include the 20 (or all, if such number is less than 20) drugs payable under Part B, covered under Part D, or both, selected for negotiation for the initial price applicability year as determined in § 429.105(c) and discussed in section II.B.2 of this proposed rule. As proposed in § 429.100(b)(2), we would also publish the list of drugs selected for renegotiation, if any, as set forth in proposed § 429.610.

For each selected drug, we are proposing at § 429.100(b)(3)(i) to add to the MFP file no later than the selected drug publication date the active moiety, active ingredient, antigen component, or, in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), the distinct combination of active moieties, active

ingredients, or antigen components,¹³ as applicable, identified as set forth in proposed § 429.125(b). For a potential qualifying single source drug identified under § 429.125(b)(4)(i), we are proposing to publish the shared active moiety/active ingredient identified under § 429.125(b)(4)(i), plus any additional active moiety/active ingredient included in new formulations of such potential qualifying single source drug. We are proposing at § 429.100(b)(4)(i) to take the same approach for each drug selected for renegotiation, if any, except we would publish the active moiety/active ingredient previously identified for the initial price applicability year for which the drug was originally selected for negotiation. We are proposing at § 429.100(b)(3)(ii) and (b)(4)(ii) to add to the MFP file no later than the selected drug publication date the NDC–11s identified in accordance with § 429.100(c)(1) and the corresponding NDC–9s and HCPCS codes, as applicable, for the selected drug and the drug selected for renegotiation, if any. For drugs selected for renegotiation, the NDC–11s (and corresponding NDC–9s

¹³ For simplicity, we hereinafter use the term “active moiety/active ingredient” to refer to the active moiety, active ingredient, antigen component, or, in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), the distinct combination of active moieties, active ingredients, or antigen components, that we propose to identify as specified at proposed § 429.125(b)(1) through (b)(4). In limited cases, we refer to active moieties, active ingredients, and antigen components in the plural (that is, “active moieties/active ingredients/antigen components” or “active moiety(ies)/active ingredient(s)/antigen component(s)”) when we believe such terminology provides greater clarity to the discussion.

¹² CMS would publish one list with respect to each initial price applicability year. The list would include the selected drug list of the drugs selected for negotiation for the initial price applicability year, as well as drugs selected for renegotiation, if any.

and HCPCS codes) added to the MFP file would also reflect information previously submitted by the Primary Manufacturer, including submissions in accordance with proposed § 429.100. At § 429.100(c), we propose the process we would use to identify the list of NDC-11s described in the prior sentences for each selected drug and each drug selected for renegotiation, if any. As proposed at § 429.100(f), the agency's list of NDC-11s would be used in the administration of the Negotiation Program, including to identify the NDC-11s of the selected drug that are subject to the negotiation process set forth in proposed subpart F and the renegotiation process set forth in proposed subpart G (as applicable), identify the NDC-11s of the selected drug to which the MFP (if one is agreed to by CMS and the Primary Manufacturer) applies for the price applicability period, to calculate the ceiling set forth in proposed § 429.410 for drugs selected for negotiation, to calculate the ceiling set forth in proposed § 429.620(b) for drugs selected for renegotiation, and to calculate how to apply the MFP, if one is agreed to by CMS and the Primary Manufacturer, and to the extent data are available to support such calculations, across dosage forms and strengths set forth in proposed § 429.700 for selected drugs and proposed § 429.600(b)(2) for drugs selected for renegotiation.

To identify the list of NDC-11s of the selected drug, including for a drug selected for renegotiation, set forth at proposed § 429.100(c), we propose at § 429.100(c)(1) to first identify NDC-11s associated with the NDA(s)/BLA(s) of the selected drug. We would compile all NDC-11s belonging to the selected drug associated with HCPCS codes that appear on NDC-HCPCS code crosswalks published by CMS¹⁴ for the most recent quarter in the total expenditures measurement period (as such term is defined in proposed § 429.20), and all NDC-11s belonging to the selected drug that had Part D PDE utilization in the total expenditures measurement period. We would also identify any additional NDC-11s associated with the NDA(s)/BLA(s) of the selected drug as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file or the NDC Directory (including its NDC Excluded Drugs Database file). In section 30.4 of the Negotiation Program Guidance, we stated that we will remove any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part

B. Based on lessons learned from policy implementation in initial price applicability years 2026 through 2028, we are proposing to remove such requirement for initial price applicability year 2029 and subsequent years. Starting with a more comprehensive list of NDC-11s holds utility for CMS and Primary Manufacturers, as it reduces the number of NDC-11s that a Primary Manufacturer must identify as missing from the list, as required in proposed § 429.100(d)(1). We would publish the selected drug list, as well as the list of drugs selected for renegotiation, in a form and manner of CMS' choosing, which may be on the CMS website.

We are proposing at § 429.100(c)(2) to transmit the list of NDC-11s identified at proposed § 429.100(c)(1) to the Primary Manufacturer. As proposed at § 429.100(c)(3), we may revise our list of NDC-11s of each selected drug, including without limitation using information submitted by the Primary Manufacturer in accordance with proposed § 429.100.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(4)(B) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200 and described in section II.C.1. of this proposed rule), we propose in § 429.100(d) that a Primary Manufacturer must review the list of NDC-11s provided by CMS at proposed § 429.100(c) and provide information on each NDC-11 on the list of NDC-11s that make up a selected drug as a part of their data submission. More specifically, we propose at § 429.100(d) that a Primary Manufacturer must review the list of NDC-11s and provide proposed revisions to the list, as needed, by adding any NDC-11s associated with the NDA(s)/BLA(s) of the selected drug that do not appear on the agency's list of NDC-11s of the selected drug, including any missing NDC-11s of a Secondary Manufacturer. A Primary Manufacturer must also provide identifying information for any NDC-11 that appears on the list of NDC-11s, including any NDC-11s added by the Primary Manufacturer, on whether NDC-11(s): are for products distributed by or under the name of a private label distributor; are not manufactured, marketed, controlled or sold by the Primary Manufacturer or a Secondary Manufacturer; represent a sample package; represent an inner package or an outer package; and whether an NDC-11 has been discontinued. As described in proposed § 429.100(c)(3), we may revise the list of NDC-11s that make up the selected drug

based on this information submitted by the Primary Manufacturer.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200), we propose in § 429.100(e) that a Primary Manufacturer has an ongoing obligation to report, at least 30 calendar days prior to the change taking effect, any changes to the information provided in § 429.100(d) to ensure the list of NDC-11s of the selected drug identified in accordance with proposed § 429.100(c) remains complete and accurate. For example, under proposed § 429.100(e), a Primary Manufacturer must report to CMS any new NDC-11s of the selected drug at least 30 days prior to their first marketed date by or on behalf of the Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug. Failure to provide timely reporting of changes to the list of NDC-11s of the selected drug as described in proposed § 429.100(e) may be considered a violation of the Negotiation Program Agreement under section 1193(a)(5) of the Act and proposed § 429.200(b).

Since the Negotiation Program's inception, interested parties have recommended greater transparency into the process for selecting drugs. In response to these recommendations and in accordance with policy established in the Negotiation Program Guidance, we published a list of the 50 top negotiation-eligible drugs for initial price applicability year 2028 (including the 15 selected drugs for initial price applicability year 2028).¹⁵ To harmonize the request from interested parties for greater transparency into the process for selecting drugs with CMS operations, for initial price applicability year 2029 and subsequent years, we are proposing to publish a list of the up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D, as determined under proposed § 429.105(a), and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable and to the extent feasible. The purpose of publishing a list of negotiation-eligible drugs beyond selected drugs was, and remains, to promote transparency in the drug selection process. The conditions that determine which drugs meet the statutory requirements for a drug to become a qualifying single source drug, negotiation-eligible drug, or selected

¹⁴ See: <https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>.

¹⁵ See: <https://www.cms.gov/files/document/factsheet-medicare-top-50-negotiation-eligible-drug-list-ipay-2028.pdf>.

drug for a given initial price applicability are not static. Such list was not, and is not, intended to predict or replicate the selected drug list for future initial price applicability years. The honed focus on the up to 30 top drugs would continue to provide transparency into the drug selection process. We believe the prior policy of publishing negotiation-eligible drugs with rankings lower than 30 (that is, #31 through #50) provided less meaningful transparency into the drug selection process for a given initial price applicability year, as identifying such drugs provides little insight into the criteria and conditions that were material to the identification of the selected drug list for that initial price applicability year. Finally, consistent with prior policy, we propose that the list of top drugs based on combined total expenditures would reflect the removal of negotiation-eligible drugs that qualify for the Biosimilar Delay.

2. Selection of Drugs for Negotiation (§ 429.105)

Section 1192(b)(1)(A) of the Act requires that, in carrying out section 1192(a) of the Act, the Secretary shall, with respect to an initial price applicability year, rank negotiation-eligible drugs, as described in section 1192(d)(1) of the Act, according to the total expenditures for such drugs under parts B and D of Title XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest. Section 1192(b)(1)(B) of the Act requires that the Secretary select from such ranked drugs with respect to such initial price applicability year the negotiation-eligible drugs with the highest such rankings. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 30.3 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We are proposing at § 429.105 to select 20 (or all, if such number is less than 20) negotiation-eligible drugs for negotiation for each initial price applicability year.

First, with respect to an initial price applicability year, we are proposing at § 429.105(a) to rank the list of negotiation-eligible drugs identified at proposed § 429.115 by combined total

expenditures under both Part B and Part D in descending order: the negotiation-eligible drug with the highest total expenditures under Part B and Part D would be listed first, and the negotiation-eligible drug with the lowest total expenditures under Part B and Part D would be listed last (the proposed methodology for the calculation of total expenditures under Part B and total expenditures under Part D is described in proposed § 429.120 and section II.B.5. of this proposed rule). If a negotiation-eligible drug appears on both the Part D high-spend drug list and Part B high-spend drug list (set forth in proposed § 429.115(a)(1) and (a)(2), respectively, and described in section II.B.4. of this proposed rule), it would receive only one ranking for purposes of selection, according to its combined total expenditures under both Part B and Part D. If a negotiation-eligible drug appears on only one high-spend list, CMS would still combine total expenditures under both Part B and Part D.

Second, with respect to an initial price applicability year, we are proposing at § 429.105(b) to remove any biological products that qualify for delayed selection under section 1192(f) of the Act, as proposed at § 429.110 and described in section II.B.3. of this proposed rule.

Finally, we propose at § 429.105(c) to select for negotiation the 20 (or all, if such number is less than 20) highest ranked negotiation-eligible drugs remaining on the ranked list for the initial price applicability year. In guidance for initial price applicability years 2026, 2027 and 2028, including, for example, section 30.3 of the Negotiation Program Guidance, we established that for initial price applicability years 2026, 2027, and 2028, in the event that two or more negotiation-eligible drugs had the same total expenditures to the dollar, and such total expenditures were the 10th or 15th highest among negotiation-eligible drugs, as applicable for the initial price applicability year, we will rank those negotiation-eligible drugs based on which drug had the earlier approval or licensure date, as applicable, associated with the earliest-approved FDA application belonging to the NDA/BLA holder and containing the drug's active moiety/active ingredient, and select based on that ranking until there were 10 or 15 (as applicable) selected drugs (or until all drugs were selected, if the number of negotiation-eligible drugs was less than 10 or 15, as applicable). In this proposed rule, we are proposing to modify this methodology. We propose that to determine whether two or more negotiation-eligible drugs have

the same total expenditures, and such total expenditures are the 20th highest among negotiation-eligible drugs (or the highest, if the number is less than 20), we would evaluate such total expenditures to the cent, rather than to the dollar as under prior policy. We believe that determining total expenditures to the cent, rather than the dollar, is more precise for purposes of determining the selected drug list. For such drugs with the same combined total expenditures under Part B and Part D to the cent, we would continue to rank those negotiation-eligible drugs based on which drug has the earliest-approved FDA application belonging to the NDA/BLA holder and containing the drug's active moiety/active ingredient, and select based on that ranking until there are 20 selected drugs (or until all drugs are selected, if the number of negotiation-eligible drugs is less than 20).

3. Request for a Biosimilar Delay (§ 429.110)

a. Overview of the Requirements for a Delay in the Selection and Negotiation of Certain Biological Products With High Likelihood of Biosimilar Market Entry

Section 1192(b)(1)(C) of the Act requires the Secretary to remove from the ranked list of negotiation-eligible drugs (described in proposed § 429.105 and section II.B.2. of this proposed rule) any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. Specifically, section 1192(f)(1)(B) of the Act allows the manufacturer of a biosimilar biological product (defined at proposed § 429.20 as the "Biosimilar Manufacturer" of a Biosimilar) to submit a request, prior to the selected drug publication date for an initial price applicability year, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (defined at proposed § 429.20 as a "Reference Drug") on the selected drug list for such given initial price applicability year (which we refer to as a "Biosimilar Delay").

Section 1192(f) of the Act provides for two potential requests for a Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request" as defined in proposed § 429.20) under section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year

(“Additional Delay Request”) under section 1192(f)(1)(B)(i)(II) of the Act. Together, CMS refers to an Initial Delay Request and an Additional Delay Request as “Biosimilar Delay Requests” as defined in proposed § 429.20. Proposed § 429.110(b) through (f) address the requirements for a Biosimilar Manufacturer to submit a Biosimilar Delay Request and for CMS to determine if the inclusion of the Reference Drug on the selected drug list should be delayed due to such Biosimilar Delay Request. As set forth in proposed § 429.110(a), for purposes of the provisions at proposed § 429.110 and in our discussion of this section herein, all references to “marketed” or “marketing” mean Bona Fide Marketing as defined in proposed § 429.20 and set forth at proposed § 429.130(a). We discuss Bona Fide Marketing further in section II.B.6.d. of this proposed rule.

Biosimilar Manufacturers that believe that the Reference Drug of their Biosimilar may be a selected drug for an initial price applicability year may submit an Initial Delay Request for the first year and an Additional Delay request for the second year, and CMS would disregard that request if the Reference Drug would not, in fact, be a selected drug for an initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for drugs payable under Part B and/or covered under Part D, including data published by CMS, including but not limited to data on the Medicare Part B Drug Spending Dashboard¹⁶ and the Medicare Part D Drug Spending Dashboard,¹⁷ which may allow them to determine the likelihood that a given drug may be a selected drug.

As discussed in further detail in section IV. of this proposed rule, we are also proposing revisions to a currently approved information collection for a manufacturer to submit an Initial Delay Request, titled the Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Section 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10844, OMB 0938–1443) (hereinafter, the “Drug Selection ICR”), for a 60-day public comment period concurrently with this proposed rule. A form and manner for submitting a Biosimilar Delay Request, consistent with proposed § 429.110(f), would be

specified in the ICR for an initial price applicability year for an Initial Delay Request or an Additional Delay Request. As discussed in further detail in the accompanying 60-day package, we are including questions specific to an Initial Delay Request only within the ICR because CMS did not grant an Initial Delay Request for initial price applicability year 2028 and thus we are not including questions pertaining to submitting an Additional Delay Request for initial price applicability year 2029. We will expand the collection to include questions pertaining to an Additional Delay Request when necessary for an upcoming initial price applicability year when there is a Biosimilar Manufacturer that would be eligible to submit an Additional Delay Request after the granting of an Initial Delay Request. Information submitted in a Biosimilar Delay Request that is trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3), (4)).

For an Initial Delay Request, if we determine that an otherwise negotiation-eligible drug should be delayed from selection because of the requirements proposed in § 429.110(c), but the Biosimilar is not licensed and marketed based on the requirements proposed in § 429.110(h) during the Initial Delay Period (which we propose to define in § 429.20 as the time period between (1) the selected drug publication date for the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request, and (2) the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request), the Biosimilar Manufacturer would have the opportunity to submit an Additional Delay Request consistent with proposed § 429.110(e). If the Biosimilar Manufacturer fails to submit an Additional Delay Request or submits an Additional Delay Request that we determine does not meet all the requirements proposed in § 429.110(e), as proposed in § 429.110(h)(1)(ii), the Reference Drug would be included on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been

included on the selected drug list if not for the successful Initial Delay Request. However, we would not include the Reference Drug on such list if another biosimilar of the Reference Drug is marketed before the publication date of the list.

If the Biosimilar named in a successful Additional Delay Request is not licensed and marketed during the Second Delay Period (which we propose to define in § 429.20 as the time period between (1) the publication date of the selected drug list for initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request, and (2) the publication date of the selected drug list for initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request), as proposed in § 429.110(h)(2), the Reference Drug would be included on the selected drug list for the initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request(s). However, if another biosimilar of the Reference Drug is marketed prior to the publication date of such list, we would not include the Reference Drug on the list.

Additionally, as proposed in § 429.110(i)(1), if CMS delayed the selection and negotiation of a Reference Drug for 1 or 2 years, but the Biosimilar was not licensed and marketed, and the Reference Manufacturer agrees to an MFP for the Reference Drug, the Reference Manufacturer would owe a rebate to the Federal Supplementary Medical Insurance Trust Fund for drugs payable under Part B or the Medicare Prescription Drug Account for drugs covered under Part D for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the successful Biosimilar Delay Requests. Consistent with section 1192(f)(4) of the Act and as described in section II.B.3.c. of this proposed rule, proposed § 429.110(i) includes the proposed requirements for the calculation of the rebate.

Consistent with section 1198(2) of the Act and proposed § 429.30, there would no administrative or judicial review of CMS' determinations under section 1192(f) of the Act and in proposed § 429.110 regarding a Biosimilar Delay Request.

¹⁶ Available at: <https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard>. Of note, this dashboard excludes MA data for Part B beneficiaries.

¹⁷ Available at: <https://data.cms.gov/tools/medicare-part-d-drug-spending-dashboard>.

b. Requirements for Granting a Biosimilar Delay Request (§ 429.110(c) Through (f))

Section 1192(f)(1)(B)(ii)(I) of the Act requires that the request for the delay be made by the Biosimilar Manufacturer and cannot be initiated by a separate party, such as CMS or the Reference Manufacturer. The Biosimilar Manufacturer, as defined in proposed § 429.20, that is specifically eligible to submit the request is the BLA holder for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by the FDA. Also included in the definition of “Biosimilar Manufacturer” at proposed § 429.20, if neither the Biosimilar has been licensed nor the BLA has been submitted to FDA, the Biosimilar Manufacturer eligible to submit the request is the organization planning to be the sponsor of the BLA submitted for review by FDA. This approach, which is consistent with the policies for implementation as described in sections 30.3.1 through 30.3.1.5 of Negotiation Program Guidance, is appropriate because: (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay Request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year; and (2) the status of the application for licensure for the Biosimilar is material to CMS’ consideration of a Biosimilar Delay Request, as described in proposed § 429.110. For both an Initial Delay Request and an Additional Delay Request, certain requirements must be met for CMS to grant such requests. These requirements are included in proposed § 429.110(c) for an Initial Delay Request and proposed § 429.110(e) for an Additional Delay Request.

Section 1192(f)(1)(B)(ii)(I) and (II) of the Act requires the Biosimilar Manufacturer to make the request prior to the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer is requesting a Biosimilar Delay. As such, we are proposing at § 429.110(f) that a Biosimilar Manufacturer may submit to CMS a request for a Biosimilar Delay at the time and in a form and manner specified by CMS. Consistent with the process and timeline for previous initial price applicability years, CMS intends to collect requests via the CMS Health Plan Management System (CMS HPMS) and provide for a 30-day submission period as discussed in the Drug Selection ICR. We will not consider late or incomplete submissions. Upon

receipt of a complete Biosimilar Delay Request, CMS will consider whether the requirements are met, as applicable, in proposed § 429.110(c) for an Initial Delay Request or proposed § 429.110(e) for an Additional Delay Request.

With respect to Initial Delay Requests, we would first determine if the proposed requirements under proposed § 429.110(c)(1) have been met. Section 1192(f)(1)(A) of the Act and, as described in proposed § 429.110(c)(1)(i), requires that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act and proposed § 429.20, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests, this means that the Reference Drug must have received its initial BLA licensure at least 12 years, but fewer than 16 years, prior to the start of the relevant initial price applicability year. Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs (definition proposed at § 429.20). Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date for an initial price applicability year and before the Reference Manufacturer would have entered into an agreement under the Negotiation Program. Therefore, we continue to believe the exception to the definition of “extended-monopoly drug” in section 1194(c)(4)(B)(ii) of the Act would not apply at the time that a delay would be requested for initial price applicability year 2029. Accordingly, we believe the Biosimilar Delay Request process under section 1192(f) of the Act is applicable for future initial price applicability years. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2029, provided that the Reference Drug named in the request would have been licensed for at least 12 years but fewer than 16 years prior to the start of the initial price applicability year beginning on January 1, 2029.

Additionally, to qualify for an Initial Delay Request, section 1192(f) of the Act requires the following (as proposed in § 429.110(c)):

- In accordance with section 1192(f)(1)(A) of the Act and as described in proposed § 429.110(c)(1)(ii), the Reference Drug must include the reference product identified in the Biosimilar’s application for licensure under section 351(k) of the PHS Act that

has been approved or accepted for review by FDA. We note that to grant a Biosimilar Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval. With respect to the reference product, the Initial Delay Request may list the brand name and/or the name of the reference product’s active ingredient.

- In accordance with section 1192(f)(2)(D)(iii) of the Act and as described in proposed § 429.110(c)(iii), a Biosimilar Delay Request would not be granted if more than 1 year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.

- In accordance with section 1192(f)(2)(D)(iv) of the Act and as described in proposed § 429.110(c)(1)(iv)(A), the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same under section 1192(f)(1)(C) of the Act. For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC), or in a partnership, shall be treated as one manufacturer in accordance with section 1192(f)(1)(C) of the Act. For the purposes of this determination, “partnership” (as proposed at § 429.20) is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.

- In accordance with section 1192(f)(2)(D)(iv) of the Act and as described in proposed § 429.110(c)(1)(iv)(B), the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that—

- ++ Requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request; or

- ++ Directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

We would consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer is requesting a Biosimilar Delay, as failing to meet this requirement.

Once we determine the requirements proposed in § 429.110(c)(1) are met, we would then determine if there is a high likelihood, as required in section 1194(f)(1)(A) of the Act and as proposed in § 429.110(c)(2), that the Biosimilar will be licensed and marketed before the date that is 2 years after the statutorily defined selected drug publication date for the initial price applicability year for which the Reference Drug would be included on the selected drug list absent a successful Initial Delay Request (“High Likelihood Deadline,” as defined in proposed § 429.20). For example, the High Likelihood Deadline for an Initial Delay Request for initial price applicability year 2029 would be February 1, 2029. Specifically, in accordance with section 1192(f)(3) of the Act and consistent with implementation of the policies in section 30.3.1.3 of Negotiation Program Guidance Program, we propose in § 429.110(d) that there is a high likelihood the Biosimilar will be licensed and marketed before the High Likelihood Deadline if each of the following criteria are met:

- An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or licensed by FDA.
- Clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline.

We propose at § 429.110(d)(1) that CMS will specify the due date by which the application for licensure must be accepted for review or approved by the FDA, which will be a date before the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests a Biosimilar Delay in order to permit sufficient time for CMS to review the information and finalize the selected drug list prior to publishing the selected drug list for the initial price applicability year. This would enable CMS to use the most recent possible data to make this determination, while still allowing for sufficient time for such requests to inform the selected drug list prior to the selected drug publication date as required by section 1192(a) of the Act. If the Biosimilar’s application for licensure has not been accepted for review by the specified date, including in the case where the Biosimilar Manufacturer submitted an application for licensure that has not been accepted for review by FDA or for which a filing determination is pending, we would deny the Initial Delay Request. Additionally, CMS would consider an application for licensure under section 351(k) of the PHS Act that has been accepted for review and received a

complete response letter from the FDA to meet the section 1192(f)(3)(A) requirement that an application for licensure under section 351(k) for the biosimilar biological product has been accepted for review by FDA.

To demonstrate clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, we propose at § 429.110(d)(2) that the Biosimilar Delay Request must include information to demonstrate both: (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date, and so we believe that evidence showing that a Biosimilar meets these two requirements is sufficient to establish clear and convincing evidence that the Biosimilar will be marketed.

First, regarding the proposal at § 429.110(d)(2)(i) that the Biosimilar Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline: we will only consider patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. For example, if a Biosimilar Manufacturer has obtained licensure with biosimilar labeling that omits a patent-protected indication or other patent-protected information, then such patents that cover the omitted indication or the omitted information will not be considered to be “applicable to the Biosimilar”. Specifically, we propose at § 429.110(d)(2)(i)(A) through (D) that the Biosimilar Manufacturer must demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline through any of four pathways specified. The first option the Biosimilar Manufacturer may demonstrate is that there will be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. The second option the Biosimilar Manufacturer may demonstrate is that one or more court decisions or decisions by the United States Patent and Trademark Office (USPTO)’s Patent Trial and Appeal Board (PTAB) establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patents relating to the reference product included in the Reference Drug that a patent holder asserted was applicable to

the Biosimilar. The third option the Biosimilar Manufacturer may demonstrate is that neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer’s patent assertion(s) pertaining to unexpired patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar, and the Biosimilar Manufacturer has publicly announced a precise launch date for the Biosimilar that is both a calendar date before the High Likelihood Deadline and is not contingent on the outcome of pending litigation. Finally, the fourth option the Biosimilar Manufacturer may demonstrate is that the Biosimilar Manufacturer has a signed agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without improper constraints on the Biosimilar Manufacturer. In accordance with the parameters set forth in section 1192(f)(2)(D)(iv) of the Act and proposed § 429.110(c)(1)(iv) of this section, an improper constraint includes, but is not limited to: circumstances in which the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same pursuant to section 1192(f)(1)(C) of the Act; an instance in which the Biosimilar Manufacturer has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request; and an instance in which a Biosimilar Manufacturer has entered into an agreement with the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after the selected drug publication date of the initial price applicability year for which the Biosimilar Manufacturer is requesting a Biosimilar Delay.

Second, regarding the proposal at § 429.110(d)(2)(ii) that the Biosimilar Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, to assess this requirement, we propose to consider the Biosimilar Manufacturer’s progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before the High Likelihood Deadline; and (2) a

manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. We propose these criteria because we believe they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In accordance with sections 1192(f)(3)(B), CMS must use information from items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act submitted to CMS by the Biosimilar Manufacturer requesting the Biosimilar Delay to identify if there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. Consistent with these statutory requirements and the policies implementing section 30.3.1.3 of the Negotiation Program Guidance, we propose at § 429.110(f)(1)(i) through (iii) the information we would review for such “clear and convincing evidence,” which must include—

- All agreements related to the Biosimilar filed with the Federal Trade Commission (FTC) or the Assistant Attorney General under subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

- To the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and

- To the extent available, the Biosimilar Manufacturer’s disclosures pertaining to the marketing of the Biosimilar (for example, in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a Biosimilar.

To illustrate what information specifically that CMS might identify within such documentation to potentially demonstrate that the Biosimilar has a high likelihood of being marketed before the High Likelihood Deadline, we provide three examples of “clear and convincing evidence” that might be included in the documentation required at section 1192(f)(3)(B) of the Act and proposed in § 429.110(f)(1)(i) through (iii). These examples are

illustrative but alone may not always constitute “clear and convincing evidence” of a high likelihood of being marketed. First, we provide two examples of evidence that could potentially demonstrate that a patent (or patents) related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed: (1) the listing of a signed agreement between the Biosimilar and Reference Drug Manufacturers under “Legal Proceedings” or another section, as appropriate, in a Form 10–K, along with a copy of the agreement if required to be filed with the Federal Trade Commission (FTC) or the Assistant Attorney General under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and (2) the lack of any adverse actions from a court or PTAB under “Legal Proceedings” or another section, as appropriate, in a Form 10–K pertaining to a Biosimilar Manufacturer’s patent assertion(s) of an unexpired patent or patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar, and the Biosimilar Manufacturer publicly announced a precise launch date for the Biosimilar by a calendar date prior to the High Likelihood Deadline within the operational preparations and/or other steps to market and/or produce the Biosimilar under “Management’s Discussion and Analysis (MD&A)” or another section, as appropriate, in a Form 10–K. Second, we provide one example of evidence that could potentially demonstrate that the Biosimilar Manufacturer is operationally ready: information regarding the operational preparations and/or other steps to market and/or produce the Biosimilar under “MD&A” or another section, as appropriate, in a Form 10–K. These distinct examples are intended to be for illustrative purposes only and do not supersede the requirements of the originating authorities for the required documentation (for example, the Securities Exchange Act of 1934 governing disclosure requirements). Consistent with section 1192(f)(1)(B)(ii)(III)(bb) of the Act, comparable documentation that is distributed to the shareholders of privately held companies could be provided in lieu of any examples of disclosures required under the Securities Exchange Act of 1934 for publicly traded companies. These examples are not exhaustive of the information that might be included in the documentation required at section 1192(f)(3)(B) of the Act and in a

submission for a request for an Initial Delay Request necessary to demonstrate “clear and convincing evidence”.

Finally, consistent with section 1192(f)(1)(B)(ii)(II) of the Act and at proposed § 429.110(f)(2), we may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request after reviewing an Initial Delay Request. Any such written request would specify the additional information required, a form and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information.

As proposed at § 429.110(g)(1), we would provide in writing a notice of determination, on or after the selected drug publication date for the initial price applicability year by a specific date to be set forth by CMS, to the Biosimilar Manufacturer that requested the Initial Delay Request regarding whether the request was successful or unsuccessful. If unsuccessful, we would specify the reason for the unsuccessful request. Such reasons provided may include: (1) failure to submit all elements of the Biosimilar Delay Request by the applicable deadline (CMS–10844, OMB 0938–1443); (2) failure to meet another statutory requirement for granting a request (other than the high likelihood requirement), including in the case that the Reference Drug would not have been a selected drug for the initial price applicability year absent the Initial Delay Request; or (3) failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. We also propose at § 429.110(g)(1)(i)(B) to notify each Reference Manufacturer named in a successful Biosimilar Delay Request. We propose that such notification would be in writing and would identify the Reference Drug that would have been a selected drug in the initial price applicability year, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests would not be notified. We will publish the number of Reference Drugs that would have been selected drugs for the initial price applicability year, absent successful Initial Delay Requests, as part of publishing the selected drug list as proposed in § 429.100 and described in section II.B.1. of this proposed rule (see proposed § 429.110(g)(2)).

Section 1192(f)(2)(B) of the Act requires CMS to determine whether each Biosimilar named in a successful Initial Delay Request is licensed and

marketed during the Initial Delay Period. CMS proposes at § 429.110(h)(1) that we would determine whether each Biosimilar named in a successful Initial Delay Request was licensed and marketed during the Initial Delay Period. If we determine that the Biosimilar is not licensed and marketed during the Initial Delay Period, we propose at § 429.110(h)(1)(i) that the Biosimilar Manufacturer will have the opportunity to submit an Additional Delay Request. In proposed § 429.110(g)(3), for successful Initial Delay Requests submitted with respect to the initial price applicability year, we propose to notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is licensed and marketed during the Initial Delay Period by a date to be specified by CMS in technical guidance, which will be no later than the end of October of the calendar year of the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer submitted the successful Initial Delay Request. For example, if CMS determined that a Biosimilar Manufacturer's Initial Delay Request was successful for initial price applicability year 2029, CMS would provide this notification to the Biosimilar Manufacturer no later than the end of October 2027.

If the Biosimilar Manufacturer chooses to submit an Additional Delay Request, sections 1192(f)(2)(B)(i)(I) and (iii) include requirements for an Additional Delay Request. We propose these requirements in § 429.110(e), along with the corresponding documentation requirements in § 429.110(f). Consistent with section 1192(f)(2) of the Act, to first be eligible for an Additional Delay Request, we would need to determine that the Biosimilar listed in the Additional Delay Request was identified in a successfully granted Initial Delay Request (consistent with proposed § 429.110(c)) and the licensure and marketing under section 351(k) of the PHS Act has not commenced between the publication date of the selected drug list for the initial price applicability year for which the Initial Delay Request was granted and the date that is 1 year following that publication date. We propose these requirements at § 429.110(e)(1)(i) and (ii). Additionally, as a threshold requirement, we would determine that the requirements proposed at § 429.110(c)(1)(ii) through (iv) for an Initial Delay Request, in accordance with sections 1192(f)(1) and

(2) of the Act, remain met for purposes of the Additional Delay Request (see proposed § 429.110(e)(1)(iii)). Further, in accordance with section 1192(f)(2)(D)(ii) of the Act and as described in proposed § 429.110(e)(1)(iv), a Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is not eligible for an Additional Delay Request if the status of the Reference Drug would change to a long-monopoly drug (as defined in proposed § 429.20), with respect to the initial price applicability year for which the Biosimilar Manufacturer is submitting an Additional Delay Request. If the requirements proposed in § 429.110(e)(1)(i) through (iv) are met, we would then reevaluate and determine whether the requirements in proposed § 429.110(d) regarding whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline continue to be met as proposed in § 429.110(e)(2). Finally, in accordance with section 1192(f)(2)(B)(i)(II) of the Act and as described in proposed § 429.110(e)(3), we must determine, on the basis of clear and convincing evidence, that the Biosimilar Manufacturer has made a significant amount of progress towards both licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request. In accordance with section 1192(f)(2)(B)(i)(II) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar Manufacturer has made a significant amount of progress towards licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request for the Biosimilar: (1) all agreements related to the Biosimilar filed with the FTC or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (as described in section 1192(f)(1)(B)(ii)(I)(bb) of the Act); and (2) additional information and documents that CMS may request after CMS has reviewed the information required for submission of the Additional Delay Request necessary to make a determination about an Additional Delay Request (as described in section 1192(f)(1)(B)(ii)(II) of the Act).

Consistent with implementation of policies in section 30.3.1.4 of the Negotiation Program Guidance,

recognizing that approximately 1 year has passed since submission of the successful Initial Delay Request, we would consider whether the Biosimilar Manufacturer demonstrates that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. Specifically, we propose at § 429.110(e)(3) that the determination of whether a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar since the successful Initial Delay Request submission for such Biosimilar will be based on a holistic review of the documentation submitted with the Additional Delay Request (as described in proposed § 429.110(f)(1), including any follow-up documentation requests from CMS to the manufacturer described in proposed § 429.110(f)(2)). Within the request we would consider if the Biosimilar Manufacturer can demonstrate affirmative progress towards being operationally ready to market the Biosimilar, meaning that we would consider the Biosimilar Manufacturer's progress on the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug since the successful Initial Delay Request submission for the Biosimilar evidenced in any updates or supplements to the documents specified in section 1192(f)(1)(B)(ii)(III) of the Act and as described in proposed § 429.110(f)(1). Additionally, we would consider if the manufacturing schedule (as provided in § 429.110(f)(1)(ii)) is consistent with the public-facing statements (that may be identified within the information provided in the materials set forth at proposed § 429.110(f)(1)(iii)) and demonstrates readiness to meet revenue expectations.

After completing our review of an Additional Delay Request, similar to the process for notification after an Initial Delay Request, we would notify the Biosimilar Manufacturer that submitted the Additional Delay Request regarding CMS' determination of whether the Additional Delay Request was successful or unsuccessful (see proposed § 429.110(g)(1)(i)(A)). We also propose to notify the Reference Manufacturer of a successful Additional Delay Request (see proposed § 429.110(g)(1)(i)(B)) and would publish the number of Reference Drugs that would have been selected drugs for the initial price applicability year if they had not been determined eligible by CMS for a Biosimilar Delay Request for that initial price applicability year (see proposed § 429.110(g)(2)).

(c) Review For Failure of the Biosimilar To be Licensed and Marketed; Rebate Owed for Failure of a Biosimilar To be Licensed and Marketed (§ 429.110(h) through (i))

As discussed previously, CMS proposes at § 429.110(h)(1) that we would determine whether each Biosimilar named in a successful Initial Delay Request was licensed and marketed during the Initial Delay Period. If we determine that the Biosimilar is not licensed and marketed during the Initial Delay Period, we propose at § 429.110(h)(1)(i) that the Biosimilar Manufacturer will have the opportunity to submit an Additional Delay Request. In proposed § 429.110(h)(1)(ii), we propose that if the Biosimilar Manufacturer chooses not to submit an Additional Delay Request, or submits an Additional Delay Request that CMS determines does not meet all requirements in proposed § 429.110(e), CMS would include the Reference Drug on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request (for example, the selected drug list for initial price applicability year 2030 for successful Initial Delay Requests for initial price applicability year 2029), unless a different biosimilar biological product is marketed before the publication of the selected drug list for the applicable initial price applicability year, in which case CMS could also determine, in accordance with section 1192(c) of the Act and described in sections II.B.6.d. of this proposed rule, that the Reference Drug no longer meets the criteria to be a selected drug and will be excluded from such applicable list of drugs selected for an initial price applicability year. Further, in accordance with section 1192(f)(2)(C) of the Act and as described in proposed § 429.110(h)(2), CMS must determine whether each Biosimilar named in a successful Additional Delay Request is licensed and marketed during the Second Delay Period. We propose at § 429.110(h)(2)(i) that if CMS determines that the Biosimilar is not licensed and marketed during the Second Delay Period, unless a different biosimilar biological product is marketed, CMS would include the Reference Drug on the selected drug list for the initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request.

In accordance with sections 1192(f)(2)(B)(ii), 1192(f)(2)(C), and 1192(f)(4)(A) of the Act and as described in proposed § 429.110(i)(1), if (1) CMS delayed the selection and negotiation of a Reference Drug for 1 or 2 years, (2) CMS determined that the Biosimilar was not licensed and marketed, and (3) the manufacturer of the Reference Drug agrees to an MFP for the Reference Drug, the Reference Manufacturer is required to pay a rebate for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the delay. In accordance with section 1192(f)(4)(B) of the Act, we specify in proposed § 429.110(i)(4) that the rebate owed by the Reference Manufacturer, for the year for which an Initial Delay Request and, if applicable, an Additional Delay Request was granted will be calculated as follows:

- In accordance with section 1192(f)(4)(B)(i) of the Act and as described in proposed § 429.110(i)(4)(ii), in the case of a Reference Drug that is a drug covered under Part D, 75 percent of the difference between the AMP, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug multiplied by the number of units dispensed under Part D for the Reference Drug in each calendar quarter of the price applicability period that would have applied but for the delay.

- In accordance with section 1192(f)(4)(B)(ii) of the Act and as described in proposed § 429.110(i)(4)(iii), in the case of a Reference Drug payable under Part B, 80 percent of the difference between the payment amount under section 1847A(b) of the Act, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug, multiplied by the number of units of the billing and payment code of the Reference Drug administered or furnished under Part B (excluding units that are packaged into the payment amount for an item or service and are not separately payable under Part B) for each calendar quarter of the price applicability period that would have applied but for the delay.

- As described in proposed § 429.110(i)(4)(iv), in the case of a Reference Drug that is a drug covered under Part D and payable under Part B, the rebate amount will be calculated by summing the rebate amount for the units payable under Part B as specified in proposed § 429.110(i)(4)(iii) and the rebate amount for units covered under Part D as specified in proposed § 429.110(i)(4)(ii).

For the year for which an Additional Delay Request was granted, we will adjust the MFP as described in section 1195(b)(1)(A) of the Act to account for changes in the CPI-U. Additionally, before applying a rebate as described in proposed § 429.110(i)(5), we will determine if the Reference Drug transitioned to a long monopoly drug, at the time of its inclusion on the selected drug list for the initial price applicability year. For drugs payable under Part B and covered under Part D, we would calculate the rebate for the units payable under Part B following the Part B formula and we would calculate the rebate for the units covered under Part D following the Part D formula.

In the case of a Reference Drug that CMS determines transitioned to a long-monopoly drug during the delay, in accordance with section 1192(f)(4)(C) of the Act and as described in proposed § 429.110(i)(5) through (6), the rebate calculation will substitute the MFP negotiated for the Reference Drug with the following amount. The amount will be equal to 65 percent of the average non-FAMP (consistent with proposed § 429.20 and defined in 38 U.S.C. 8126(h)(5)) for 2021 (or the first full year following market entry if there is no non-FAMP for 2021) increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry) to September of the year prior to the selected drug publication date for the initial price applicability year that would have applied but for the Initial Delay Request. For example, if inclusion of the Reference Drug on the selected drug list is delayed until initial price applicability year 2030 due to a successful Initial Delay Request, and the Reference Drug transitions to a long-monopoly drug, the rebate calculation will use September of the year prior to the selected drug publication date for initial price applicability year 2029 (September 2026) for the purposes of adjusting for inflation the average non-FAMP for 2021. As described in proposed § 429.110(i)(6), the rebate calculation will substitute the MFP negotiated for the Reference Drug with the amount that is further adjusted by the annual percentage increase in the CPI-U for the 12-month period ending with July of the calendar year that is 2 years before the initial price applicability year for which the Additional Delay Request was granted.

In accordance with section 1192(f)(4)(B) of the Act and as described in proposed § 429.110(i)(4)(i), we intend to apply the MFP to the rebate calculation for all the previous initial applicability years where the Reference

Drug would have been on the selected drug list if not for the successful Biosimilar Delay Request. For example, if the Reference Drug would have been on the list for initial price applicability years 2029 and 2030 but for the approval of an Initial Delay Request and an Additional Delay Request, and CMS determines the Biosimilar was not licensed and marketed, we will use the MFP agreed to for initial price applicability year 2031 to calculate the rebate amount for initial price applicability years 2029 and 2030.

In accordance with section 1192(f)(4)(D) of the Act and as described in proposed § 429.110(i)(3), the rebates paid for drugs payable under Part B would be deposited in the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act. The rebates paid for drugs covered under Part D would be deposited in the Medicare Prescription Drug Account established under section 1860D–16 of the Act, which is within the Federal Supplementary Medical Insurance Trust Fund. Under proposed § 429.110(i)(2), we would specify a form and manner for the administration of rebates, including the timing and mechanism for notifying manufacturers when a rebate is owed and the process for payment, in future rulemaking.

4. Identification of Negotiation-Eligible Drugs (§ 429.115)

Section 1192(d)(1) of the Act requires that a “negotiation-eligible drug” means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in section 1192(e) of the Act, that is either a Part D high spend drug or a Part B high spend drug. Section 1192(d)(1)(A) of the Act describes a Part D high spend drug as a qualifying single source drug that is among the 50 qualifying single source drugs with the highest total expenditures under part D of Title XVIII, as determined by the Secretary in accordance with section 1192(d)(3) of the Act, during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date). Section 1192(d)(1)(B) of the Act describes a Part B high spend drug as a qualifying single source drug that is among the 50 qualifying single source drugs with the highest total expenditures under part B of Title XVIII, as determined by the Secretary in accordance with section 1192(d)(3) of the Act, during such most recent 12-month period describes in section

1192(d)(1)(A) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 30.2 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We are proposing to codify the statutory requirements in section 1192(d) of the Act at § 429.115, including that a negotiation-eligible drug for an initial price applicability year is a qualifying single source drug, as identified under proposed § 429.125, that is among the 50 qualifying single source drugs with the highest total expenditures under Part D, or among the 50 qualifying single source drugs with the highest total expenditures under Part B. We are proposing to codify our process for identifying the negotiation-eligible drugs for each initial price applicability year, consistent with the process implemented through prior guidance, as follows.

We propose at § 429.115(a)(1) to identify Part D high spend drugs described in section 1192(d)(1)(A) of the Act using the following steps. We would first remove from negotiation eligibility any qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act. Next, for remaining qualifying single source drugs, CMS would calculate a qualifying single source drug’s total expenditures under Part D using the methodology set forth at proposed § 429.120(a) and described in section II.B.5. of this proposed rule and rank those qualifying single source drugs by total expenditures under Part D during the total expenditures measurement period. Finally, we would identify the 50 qualifying single source drugs that have the highest total expenditures under Part D during the total expenditures measurement period (that is, Part D high spend drugs).

Then, we are proposing at § 429.115(a)(2) to identify Part B high spend drugs described in section 1192(d)(1)(B) of the Act using the following steps. As with Part D high spend drugs, we would first remove from negotiation eligibility any qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act.¹⁸ Next, for remaining qualifying single source drugs, CMS would calculate a qualifying single source drug’s total expenditures under Part B

using the methodology set forth at proposed § 429.120(b) and described in section II.B.5. of this proposed rule and rank the remaining qualifying single source drugs by total expenditures under Part B during the total expenditures measurement period. Finally, we would identify the 50 qualifying single source drugs that have the highest total expenditures under Part B during the total expenditures measurement period (that is, Part B high spend drugs).

We are proposing at § 429.115(b) that, when identifying Part D high spend drugs and Part B high spend drugs as proposed at § 429.115(a)(1)(iv) and (a)(2)(iv), respectively, if two or more qualifying single source drugs have the same total expenditures to the cent under Part D or Part B, and such total expenditures are the 50th highest among qualifying single source drugs under Part D or Part B, we would rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the earliest-approved FDA application belonging to the NDA/BLA holder and containing the active moiety/active ingredient in the drug, until we have identified 50 Part D high spend drugs and 50 Part B high spend drugs, respectively. These 50 Part D high spend drugs and 50 Part B high spend drugs, identified in accordance with proposed § 429.115(a)(1) and (a)(2), respectively, would be the negotiation-eligible drugs for the initial price applicability year. This proposal is a modification from Negotiation Program Guidance, which established that for initial price applicability years 2026, 2027, and 2028, we would identify qualifying single source drugs with the same total expenditures to the dollar. As noted in section II.B.2. of this proposed rule, we believe that using information to the cent, rather than to the dollar as under prior policy, is more precise for purposes of determining negotiation-eligible drugs.

5. Calculation of Total Expenditures (§ 429.120)

As described in sections II.B.2., II.B.4., and II.B.6.c.2. of this proposed rule, we are proposing at §§ 429.105(a), 429.115(a), and 429.125(e)(2) to calculate total expenditures under Part B and Part D as a step in the processes for identifying selected drugs, negotiation-eligible drugs, and drugs eligible for the low-spend Medicare drug exclusion, respectively. Section 1191(c)(5) of the Act defines the term “total expenditures” to include, in the case of expenditures with respect to Part D, the total gross covered prescription

¹⁸ This removal would encompass qualifying single source drugs that have been selected for initial price applicability years 2026 and 2027 based on Part D total expenditures.

drug costs (as defined in section 1860D–15(b)(3) of the Act). In the case of “total expenditures” with respect to Part B, section 1191(c)(5) of the Act specifies that such term excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service. With respect to initial price applicability years 2026 through 2028, we explained through guidance how we will implement the statutory requirement to calculate total expenditures under Part B and total expenditures under Part D, including, for example, section 30 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We are proposing to codify the definition of total expenditures in section 1191(c)(5) of the Act at § 429.20, and we propose how we would calculate total expenditures under Part B and Part D at § 429.120.

a. Calculation of Total Expenditures Under Part D

At § 429.120(a), we propose to calculate total expenditures under Part D for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug, as the sum of gross covered prescription drug costs for each PDE record for such drug that meets the criteria in proposed § 429.120(a)(1) through (a)(5). CMS would identify these PDE records as follows: (1) the dates of service are during the total expenditures measurement period (to allow a reasonable time for Part D plan sponsors to submit PDE data, we would use PDE data for the dates of service in the total expenditures measurement period that are available in CMS’ data repository by the November 30 following the total expenditures measurement period (or the first business day following November 30 if November 30 does not fall on a business day)); (2) total gross covered prescription drug costs on the PDE record is greater than zero dollars; (3) the PDE record is considered final action;¹⁹ (4) the drug coverage status code indicates the PDE record is for a drug covered under Part D; and (5) the compound code indicates the PDE record is not for a compounded drug.²⁰

¹⁹ A PDE record is considered final action based on the final action indicator for the claim and claim line.

²⁰ As described in Negotiation Program Guidance, we provide that, for operational reasons at this time, MFP refunds would not be required for PDE records for selected drugs that were billed as compounds. For alignment, we provide in proposed § 429.120 that PDE records with a compound code indicating the PDE record is for a compounded drug would be excluded from the PDE data used to calculate total expenditures under Part D used for the low-spend

b. Calculation of Total Expenditures Under Part B

At § 429.120(b), we propose a methodology for calculating total expenditures under Part B for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug. This methodology would use a combination of total allowed charges from Original Medicare (OM) Part B claims data (inclusive of beneficiary coinsurance and Medicare payment) and a comparable amount calculated using Medicare Advantage (MA) encounter data for Part B items and services, which would reflect the amount that would have been applicable under OM. Then, we would sum total expenditures under Part B based on OM Part B claims data and total expenditures under Part B for MA encounter data. To allow a reasonable time for providers and suppliers to submit OM Part B claims data and Medicare Advantage Organizations to submit MA encounter data for Part B items and services, we would use Part B data for the dates of service in the total expenditures measurement period that are available in CMS’ data repository by November 30 following the total expenditures measurement period (or the first business day following November 30 if November 30 does not fall on a business day).

We received many comments on the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028 suggesting that CMS should account for expenditures on drugs payable under Part B and administered to MA enrollees when identifying Part B high spend drugs. In response to these comments, we stated in the Negotiation Program Guidance that we agreed with these commenters

Medicare drug exclusion (proposed § 429.125(e)(2)) and to identify negotiation-eligible drugs and selected drugs (proposed §§ 429.115 and 429.105). We are proposing to apply this same exclusion to the ceiling for the MFP (proposed § 429.410), the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative(s) (proposed §§ 429.20 and 429.510(d)), and the application of the MFP across dosage forms and strengths (proposed § 429.700). A PDE record for a selected drug billed as a compound refers to a PDE record with a compound code field equal to “2=Compound.” We would only use PDE records with a compound code field equal to “1=Not a Compound.” A Part B claim billed as a compounded drug refers to Part B claims billed with HCPCS code J7999. For consistency with the treatment of compounded drugs covered under Part D, we also would exclude Part B claims billed as compounded drugs when calculating the low-spend Medicare drug exclusion, the identification of negotiation-eligible drugs and selected drugs, the ceiling for the MFP, and the application of the MFP across dosage forms and strengths.

that MA expenditures for such drugs should be accounted for and included in the calculation of total expenditures under Part B, and we described CMS’ methodology, consistent with the previous paragraph, for including such expenditures in the calculation of total expenditures under Part B. In this proposed rule, we reiterate and expand upon the discussion in the Negotiation Program Guidance.

More than half (54 percent²¹) of Medicare enrollees were enrolled in MA plans in 2025. We would therefore exclude a significant portion of total spending on drugs payable under Medicare Part B by only using Part B claims data in the calculation of total expenditures under Part B. Such an approach would skew the negotiation-eligible drug list toward drugs with high expenditures under Part D and away from drugs with high expenditures under Part B and therefore could misrepresent the highest spend drugs. There is no indication that statute intends the negotiation-eligible drug list to skew towards drugs with high expenditures under Part D; rather, section 1192(d)(1) of the Act indicates equal treatment of drugs with high expenditures under Part D and drugs with high expenditures under Part B, requiring CMS to identify 50 Part D high spend drugs and 50 Part B high spend drugs beginning in initial price applicability year 2028.

Consistent with the policy adopted in Negotiation Program Guidance, in this proposed rule we propose that the term “total expenditures under part B of Title XVIII” as defined at section 1191(c)(5) of the Act and as used in the Negotiation Program, is best read to include MA expenditures for drugs payable under Part B and administered to MA enrollees. In the case of expenditures with respect to Part B, section 1191(c)(5) of the Act provides only that the term “total expenditures” excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

Statutory language in Title XVIII of the Act and sections 11001 and 11002 of the IRA suggest MA expenditures ought to be included in “total expenditures under part B of title XVIII” for purposes of the Negotiation Program. First, section 1852(a)(1) of the Act requires MA plans to provide to enrollees the “benefits under the original [M]edicare [Fee-For-Service]

²¹ Nancy Ochieng et al., “Medicare Advantage in 2025: Enrollment Update and Key Trends,” KFF (July 28, 2025) <https://www.kff.org/medicare/medicare-advantage-enrollment-update-and-key-trends/>.

program option,” including, as relevant here, drugs payable under Part B. For purposes of determining “total expenditures” with respect to Part B for purposes of the Negotiation Program, we believe that MA expenditures for drugs payable under Part B may thus be understood as expenditures provided under this requirement to provide benefits available under Part B, and appropriately included in total expenditures under Part B for such drugs.

Further, section 1191(c)(2)(B) of the Act requires that, for purposes of the Negotiation Program, a “maximum fair price eligible individual” includes “in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of title XVIII, including an individual who is enrolled in an MA plan under part C of such title, if payment may be made under part B for such selected drug.” Including MA expenditures in the definition of total expenditures under Part B is consistent with the statutory approach reflected in this definition, which considers “individual[s] enrolled in an MA plan” to be “include[d]” within the reference to individuals “enrolled under part B of Title XVIII” to the extent “payment may be made under part B” for a selected drug.

Finally, section 1191(c)(5) of the Act’s definition of total expenditures under Part B identifies explicitly one exclusion—expenditures where payment for the drug is bundled with payment for another Part B service—but does not similarly exclude MA expenditures. As noted previously, the exclusion of MA expenditures would result in far more significant consequences for the identification of negotiation-eligible and selected drugs under the Negotiation Program than the exclusion that is identified explicitly. In light of the statutory indicia favoring inclusion of MA expenditures discussed previously and the significant consequences with respect to the Negotiation Program should MA expenditures be excluded, we believe the absence of clear statutory language excluding such expenditures weighs in favor of including MA expenditures in the definition of total expenditures under Part B.

For these reasons, we are proposing at § 429.120(b) a methodology to include MA expenditures in the calculation of total expenditures under Part B. As we noted in the Negotiation Program Guidance, MA encounter data for Part B items and services does not reliably include the actual amount paid by the

MA plan sponsor. Due to this gap in MA encounter data for Part B items and services, we believe it appropriate to estimate MA expenditures for drugs payable under Part B by using MA encounter data for Part B items and services to identify the units of drugs payable under Part B that were administered under MA and then determining what Medicare would have paid for such units under OM Part B. Accordingly, we propose to use the following methodology to calculate total expenditures under Part B:

- *Total expenditures under Part B based on OM Part B claims data* would equal the sum of the total allowed charges for each OM Part B claim for a qualifying single source drug that meets the following criteria: (1) date of service is during the total expenditures measurement period; (2) the claim type is associated with an OM Part B claim in an outpatient setting (including but not limited to clinics, Federally Qualified Health Centers, and ambulatory surgical centers), a professional services claim, or durable medical equipment claim (currently, these claim type codes are 40, 71, 72, 81, or 82); (3) the total allowed charges (defined as the amount that is inclusive of the beneficiary coinsurance and Medicare payment for covered Part B items and services) for the claim line is greater than \$0; (4) the claim is considered final action;²² (5) the claim is not billed as a compounded drug; and (6) the claim is not for a drug or biological product that is bundled or packaged into the payment for another service under Part B OM. We have identified rare instances where claims for separate payment have been submitted for drugs payable under Part B when such claims are typically payable only as part of a bundled payment. We are proposing to exclude such separately billed claims.

- *Total expenditures under Part B based on MA encounter data for Part B items* would equal the sum of the total allowed charges that would have been applicable under OM Part B for each MA encounter data record for Part B services for such drug that meets the following criteria: (1) date of service is during the total expenditures measurement period; (2) the claim type is associated with an MA encounter record in an outpatient setting (including but not limited to clinics, Federally qualified health centers, and ambulatory surgical centers), professional services, or durable

medical equipment record, as determined by CMS (currently, these claim types are 4012, 4013, 4014, 4022, 4023, 4032, 4034, 4071, 4072, 4073, 4074, 4075, 4076, 4077, 4079, 4083, 4085, 4087, 4089, 4700, and 4800); (3) the reported total number of units on the MA encounter data record line is greater than zero; (4) the encounter data record is considered final action;²³ (5) the encounter data record is not denied; (6) the encounter data record is not a chart review record; (7) the encounter data record line is not for a supplemental benefit; (8) the encounter data record is not reported as a compounded drug; and (9) the encounter data record is not for a drug or biological product that is bundled or packaged into the payment for another service under Part B OM. In instances where an encounter data record for separate payment is submitted for a drug payable under Part B when such a claim is typically payable under Part B OM payment rules only as part of a bundled payment, such claim will be considered to be bundled or packaged into the payment for another service and will not be included in the total allowed charges calculation. To calculate the total allowed charges that would have been applicable under OM Part B for each of the aforementioned MA encounter data records, we would first adjust the unit field in MA encounter data for Part B items and services by referencing the Medically Unlikely Edits (MUEs), which are designed to reduce improper payments.²⁴ Because Medicare Administrative Contractors apply these edits to OM Part B claims, this would bring the MA encounter data for Part B items and services into closer alignment. We would then multiply the adjusted units by the appropriate published payment limit (for example, Average Sales Price (ASP)-based) or payment rate (for example, Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center (ASC)) to calculate what would have been applicable for the Part B items and services under OM.

Typically, “single source drugs and biologicals” as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes; however, there may be cases where a qualifying single source drug is assigned to a HCPCS code with other products. In such cases, we are proposing to use the apportionment

²³ Final action for MA encounter data for Part B items and services indicates the encounter was accepted by CMS and not subsequently voided by the Medicare Advantage organization or superseded by another encounter accepted by CMS.

²⁴ See: <https://www.cms.gov/medicare/coding-billing/ncci-medicare>.

²² An OM Part B claim is considered final action based on the final action indicator for the claim and claim line.

methodology proposed in § 429.120(b)(3) wherein CMS would use ASP sales volume data to apportion Part B total expenditures based on the ratio of reported sales volume of the qualifying single source drug compared to reported sales volume of all products assigned to the HCPCS code to calculate the total expenditures under Part B.

6. Identification of Qualifying Single Source Drugs (§ 429.125)

Section 1192(e)(1) of the Act requires that the term “qualifying single source drugs” means, with respect to an initial price applicability year, subject to sections 1192(e)(2) through 1192(e)(4) of the Act, a covered part D drug (as defined in section 1860D–2(e) of the Act) that is described in section 1192(e)(1)(A) or section 1192(e)(1)(B) of the Act, or a drug or biological product for which payment may be made under part B of title XVIII that is described in section 1192(e)(1)(A) or section 1192(e)(1)(B) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example section 30.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We are proposing that, with respect to each initial price applicability year, a qualifying single source drug is a drug covered under Part D, a drug payable under Part B, or both, as such terms are defined at proposed § 429.20, that meets the statutory criteria set forth in section 1192(e) of the Act. Specifically, we propose in § 429.125(a)(1) to codify the requirements in section 1192(e)(1)(A) of that Act that, for drug products, a qualifying single source drug is a drug covered under Part D, payable under Part B, or both: (1) that is approved under section 505(c) of the FD&C Act and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the date of such approval; and (3) that is not the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act. We propose in § 429.125(a)(2) to codify the requirements in section 1192(e)(1)(B) of the Act that, for biological products, a qualifying single source drug is a drug covered under Part D, payable under Part B, or both: (1) that is licensed under section 351(a) of the Public Health Service Act (“PHS Act”) and marketed pursuant to such licensure; (2) for which, as of the selected drug

publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and (3) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

a. Identification of Potential Qualifying Single Source Drugs (§ 429.125(b))

To identify drugs or biological products for purposes of identifying qualifying single source drugs that meet the criteria in section 1192(e) of the Act, we propose to identify drugs and biological products that are potential qualifying single source drugs as described at proposed § 429.125(b).

Sections 11001 and 11002 of the IRA do not define what a “drug” or “biological product” is for purposes of identifying whether such a drug or biological product is a qualifying single source drug. However, the Act provides that a drug or biological product may have multiple dosage forms, strengths, formulations, package sizes, or package types, and multiple applications and approvals. Specifically, for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act, section 1192(d)(3)(B) of the Act states that CMS shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or package type of the drug. Likewise, section 1192(d)(3)(B) of the Act’s aggregation rule applies to the calculation of a drug or biological product’s total expenditures for purposes of determining whether such drug or biological product meets the low-spend Medicare drug exclusion from a qualifying single source drug, described in section 1192(e)(3)(B) of the Act. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures “to compute and apply the MFP different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.” In addition, section 1194(e)(1)(D) of the Act instructs CMS, for purposes of the negotiation process (discussed in further detail in section II.F. of this proposed rule), to consider, among other information, “applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act,” in the plural, for the “drug,” in the singular.

Different dosage forms and strengths, as well as different formulations, of a drug or biological product, containing

the same active moiety/active ingredient, may be approved or licensed in multiple NDAs or BLAs. Defining a potential qualifying single source drug on the basis of a single NDA/BLA, and thereby excluding from such potential qualifying single source drug dosage forms and strengths and new formulations of the drug or biological product approved or licensed under other NDAs/BLAs, would be inconsistent with these statutory provisions. To give full effect to all relevant provisions of the statute, including sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act, we are proposing at § 429.125(b) a process, consistent with policies for implementation as described in, for example, section 30.1 of the Negotiation Program Guidance subject to proposed modifications as noted herein, to identify a potential qualifying single source drug, for purposes of identifying qualifying single source drugs that meet the statutory criteria under section 1192(e) of the Act, using the specific constituent dosage forms and strengths (at the NDC–9 or NDC–11 level) that are identified as aggregated under the same NDA/BLA holder for the same active moiety/active ingredient.²⁵ The policies proposed in § 429.125(b), like the policies in, for example, section 30.1 of the Negotiation Program Guidance, would address how CMS is interpreting the statutory directive in section 1192(e) of the Act to identify “drug[s]” or “biological product[s]” for purposes of evaluating whether such drug or biological product satisfies the criteria for qualifying single source drugs.

For drugs, we are proposing at § 429.125(b)(1) to identify a potential qualifying single source drug using all dosage forms and strengths of the drug with the same active moiety and the same holder of an NDA, inclusive of products that are marketed pursuant to different NDAs. If there are multiple NDAs with the same active moiety that include non-identical names reported for the NDA holder, including situations where it appears the NDA holder name has not yet been updated, we are proposing that we may further investigate whether such NDA(s) are held by the same entity for the purposes

²⁵ In the context of identifying qualifying single source drugs and calculating total expenditures for purposes of identifying negotiation-eligible drugs and selected drugs, in this proposed rule we use the term “aggregation” to refer to the process of identifying the formulations and dosage forms and strengths that constitute a qualifying single source drug, and that, if applicable, CMS will use to calculate total expenditures when determining whether such drug is a negotiation-eligible drug or selected drug.

of identifying a potential qualifying single source drug using FDA sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug would also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentences that are: (1) repackaged and relabeled products (defined at proposed § 429.20 to be consistent with 21 CFR 207.1) that are marketed pursuant to such NDA(s); (2) authorized generic drugs (defined in section 1192(e)(2)(B)(i) of the Act and at proposed § 429.20 and described further later in this section) that are marketed pursuant to such NDA(s); or (3) multi-market approval (MMA)²⁶ products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s). Any dosage forms and strengths of the drug with the same active moiety that are distributed by a private label distributor and marketed pursuant to such NDAs would also be aggregated in the potential qualifying single source drug of that NDA holder consistent with the policies for implementation as described in, for example, section 30.1 of the Negotiation Program Guidance.

For biological products, we are proposing at § 429.125(b)(2) to identify a potential qualifying single source drug using all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a BLA, inclusive of products that are marketed pursuant to different BLAs. If there are multiple BLAs with the same active ingredient (or the same antigen component for a biological product that is a vaccine for infectious disease(s), as further described later in this section) that include non-identical names reported for the BLA holder, including situations where it appears the BLA holder name has not yet been updated, we are proposing that we may further investigate whether such BLA(s) are held by the same entity for the purposes of identifying a potential qualifying single source drug using FDA sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug would also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentences

that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s); (2) authorized generic drugs, the definition of which at section 1192(e)(2)(B)(ii) of the Act and proposed § 429.20 (described further later in this section) includes unbranded biological products that are marketed pursuant to such BLA(s); or (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s). Any dosage forms and strengths of the biological product with the same active ingredient that are distributed by a private label distributor and marketed pursuant to such BLAs would also be aggregated in the potential qualifying single source drug of that BLA holder consistent with the policies for implementation as described in, for example, section 30.1 of the Negotiation Program Guidance.

Although assessing biological products on the basis of their active ingredient is appropriate in most circumstances, we understand that a discrete category of biological products—namely, vaccines for infectious disease(s)—are more appropriately assessed using their antigen component due to the evolving nature of pathogen strains over time. Therefore, and as proposed at § 429.125(b)(3), in the context of vaccines for infectious disease(s), we would identify a potential qualifying single source drug on the basis of such vaccines' antigen component on such vaccines' labeling, as accessed in public sources such as those discussed later in this section. We believe our proposal to identify drugs based on their active moiety and biological products based on their active ingredient, subject to the proposal for vaccines for infectious disease(s), is the best reading of the statutory directives in sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act as they relate to identifying qualifying single source drugs. We note further that in the context of drugs, “active moiety” (as contrasted with “active ingredient”) describes the active molecule or ion in the drug, as this term excludes those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule.²⁷ The term “active moiety” is not applicable in the context of biological products, and it is thus appropriate to evaluate biological

products based on their active ingredient.

Consistent with the policies for implementation as described in Negotiation Program Guidance, we are proposing to use public sources such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify the active ingredient/active moiety/antigen component of the drug or biological product. We may also consult with FDA as appropriate, for example, to clarify whether a suffix or prefix in an active moiety/active ingredient/antigen component name represents a genuine difference in active moiety/active ingredient/antigen component.

Section 1192(e)(2)(A) of the Act states that an authorized generic drug and the qualifying single source drug that includes the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act and in proposed § 429.20 as: (1) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act); and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act²⁸ and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product. We are proposing at § 429.125(b)(1)(iii) that a potential qualifying single source drug that is a drug is inclusive of authorized generic drugs that are marketed under the NDA(s) described therein, and at proposed § 429.125(b)(2)(iii) that a potential qualifying single source drug that is a biological product is inclusive of authorized generic drugs that are marketed under the BLA(s) described therein.

(1) Fixed Combination Drugs

At proposed § 429.125(b)(4), for the purpose of identifying potential qualifying single source drugs and subject to the narrow modification for certain fixed combination drugs proposed at § 429.125(b)(4)(i) to clarify our treatment of new formulations, we

²⁶ See: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-and>.

²⁷ See 21 CFR 314.3(b) (defining the terms “active ingredient” and “active moiety”).

²⁸ CMS is interpreting the reference to “licensed under section 351(a) of such Act” to mean licensed or deemed licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.

propose that if a drug is a fixed combination drug (defined in proposed § 429.20) with two or more active moieties, active ingredients, or, for vaccines for infectious disease(s), antigen components, the distinct combination of active moieties, active ingredients, or antigen components would generally be treated as one active moiety, active ingredient, or antigen component. Therefore, all formulations with this distinct combination offered by the same NDA/BLA holder would be aggregated across all dosage forms and strengths of the fixed combination drug (that is, all formulations and dosage forms and strengths of this distinct combination would be considered the same potential qualifying single source drug and, if applicable, CMS would aggregate total expenditures for all such formulations and dosage forms and strengths when determining whether such drug is a negotiation-eligible drug or selected drug). Under this proposal, a product containing only one (but not all) of the active moieties, active ingredients, or antigen components that is offered by the same NDA/BLA holder would generally not be aggregated with the formulations of the fixed combination drug and would be considered a separate potential qualifying single source drug. For example, a corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA/BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

In the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028, we stated our belief that treating distinct combinations of active moieties/active ingredients as one active moiety/active ingredient for the purpose of identifying potential qualifying single source drugs is generally appropriate. However, we acknowledged that there may exist fixed combination drugs for which one of the active ingredients or active moieties contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference. We solicited comments on whether the addition of drugs payable under Part B may impact the fixed combination drug policy described in the draft guidance. In particular, we solicited comments on how CMS might consider grouping such fixed combination drug products with

products containing at least one but not all of the active moiety(ies)/active ingredient(s) into the same potential qualifying single source drug for both drugs payable under Part B and/or covered under Part D, including input on terminology that could facilitate the effectuation of such a policy.

We received many comments in response to this comment solicitation. Some commenters supported a modification to the fixed combination drug policy as a way to close a loophole for manufacturers to avoid selection by making minor changes to existing drugs, specifically citing the addition of hyaluronidase to drugs payable under Part B. Other commenters opposed such a modification, citing concerns that CMS lacks the statutory authority to do so, that the approach described in the comment solicitation does not align with how FDA regulates and reviews the approvals of fixed combination drugs, or that CMS would not be able to apply a consistent definition to the terminology described in comment solicitation, including the terms “biologically active against the disease state” or “clinically meaningful difference”. Some commenters raised concerns that the modification would potentially harm patients and discourage the innovation of pharmaceutical manufacturers. In the Negotiation Program Guidance, we stated that, due to the complexity and scope of the issue as noted in the stakeholder comments, we believed additional time would be necessary to develop objective policy criteria if we were to finalize such a policy, and thus did not make a change to the fixed combination drug policy in the Negotiation Program Guidance. We stated our intent to address the program integrity risk posed by certain fixed combination drugs and that we were continuing to consider appropriate policy to potentially propose in rulemaking for initial price applicability year 2029 and subsequent years.

Since publishing the Negotiation Program Guidance, we have continued to consider program integrity risks posed by certain fixed combination drugs. Specifically, we are aware of a program integrity risk in which, under Negotiation Program policies for identifying qualifying single source drugs set forth in guidance with respect to previous initial price applicability years, a manufacturer may avoid selection of a qualifying single source drug or, in the case that a qualifying single source drug becomes a selected drug, avoid the application of the MFP, by marketing a new formulation of the qualifying single source drug that

includes, in addition to the active moiety(ies)/active ingredient(s)/antigen component(s) in the original qualifying single source drug, an active moiety, antigen component, or active ingredient, such as hyaluronidase, that enables an alternative route of administration for the shared active moiety(ies)/active ingredient(s)/antigen component(s) in the original qualifying single source drug. Under the general fixed combination drug policy set forth in guidance with respect to previous initial price applicability years, including, for example, section 30.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028, CMS is aware that such a manufacturer may avoid having all dosage forms and strengths of a drug, including the new formulation of such drug, with its active moiety(ies)/active ingredient(s)/antigen component(s) included in a qualifying single source drug in instances in which a new formulation differs from other formulations of the qualifying single source drug based on the inclusion of an additional active moiety/active ingredient/antigen component that enables an alternative route of administration for the shared active moiety(ies)/active ingredient(s)/antigen component(s).

In this scenario, we are concerned that application of CMS’ general fixed combination drug policy would be in tension with statutory requirements under sections 1192(d)(3)(b) and 1196(a)(2) of the Act because we would not aggregate together the original qualifying single source drug and the new formulation containing the additional active moiety/active ingredient/antigen component, even though these may be appropriately understood as different formulations of the same drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

First, application of the general fixed combination drug policy to such products would be in tension with section 1192(d)(3)(B) of the Act in the course of drug selection because we would not treat the original qualifying single source drug and the new formulation containing the additional active moiety/active ingredient/antigen component as one qualifying single source drug. Thus, when determining whether a qualifying single source drug is a negotiation-eligible drug, as proposed at § 429.115, we would calculate the combined total expenditures under Part B and Part D separately for the original qualifying single source drug and the new formulation. We believe that separately calculating total expenditures for such products under these circumstances

may be inconsistent with the statutory direction at section 1192(d)(3)(B) of the Act to use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, in determining whether a qualifying single source drug is a negotiation-eligible drug. Because under the general fixed combination drug policy we would evaluate the original qualifying single source drug and the new formulation separately during the drug selection process, the time since approval or licensure (determined as proposed at § 429.125(c)) for the new formulation would likely be later than for the original qualifying single source drug, thereby extending the years before which the new formulation could potentially be selected and, if selected and if an MFP is agreed to, be subject to an MFP. This dynamic presents program integrity risks because evaluating the time since approval or licensure separately for the original qualifying single source drug and the new formulation and splitting combined total expenditures under Part B and Part D between such products could lead to a scenario where the original qualifying single source drug or the new formulation or both are never selected or are not selected until a future initial price applicability year, which would reduce or delay the ability of the Negotiation Program to negotiate MFPs for high expenditure, single source drugs and biological products.

Second, if the original qualifying single source drug is selected for negotiation, and a negotiated MFP is agreed upon for that drug, the general fixed combination drug policy may be in tension with section 1196(a)(2) of the Act, which directs CMS to apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulations or package size or package type of such drug, because the MFP would not apply to the new formulation. This dynamic presents further program integrity risks. If the new formulation is not part of the selected drug, then the Primary Manufacturer would be able to market the new formulation without the new formulation being subject to MFP effectuation requirements, thereby creating a new incentive for the Primary Manufacturer to drive patient utilization toward the new formulation and circumvent the application of the MFP to the original qualifying single source drug for such patients.

To address these program integrity risks, and to clarify how CMS interprets sections 1192(d)(3)(B) and 1196(a)(2) of the Act as applied to new formulations of a drug, including in the context of

fixed combination drugs, we are proposing at § 429.125(b)(4)(i) a narrow modification to the application of the general fixed combination drug policy: if CMS determines that a fixed combination drug with two or more active moiety(ies), active ingredient(s), or, for a vaccine for infectious disease(s), antigen component(s) shares one or more active moiety(ies), active ingredient(s), or antigen component(s) with another drug or biological product(s) with the same NDA/BLA holder, and such products differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), CMS would, for purposes of identifying the potential qualifying single source drug under proposed § 429.125(b)(1) and (b)(2), use all dosage forms and strengths of the drug or biological product with the shared moiety(ies), active ingredient(s), or antigen component(s) and the same NDA/BLA holder. In other words, we would identify the potential qualifying single source drug as including all dosage forms and strengths with the shared active moiety(ies), active ingredient(s), or antigen component(s) that is offered by the same NDA/BLA holder. An example is the inclusion of active ingredient X with a different active ingredient Y, where active ingredient X creates a new formulation and enables an alternative route of administration for active ingredient Y. In the described example and as set forth in proposed § 429.125(b)(4)(i), CMS would identify the potential qualifying single source drug using all dosage forms and strengths of the drug or biological product that contain active ingredient Y and share the same BLA holder.²⁹

We are proposing the policy at § 429.125(b)(4)(i) at this time because the program integrity concerns this policy would address relate primarily to biologics that are more likely payable under Part B, and drugs were not selected based on total expenditures under Part B until initial price applicability year 2028. The program

²⁹ If a drug product or biological product included active moiety/active ingredient/antigen component X, active moiety/active ingredient/antigen component Y, and an additional active moiety/active ingredient/antigen component Z that did not meet the criteria set forth in proposed § 429.125(b)(4)(i), CMS would not include such drug product or biological product under the same potential qualifying single source drug.

integrity concerns raised by fixed combination drugs that are new formulations have not yet impacted drug selection but may soon as more drugs with significant total expenditures under Part B become qualifying single source drugs and negotiation-eligible drugs. We do not believe that significant reliance interests have arisen around the fixed combination policy established in Negotiation Program guidance for initial price applicability years 2026 through 2028, as incentives for pharmaceutical manufacturers to develop new formulations like the ones we propose to address in this policy long predate the Negotiation Program. In the absence of this proposed policy, however, pharmaceutical manufacturers may have increased incentives under Negotiation Program policy to drive patient utilization toward new formulations that would be treated as distinct qualifying single source drugs, and if selected, as distinct selected drugs.

This proposal incorporates feedback from commenters that raised concerns about how we would operationalize terms used in the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028, such as “biologically active against the disease state”. We understand from these commenters’ concerns the importance of developing a modification to the general fixed combination drug policy that is narrowly tailored to the development of new formulations that pose program integrity concerns and does not group products together under the same potential qualifying single source drug beyond what the statute permits. Additionally, we understand the importance of developing criteria that allow the narrow modification to be operationalized in a consistent and objective manner over a large set of active moieties/active ingredients/antigen components. We believe that the terminology proposed at § 429.125(b)(4)(i) would achieve both these goals.

First, we believe the criteria proposed at § 429.125(b)(4)(i) can be operationalized in a consistent and objective manner using public sources. Specifically, we are proposing to use public sources such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA’s Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify the active moiety(ies)/active ingredient(s)/antigen component(s) of the drug or biological products, as described in section II.B.6.a. of this proposed rule, and to use public sources such as, but not limited

to, Orange Book, Purple Book, Drugs@FDA, and DailyMed to identify the routes of administration of the fixed combination drug and the drug or biological product with the same NDA/BLA holder that shares one or more active moiety(ies)/active ingredient(s)/antigen component(s) with the fixed combination drug. We may also consult with FDA, as appropriate. We solicit comments on recommended approaches to inform CMS identification of active moiety(ies)/active ingredient(s)/antigen component(s) that enable a new route of administration for co-administered active moiety(ies)/active ingredient(s)/antigen component(s), including what types of information or descriptions we should look for within product labeling when identifying such cases.

Second, focusing on active moieties/active ingredients/antigen components that enable an alternative route of administration would reduce the number of products qualifying for the narrow modification as compared to the previous language citing active moieties/active ingredients not biologically active against the disease state(s) for which the drug is indicated. For example, we believe that the terminology proposed at § 429.125(b)(4)(i) would currently only impact biological products licensed in BLAs.

In developing this proposed policy, CMS also considered other feedback from commenters on our prior proposal to modify our fixed combination drug policy. As we noted in the Negotiation Program Guidance, many commenters raised concerns that a modification to CMS' fixed combination drug policy would not align with how FDA regulates and reviews the approvals of fixed combination drugs. We considered this feedback but maintain that the language at proposed § 429.125(b)(4)(i) clarifies how CMS would comply with sections 1192(d)(3)(B) and 1196(a)(2) of the Act for fixed combination drugs that are new formulations, and the commenters' suggestion that CMS must treat fixed combination drugs in the same manner as what such commenters assert is how the FDA may treat such products under FDA authorities is not persuasive in this instance. This proposal to identify such products as a single potential qualifying single source drug reflects CMS' proposed interpretation of sections 1192(d)(3)(B) and 1196(a)(2) of the Act and would solely be for the purposes of implementing the Negotiation Program.

We also considered comments on how a modification to CMS' fixed combination drug policy would potentially impact pharmaceutical

innovation. Although a few commenters stated a modification to the fixed combination drug policy would potentially harm patients by discouraging the innovation of pharmaceutical manufacturers, another commenter noted that manufacturers already have substantial financial motivations beyond the Negotiation Program to pursue the development of new formulations—including new formulations that are fixed combination drugs—to delay generic or biosimilar competition. We agree with this latter argument and note further our belief that the policy proposed at § 429.125(b)(4)(i) would effectuate section 1192(d)(3)(B) and 1196(a)(2) of the Act, address the program integrity concerns in the Negotiation Program that we and commenters have identified, while not meaningfully impacting incentives for innovation. We also reiterate our statement in the Negotiation Program Guidance that we are committed to a negotiation process that recognizes the clinical benefit of products, including products with different dosage forms and strengths, formulations or routes of administration from other products that are aggregated as part of the same qualifying single source drug, and we direct readers to proposed § 429.510(e) and section II.F.3.d.1. of this proposed rule for discussion of CMS' approach to adjusting the starting point for an initial offer based on section 1194(e)(2) factors, which includes factors related to clinical benefit as compared to therapeutic alternatives.

(2) Alternatives Considered

We considered expressly limiting the proposed modification of the application of the general fixed combination drug policy to biological products (other than vaccines for infectious disease(s) identified at proposed § 429.125(b)(3)), as currently such biological products licensed in BLAs pose the program integrity risks of which we are currently aware. However, in line with our aim to apply the statutory requirements at sections 1192(d)(3)(B) and 1196(a)(2) of the Act equally to all new formulations of a drug, whether the new formulation is approved in an NDA or licensed in a BLA, and to account for the possibility that the narrow modification for fixed combination drugs proposed at § 429.125(b)(4)(i) could apply to drugs in the future, we are not proposing to limit the proposed modification to these biological products. This approach would ensure that we are treating new formulations equally, whether that new

formulation is a drug or biological product.

We also considered proposing an alternative modification to the general fixed combination drug policy that would target the program integrity risk as described in the Negotiation Program Guidance wherein CMS identification of potential qualifying single source drugs under the fixed combination drug policy would not take into account an active moiety, active ingredient, or antigen component that is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference from other drug or biological products that otherwise have the same active moiety(ies)/active ingredient(s)/antigen component(s). However, we are instead proposing to focus on products that differ in active moiety(ies)/active ingredient(s)/antigen component(s) due to the inclusion of an active moiety/active ingredient/antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies)/active ingredient(s)/antigen component(s). As noted in section II.B.6.a.1. of this proposed rule, we believe the proposed approach narrowly addresses the program integrity risks with the general fixed combination policy and the specific elements of the policy that are in tension with section 1192(d)(3)(B) of the Act, which directs CMS to aggregate across dosage forms and strengths, including new formulations of the drug, and section 1196(a)(2) of the Act, which directs CMS to apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulations or package size or package type of such drug.

We considered maintaining the policy established for initial price applicability years 2026 through 2028, wherein, for a fixed combination drug with two or more active moieties/active ingredients/antigen components, we would treat the distinct combination of active moieties/active ingredients/antigen components as one active moiety/active ingredient/antigen component. However, for the reasons described in section II.B.6.a.1. of this proposed rule, we believe that this policy poses program integrity risks and is in tension with sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

Finally, we considered proposing policy to address program integrity risks posed by co-packaged drugs. In the Negotiation Program Guidance, we stated that the general fixed combination drug policy would apply to a co-packaged drug, in which two active moieties/active ingredients are not co-

formulated but rather co-packaged and sold in a single package, but that we may address co-packaged drugs in rulemaking for initial price applicability year 2029 and subsequent years. That is, for purposes of the Negotiation Program in initial price applicability year 2028, if a drug (including a co-packaged drug) contained two or more active moieties/active ingredients/antigen components, the distinct combination of active moieties/active ingredients/antigen components would be considered as one active moiety/active ingredient/antigen components for the purpose of identifying potential qualifying single source drugs, whether such drug was co-formulated or co-packaged. After further consideration, and based on our assessment that at this time co-packaged drugs do not appear to pose substantive program integrity risks to the Negotiation Program because manufacturers are not adopting co-packaging practices that abuse current program policies, we are proposing that the general fixed combination drug policy at proposed § 429.125(b)(4) continue to apply to co-packaged drugs. We are monitoring this approach and potential gaming of co-packaged drugs and may consider revisiting this policy in the future.

We solicit comments on our proposal and these alternatives.

b. Time Since Approval or Licensure (§ 429.125(c))

In accordance with section 1192(e)(1) of the Act and consistent with policies for implementation as described in Negotiation Program Guidance, and accounting for the treatment of certain former orphan drugs in accordance with section 1192(e)(4) of the Act as addressed in proposed § 429.125(c)(3), we are proposing at § 429.125(c)(1) and (c)(2) that at least 7 years (for drugs) or 11 years (for biological products) must have elapsed between the FDA date of approval or licensure of the potential qualifying single source drug identified at proposed § 429.125(b) and the selected drug publication date with respect to an initial price applicability year. To determine the date of approval for a potential qualifying single source drug that is a drug with more than one FDA application number, we would use the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing the active moiety (or in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), for the distinct combination of active moieties). For a potential qualifying single source

drug identified under § 429.125(b)(4)(i) that is a drug, we would use the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing the shared active moiety(ies) used to identify the potential qualifying single source drug. To determine the date of licensure for a potential qualifying single source drug that is a biological product (except in the case of a vaccine for infectious disease(s), for which we would determine the date of licensure as described later in this section) with more than one FDA application number, we would use the initial date of licensure associated with the earliest-approved FDA application belonging to the BLA holder and containing the active ingredient (or in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), for the distinct combination of active ingredients). For a potential qualifying single source drug identified under § 429.125(b)(4)(i) that is a biological product, we would use the initial date of licensure associated with the earliest-approved licensure of the FDA application belonging to the BLA holder and containing the shared active ingredient(s) used to identify the potential qualifying single source drug.³⁰ Consistent with prior initial price applicability years, we are also proposing that the identification of the earliest-approved FDA application belonging to the NDA/BLA holder and containing the active moiety/active ingredient, respectively, would be made irrespective of whether the indication(s) approved in such NDA/BLA were or are covered under Part D or payable under Part B or both. We would determine whether a product is not covered under Part D or payable under Part B at the NDC-11 level via the Primary Manufacturer's submission of information on NDC-11s as proposed at § 429.100(d) and described in section II.B.1. of this proposed rule.

As described in section II.B.6.a. of this proposed rule, to give full effect to all relevant provisions of the statute, including sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act, we are proposing to identify a potential qualifying single source drug using the specific constituent dosage

forms and strengths that are identified as aggregated under the same NDA/BLA holder for the same active moiety/active ingredient, inclusive of products that are marketed under different NDAs/BLAs. Therefore, to identify the date of approval or licensure, as applicable, for a potential qualifying single source drug with more than one FDA application, sections 1192(e)(1)(A)(ii) and 1192(e)(1)(B)(ii) of the Act require CMS to use the initial approval or licensure date associated with the earliest-approved FDA application for such potential qualifying single source drug to ensure that CMS captures the full time since the earliest product in the potential qualifying single source drug was approved or licensed.

To provide an example for how we would determine the approval or licensure date set forth at proposed § 429.125(c)(1) and (c)(2), respectively, the selected drug publication date for initial price applicability year 2029 is February 1, 2027, consistent with section 1191(b)(3) of the Act and proposed § 429.20. As such, for initial price applicability year 2029, the initial date of approval for a drug to be considered a qualifying single source drug must have been on or before February 1, 2020, and the initial date of licensure for a biological product to be considered a qualifying single source drug must have been on or before February 1, 2016.

We are aware that some manufacturers of vaccines for infectious disease(s) update the antigen component(s) of their products through supplemental BLAs. Consistent with the policies for implementation as described in Negotiation Program Guidance, for each unique potential qualifying single source drug that CMS identifies based on its antigen component(s) in accordance with proposed § 429.125(b)(3), we are proposing at § 429.125(c)(2)(i) that CMS will use the initial date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of identifying the starting date from which to measure the 11 years described in proposed § 429.125(c)(2).

Additionally, consistent with the policies for implementation as described in Negotiation Program Guidance and as proposed in § 429.125(c)(2)(ii), for biological products with an approved NDA that was deemed to be a BLA on March 23, 2020, in accordance with section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed biological products under

³⁰ The determination of the date of licensure for a potential qualifying single source drug that is a biological product, including a potential qualifying single source drug identified under § 429.125(b)(4)(i), is subject to the proposals at § 429.125(c)(2)(i) and (c)(2)(ii) for a biological product that is a vaccine for infectious diseases, and a biological product with an approved NDA that was deemed to be a BLA.

section 351 of the PHS Act (hereinafter “deemed biologics”), we would consider March 23, 2020 to be the licensure date for purposes of identifying the starting date from which to measure the 11 years described in proposed § 429.125(c)(2).³¹

In accordance with section 1192(e)(4) of the Act and as proposed at § 429.125(c)(3), if, as of the date of a drug or biological product’s initial approval or licensure, such drug or biological product met or meets the criteria for the orphan drug exclusion proposed at § 429.125(e)(1), we would measure the 7- and 11-year periods identified in proposed § 429.125(c)(1) and (c)(2) starting from the first day after such initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion at proposed § 429.125(e)(1). We would identify this day as the earlier of (1) the date on which the FDA approves such drug or biological product for an indication for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act; or (2) the date on which an orphan drug designation is withdrawn, if that withdrawal results in the drug or biological product no longer qualifying for the orphan drug exclusion.³²

As noted previously, section 1192(e)(4) of the Act requires that CMS measure the 7- and 11-year periods set forth in proposed § 429.125(a)(1)(ii) and (a)(2)(ii) starting from “the first day” after the drug’s initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. We are thus proposing that the determination of the date on which the FDA approves the drug or biological product for an indication for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under

section 526 of the FD&C Act would be made irrespective of whether approval of such indication is later withdrawn. We are aware that this proposal could result in a scenario where the 7- and 11-year periods set forth in proposed § 429.125(a)(1)(ii) and (a)(2)(ii) would not yet have elapsed between the last day that the drug most recently qualified for the orphan drug exclusion at section 1192(e)(3)(A) of the Act and proposed at § 429.125(e)(1) and the selected drug publication date, but we believe this approach aligns best with statute given the requirement at section 1192(e)(4) of the Act to measure the 7- and 11-year periods starting from “the first day” after the drug’s initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. We are not currently aware of any instances in which this scenario—wherein the 7- and 11-year periods would not yet have elapsed between the last day that the drug most recently qualified for the orphan drug exclusion and the selected drug publication date—would occur in practice and believe the chances of this scenario occurring in the future are low.

c. Exclusions From Qualifying Single Source Drugs (§ 429.125(e))

Section 1192(e)(3) of the Act requires that the term “qualifying single source drug” not include certain orphan drugs described in section 1192(e)(3)(A) of the Act, low-spend Medicare drugs described in section 1192(e)(3)(B) of the Act, or plasma-derived products described in section 1192(e)(3)(C) of the Act. With respect to initial price applicability years 2026 through 2028, CMS implemented these requirements through guidance, including, for example, sections 30.1.1 through 30.1.3 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We are proposing at § 429.125(e) to exclude certain drugs when identifying qualifying single source drugs.

(1) Orphan Drug Exclusion From Qualifying Single Source Drugs (§ 429.125(e)(1))

Section 1192(e)(3)(A) of the Act excludes certain orphan drugs from the definition of a qualifying single source drug (hereinafter “the orphan drug exclusion”). As such, and in accordance with section 30.1.1 of the Negotiation Program Guidance, in proposed § 429.125(e)(1), we propose to codify the existing policy established in section 30.1.1 of the Negotiation Program Guidance, which incorporated amendments to the orphan drug

exclusion in accordance with the “Working Families Tax Cut” legislation (Pub. L. 119–21), to exclude from the definition of a qualifying single source drug a drug or biological product that is designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act and for which the only approved indication (or indications)³³ is for one or more such rare diseases or conditions (as such term is defined in section 526(a)(2) of the FD&C Act and proposed § 429.20).

To be considered for the orphan drug exclusion with respect to each initial price applicability year beginning with initial price applicability year 2029, the drug or biological product must: (1) be designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act; and (2) be approved by the FDA only for one or more indications within such designated rare disease(s) or condition(s). We would not consider withdrawn orphan drug designations or withdrawn approvals when determining whether a drug meets the orphan drug exclusion.³⁴

To determine whether a potential qualifying single source drug qualifies for the orphan drug exclusion, we propose to consider all dosage forms and strengths of the potential qualifying single source drug, as described previously and as identified in proposed § 429.125(b). We would use the FDA Orphan Drug Product designation database³⁵ and information on FDA-approved indications from other publicly available databases and documents (such as, but not limited to, FDALabel,³⁶ FDA Online Label Repository,³⁷ Drugs@FDA,³⁸ and NLM DailyMed³⁹) to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion. We would also consult with FDA, as appropriate, including as to whether the approved indication(s) is for a rare disease(s) or

³¹ For a biological product with an approved application under section 505(c) of the FD&C Act that was deemed to be a BLA under section 7002(e)(4)(B) of the BPCI Act, as amended by the Further Consolidated Appropriations Act of 2020, we would consider the approval date determined in accordance with section 7002(e)(4)(B) of the BPCI Act to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B)(ii) of the Act.

³² For orphan drug designations withdrawn after August 12, 2013, the FDA Orphan Drug Product designation database includes the date of such withdrawal. For orphan drug designations withdrawn prior to or on August 12, 2013, we would use August 12, 2013, as the date on which the orphan designation is withdrawn for purposes of identifying the first day after the drug or biological product’s approval or licensure that such drug or biological product does not qualify for the orphan drug exclusion.

³³ For purposes of applying the orphan drug exclusion, CMS understands “approved indication,” as that term is used in section 1192(e)(3)(A) of the Act, to refer to the FDA-approved indication that is described in information included in drug labeling per 21 CFR 201.57(c)(2) or other applicable FDA regulation(s).

³⁴ For purposes of the Negotiation Program, we use the term “withdrawn” with respect to an orphan drug designation to refer to a voluntary withdrawal of an orphan drug designation as described at 23 CFR 316.24 or a revoked orphan drug designation as described at 23 CFR 316.29.

³⁵ See: <https://www.accessdata.fda.gov/scripts/opdlisting/oopd>.

³⁶ See: <https://nctr-crs.fda.gov/fdalabel/ui/search>.

³⁷ See: <https://labels.fda.gov>.

³⁸ See: <https://www.accessdata.fda.gov/scripts/cder/daf>.

³⁹ See: <https://dailymed.nlm.nih.gov/dailymed>.

condition(s) for which the drug or biological product is designated under section 526 of the FD&C Act. We would not consider whether an FDA-approved indication was or is covered under Part D or payable under Part B or both when determining whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion.

(2) Low-Spend Medicare Drug Exclusion From Qualifying Single Source Drugs (§ 429.125(e)(2))

Section 1192(e)(3)(B) of the Act also excludes low-spend Medicare drugs or biological products with combined expenditures under Medicare Part B and Part D during the total expenditures measurement period less than the inflation-adjusted threshold for the previous initial price applicability year, increased by the annual percentage increase in the CPI-U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to a given initial price applicability year, when identifying qualifying single source drugs (“the low-spend Medicare drug exclusion”). As such, in proposed § 429.125(e)(2), we propose to codify the policy established in section 30.1.2 of the Negotiation Program Guidance to exclude such low-spend Medicare drugs or biological products from the definition of a qualifying single source drug.

To identify drugs and biological products meeting the statutory criteria for the low-spend Medicare drug exclusion with respect to each initial price applicability year beginning with initial price applicability year 2029, we propose to calculate combined total expenditures under Part B and Part D for a potential qualifying single source drug as the sum of total expenditures under Part B plus total expenditures under Part D, calculated as set forth in proposed § 429.120 and described in section II.B.5. of this proposed rule. We would exclude from the final list of qualifying single source drugs for the initial price applicability year any drugs for which the sum of total expenditures under Part B and Part D is less than the inflation-adjusted threshold for that initial price applicability year. As set forth in sections 1192(e)(3)(B)(i) and (e)(3)(B)(ii) of the Act and codified in proposed § 429.125(e)(2)(ii), the inflation-adjusted threshold for an initial price applicability year is equal to the inflation-adjusted threshold for the previous initial price applicability year, increased by the annual percentage increase in the CPI-U for the 12-month period ending on September 30 of the

year prior to the year of the selected drug publication date for such initial price applicability year, starting from the inflation-adjusted threshold for initial price applicability year 2028 equal to \$212,907,518.30.

(3) Plasma-Derived Product Exclusion From Qualifying Single Source Drugs (§ 429.125(e)(3))

Additionally, section 1192(e)(3)(C) of the Act excludes plasma-derived products from the definition of a qualifying single source drug. As such, in proposed § 429.125(e)(3), we propose to codify the existing policy established in section 30.1.3 of the Negotiation Program Guidance to exclude plasma-derived products when identifying qualifying single source drugs (“the plasma-derived product exclusion”) with respect to each initial price applicability year beginning with initial price applicability year 2029. Under section 1192(e)(3)(C) of the Act, a plasma-derived product is a biological product that is derived from human whole blood or plasma. In implementing this statutory exclusion, we would identify plasma-derived products by referring to product information, including approved product labeling, available on the FDA Approved Blood Products website, including the list of fractionated plasma products,⁴⁰ and would refer to databases such as, but not limited to, FDALabel⁴¹ and the FDA Online Label Repository⁴² to verify if the product is derived from human whole blood or plasma. CMS also would consult with FDA, as appropriate. Consistent with existing policy under Negotiation Program Guidance, for purposes of applying the exclusion, we consider only whether the active moiety/active ingredient is derived from human whole blood or plasma.

d. Bona Fide Marketing of an Approved Generic Drug or Licensed Biosimilar and Deselection of a Selected Drug (§ 429.125(d), § 429.130, and § 429.135)

Key provisions of the Negotiation Program statute govern CMS’ evaluation of generic and biosimilar competitors to potential qualifying single source drugs and CMS’ further consideration of such products in the deselection of selected drugs. First, section 1192(e)(1)(A)(iii) of the Act states that, to be considered a qualifying single source drug, a drug cannot be the listed drug for any drug approved and marketed under an ANDA

under section 505(j) of the FD&C Act. For a biological product, section 1192(e)(1)(B)(iii) of the Act states that the biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act (that is, a biosimilar). Second, section 1192(c)(1) specifies a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines: (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or FDA has licensed a biosimilar under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and (2) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure.

Based on the authorities described previously, CMS conducts the following inquiry to determine whether a drug or biological product can be considered a qualifying single source drug. First, using FDA reference sources including the Orange Book and Purple Book, CMS would evaluate whether at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the potential qualifying single source drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the potential qualifying single source drug as the reference product, consistent with proposed § 429.125(d)(1). This approach is consistent with the approach of aggregating different dosage forms and strengths as a single potential qualifying single source drug as required under section 1192(d)(3)(B) of the Act (stating that a qualifying single source drug is inclusive of all strengths and dosage forms, which is described in further detail in section II.B.6.a. of this proposed rule). In other words, consistent with proposed in § 429.125(d), if CMS determines there is a generic drug or biosimilar that is approved or licensed, as applicable, for any dosage form or strength of a drug or biological product, and such generic drug or biosimilar is subject to Bona Fide Marketing, then that drug or biological product would not meet the statutory criteria in section 1192(e)(1)(A)(iii) or section 1192(e)(1)(B)(iii) of the Act to be a

⁴⁰ See: <https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products>.

⁴¹ See: <https://nctr-crs.fda.gov/fdalabel/ui/search>.

⁴² See: <https://labels.fda.gov/>.

qualifying single source drug. We are proposing that the determination of whether a potential qualifying single source drug includes the listed drug or reference product for an approved generic drug or licensed biosimilar, respectively, would be made irrespective of whether the indication(s) approved for the listed drug or reference product were or are covered under Part D, payable under Part B, or both.

We note that because section 1192(e)(2)(A) of the Act provides that an “authorized generic” drug “shall be treated as the same qualifying single source drug,” we will not consider an authorized generic drug to be a generic drug or biosimilar for the purposes of identifying whether there is an approved generic drug or licensed biosimilar for any strength or dosage form of a potential qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as: (1) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act); and (2) in the case of a biological product, a product that has been licensed under section 351(a) of such Act⁴³ and is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

Second, consistent with the policies for implementation of section 30.1 of the Negotiation Program Guidance, we would conduct a holistic inquiry based on the totality of the circumstances when evaluating whether the manufacturer(s) of any approved generic drug(s) or licensed biosimilar(s) is or are engaged in Bona Fide Marketing of that generic drug or biosimilar as defined at proposed § 429.20 and described in proposed § 429.130. CMS must evaluate, as part of the determination described in section 1192(e) of the Act, whether a generic drug or biosimilar “is . . . marketed” and whether the potential qualifying single source drug is a listed drug “for any drug that is approved and marketed under section 505(j) of the FD&C Act” or a reference product “for any biological product that is licensed and marketed under section 351(k) of the PHS Act.” The terminology

specified in sections 1192(e) of the Act for purposes of the Negotiation Program is distinct from the terminology specified elsewhere in the Act for purposes of the Medicare Part B Inflation Rebate Program (section 1847A(i) of the Act) and the Medicare Part D Inflation Rebate Program (section 1860D–14B of the Act), also established through the IRA. For Medicare inflation rebates, the statute refers to the date that a drug is “first marketed”. The absence of the term “first marketed” in section 1192 of the Act indicates that, for purposes of the Negotiation Program, a generic drug or biosimilar must have a continuing presence on the market in order to affect the status of a listed drug/reference product. Consistent with the statutory purpose of lowering drug prices through the mechanisms described in Title I, Subtitle B, Part 1 of the Inflation Reduction Act, and as CMS has explained in response to comment on the Negotiation Program Guidance, CMS will consider whether meaningful competition exists on an ongoing basis between any dosage form or strength of a potential qualifying single source drug that includes the listed drug or reference product and any one or more generic drug(s) or biosimilar(s). Therefore, as reflected in proposed § 429.130(a)(1) and (2), we understand that whether a product “is marketed” requires more than solely token or de minimis availability. We appreciate that, while sales and utilization data provide important indicators of market competition, they are not the only sources of information that may illustrate whether such competition exists between a listed drug or reference product and a generic drug or biosimilar. For example, we are also aware there may be situations in which a manufacturer of a brand name drug or biologic has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar, where the generic drug or biosimilar manufacturer agrees to limit production or distribution of the generic drug or biosimilar, such that only a nominal quantity of product is allowed to enter the market. The result is a lack of meaningful price competition, and in that circumstance the generic drug or biosimilar is not “marketed” within the meaning of that term as it is used in the section 1192 of the Act (for example, specifically within the context of marketed at section 1192(e) of the Act). Therefore, as proposed in § 429.130(b), whether such competition exists between a listed drug or reference product and an approved generic drug or licensed biosimilar would depend on

a holistic inquiry based on the totality of circumstances in existence at the time that CMS evaluates whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing and not on the presence, or absence, of any single factor.

Specifically, in accordance with sections 1192(e) of the Act, to consider whether there are ongoing sales and/or utilization of a generic drug or biosimilar in the market, we propose at § 429.130(a)(1)(i) through (iii) to review the following data sources: PDE data, AMP data, and ASP data. Additionally, as part of CMS’ holistic consideration of whether one or more manufacturers of a generic drug or biosimilar are engaging in Bona Fide Marketing of the approved generic drug or licensed biosimilar, we propose at § 429.130(a)(1)(iv) that CMS may also review sales and/or utilization data from additional data sources, including, but not limited to, Medicaid State Drug Utilization Data, and data from nationally representative and commercially available databases. Further, to consider whether there is meaningful competition, CMS may also consider other factors proposed at § 429.130(a)(2) and (3) that include whether the approved generic drug or licensed biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain, whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar, and other available data and informational sources on market share and relative market competition of the approved generic drug or licensed biosimilar that CMS may identify.

If any dosage form or strength of a potential qualifying single source drug is the listed drug or reference product for one or more generic drugs or biosimilars that CMS determines are approved or licensed and subject to Bona Fide Marketing based on the information as described in proposed § 429.130(a), the potential qualifying single source drug would not be considered a qualifying single source drug for the applicable initial price applicability year (as described in proposed § 429.125(d)). As set forth in proposed § 429.125(d) and in accordance with § 429.130(c)(1), we would review the information set forth in proposed § 429.130(a) for any potential qualifying single source drug for initial price applicability year 2029 and any initial price applicability year thereafter in January prior to the selected drug publication date

⁴³ CMS is interpreting the reference to “licensed under section 351(a) of such Act” to mean licensed or deemed licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.

(proposed at § 429.20 and described in section II.A.2. of this proposed rule). For example, for initial price applicability year 2029, CMS would review this information for any potential qualifying single source drugs in January 2027, prior to the February 1, 2027 selected drug publication date.

Consistent with section 1192(c)(1) of the Act, a drug selected for negotiation for an initial price applicability year would remain a selected drug for that initial price applicability year and each subsequent year beginning before the first year that begins at least nine months after the date as of which CMS determines at least one generic drug is approved under section 505(j) of the FD&C Act using the selected drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using the selected drug as the reference product, and such generic drug or biosimilar is marketed pursuant to such approval or licensure, as applicable. As discussed previously in this section, we understand that whether a product “is marketed” requires more than solely token or de minimis availability. Therefore, when evaluating whether a generic drug or biosimilar for a selected drug is subject to Bona Fide Marketing for the purposes of determining if a selected drug ceases to be a selected drug consistent with section 1192(c) of the Act and proposed § 429.135(a), we would implement the same approach that we propose for evaluating whether a generic drug or biosimilar for a potential qualifying single source drug is subject to Bona Fide Marketing.

If CMS determines that a generic drug is approved or a biosimilar is licensed for the selected drug, and such generic drug or biosimilar is subject to Bona Fide Marketing (as set forth in proposed § 429.130(a)) on a date during the period beginning on the selected drug publication date (as defined in proposed § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for negotiation, consistent with section 1192(c)(2) of the Act and proposed § 429.135(b)(1)(i), the selected drug is no longer subject to the negotiation process—including, for example, any applicable negotiation meeting(s) or offer and counteroffer exchanges—for such initial price applicability year. Similarly, consistent with section 1194(f)(5)(B) of the Act and proposed § 429.135(b)(2), if CMS determines that a generic drug is approved or a biosimilar is licensed for a selected drug and that such generic drug or biosimilar is subject to Bona Fide Marketing (as set forth in proposed

§ 429.130(a)) on a date during the period beginning on the selected drug publication date (as defined in proposed § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for renegotiation, then the selected drug is no longer subject to the renegotiation process. Therefore, for drugs selected for negotiation and renegotiation (if any) for an initial price applicability year, we would review the information set forth in proposed § 429.130(a) on a monthly basis starting in March of the calendar year of the negotiation period (or renegotiation period, as applicable) until November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation (or renegotiation, as applicable) (see proposed § 429.130(c)(4) and (c)(5)).

Pursuant to section 1192(c)(1) of the Act, once the negotiation period concludes, a selected drug would cease to be a selected drug if CMS determines that a generic drug is approved or a biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing based on the information considered in proposed § 429.130(a). We propose that we would review the information set forth in proposed § 429.130(a), biannually in March and October, starting in October of the calendar year after CMS and the Primary Manufacturer reached an agreement on an MFP for the initial price applicability year for which the drug was selected originally for negotiation and until CMS determines that a selected drug meets the requirements at proposed § 429.135(a) to cease being a selected drug.

Section 1194(f)(5) of the Act clarifies that a renegotiation-eligible drug for which CMS determines there is a generic drug that is approved or biosimilar that is licensed, and such generic drug or biosimilar is subject to Bona Fide Marketing before or during the renegotiation period shall not be subject to the renegotiation process. Thus, for any renegotiation-eligible drug, we would review the information set forth in proposed § 429.130(a), in January, prior to the selected drug publication date (defined at § 429.20 and described in section II.A.2. of this proposed rule) as proposed in § 429.130(c)(3).

Finally, after determining that a generic drug is approved or biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing, we would monitor that the approved generic drug or licensed biosimilar continues to be subject to

Bona Fide Marketing. We would review the information set forth in proposed § 429.130(a) to monitor whether the manufacturer(s) of such generic drug(s) or biosimilar(s) continue to engage in Bona Fide Marketing of such generic drug(s) or biosimilar(s) consistent with the schedule proposed at § 429.130(c)(2) and (7), which includes, but is not limited to January of each calendar year.

For each of these points in time CMS reviews the applicable data to determine whether a generic drug is approved or a biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing (which includes prior to selection for negotiation or renegotiation of selected drugs, after selection of drugs for negotiation or renegotiation, or after a selected drug ceases to be a selected drug), beginning with drug selection for negotiation and renegotiation for initial price applicability year 2029 and initial price applicability years thereafter, we are proposing a schedule for reviewing the data at proposed § 429.130(c) that varies from the policies in the applicable guidance for drugs that were potentially eligible for selection or have been selected for initial price applicability years 2026, 2027, and 2028. We have observed across the administration of the Negotiation Program to date that there are certain points in time across a calendar year that are key to the drug selection process of the Negotiation Program and/or have an impact on CMS and manufacturer operations related to plan year coverage contracts and related determinations. For example, it is necessary for CMS to review whether any applicable generic drugs and biosimilars are subject to Bona Fide Marketing as part of the review steps CMS undertakes to identify qualifying single source drugs for purposes of drug selection for negotiation (proposed at § 429.130(c)(1)) and to identify selected drugs ineligible to be selected for renegotiation (proposed at § 429.130(c)(3)) prior to the selected drug publication date. Once a drug is selected, but prior to the agreement of an MFP or the end of the negotiation period during the negotiation process, CMS must regularly review if any applicable generic drugs and biosimilars are subject to Bona Fide Marketing as an essential part of determining if a selected drug remains subject to the negotiation process. Therefore, consistent with the policies for implementation as described in Negotiation Program Guidance, CMS would maintain monthly reviews of data during this period as proposed at § 429.130(c)(4) for drugs selected for

negotiation and as proposed at § 429.130(c)(5) for drugs selected for renegotiation (if any) for initial price applicability years 2029 and thereafter. However, after the negotiation period ends, we believe that less frequent reviews are sufficient and would provide manufacturers, Part D plan sponsors, and other interested parties with notice regarding the specific points in time across a calendar year at which CMS would review the specified data and provide public notice of any selected drugs that are deselected (consistent with proposed § 429.135(a) and (d)) because CMS determined that a generic drug is approved or a biosimilar is licensed for the selected drug and such generic drug or biosimilar is subject to Bona Fide Marketing. For example, we understand that manufacturers, plan sponsors, and other relevant parties may begin negotiations for Part D plan bids more than a year prior to the plan year and CMS' deadline for Part D sponsor bids (see § 423.265(b)). Therefore, we believe that one key date includes October to ensure manufacturers and Part D plan sponsors are aware prior to the subsequent June due date for Part D plan sponsors to provide CMS with any required plan bids for the next Medicare plan contract year (as indicated in § 423.265(b)(1)) of any selected drugs that may be deselected. For example, if we determine in October 2028 that a generic drug or biosimilar is approved or licensed, as applicable, for a selected drug for initial price applicability year 2029 and that generic drug or biosimilar is subject to Bona Fide Marketing, that selected drug ceases to be a selected drug on January 1, 2030 and the MFP would not be applicable for that year. Manufacturers and plan sponsors would then be aware in November 2028 that the selected drug would cease to be a selected drug in contract year 2030, bids for which are due in June 2029. Finally, as described in proposed § 429.130(c)(2) and (7), we would periodically monitor, including at least annually in January prior to each selected drug publication date, the marketing of any applicable generics and biosimilars in the following circumstances: (1) if a potential qualifying single source drug was determined by CMS not to qualify as a qualifying single source drug for any prior initial price applicability year because CMS determined that at least one generic drug was approved using the potential qualifying single source drug as the listed drug or at least one biosimilar was licensed using the potential qualifying source drug as the reference product, and such generic

drug or biosimilar was subject to Bona Fide Marketing, and (2) if a selected drug ceases to be a selected drug in accordance with proposed § 429.135(a) (in other words, because CMS determined that a generic drug is approved or a biosimilar is licensed for the selected drug and such generic drug or biosimilar is subject to Bona Fide Marketing).

For awareness for manufacturers and other interested parties, we propose in § 429.130(a)(1)(i) through (iv) that CMS would review the last 12 months or the four quarters of data, as applicable, ending with the last full month or quarter of data available to CMS at the time of its review. Specifically, for PDE data, consistent with proposed § 429.130(a)(1)(i) and using the example of CMS' review in October, this means that CMS would review PDE data reported from October of the prior calendar year through September of the current calendar year. Submission deadlines for the data source would determine the data available to CMS at the time of review. For example, AMP and ASP data are submitted to CMS by manufacturers on a monthly or quarterly basis in accordance with regulations (42 CFR 447.510 and 42 CFR 414.805(a)(5)), whereas PDE data for selected drugs are submitted to CMS by Part D plan sponsors within 7 days from the date the Part D plan sponsor receives the claim for selected drugs or within 30 days for all other drugs (per 42 CFR 423.325). CMS would pull such data in the month CMS reviews such data, and the specific date on which CMS may pull the data would vary year to year and may be impacted, for example, by the date of Federal holidays.

Consistent with the policies for implementation as described in Negotiation Program Guidance, we provide the following examples of potential factors considered in CMS' review of whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing. While the circumstances illustrated in these examples weigh in favor of, or against, considering a generic drug or biosimilar to be subject to Bona Fide Marketing, CMS' inquiry for any particular drug would be based on the totality of the circumstances and not on the presence, or absence, of any single factor. First, as an example, if a potential qualifying single source drug has at least one approved generic drug or licensed biosimilar that has high and consistent PDE utilization, AMP sales, and/or ASP sales, we would consider the generic(s) or biosimilar(s) of the potential qualifying single source drug to be subject to Bona Fide Marketing. As a

second example, a potential qualifying single source drug might have a newly or recently approved generic drug or licensed biosimilar and the product has relatively low PDE utilization, AMP sales, and/or ASP sales. In this example, if CMS finds in additional review of public information that the generic drug or biosimilar manufacturer has successfully launched their product, and there is no evidence of agreements limiting distribution of the generic drug or biosimilar, then we may consider the generic drug or biosimilar of the potential qualifying single source drug to be subject to Bona Fide Marketing. As a third example, a potential qualifying single source drug might have an approved generic drug or licensed biosimilar product with no PDE utilization, AMP sales, and/or ASP sales. In this example, if CMS finds in additional review of public information that there are ongoing patent disputes and no generic drug or biosimilar manufacturer has successfully launched their product, then we may consider the generic drug or biosimilar of the potential qualifying single source drug as not subject to Bona Fide Marketing.

As discussed in section I.A.2. of this proposed rule, because sections 11001(c) and 11002(c) of the IRA require CMS to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA for 2026, 2027, and 2028 through program instruction or other forms of program guidance, prior to January 1, 2029, the requirements and processes, including with respect to Bona Fide Marketing and deselection of a selected drug, for a selected drug that was included on the list of selected drugs with respect to initial price applicability year 2026, 2027, or 2028 are set forth with respect to such years in the applicable program guidance. Revisions to the implementation of such policies for 2026, 2027, and 2028 with respect to drugs selected for initial price applicability years 2026, 2027, and 2028 would be addressed by CMS through publication of revised guidance. In accordance with the expiration of the statutory program instruction requirement at the end of 2028, we propose in section I.A.2. of this proposed rule that the provisions of this proposed rule, including the policies set forth in §§ 429.130 and 429.135 with respect to Bona Fide Marketing and deselection of a selected drug, as applicable, would apply starting in 2029 with respect to the drugs selected for initial price applicability years of 2026, 2027, or 2028.

Section 1192(c)(1) of the Act specifies that each negotiation-eligible drug

included on the list of drugs published for an initial price applicability year consistent with section 1192(a) of the Act will be a “selected drug” with respect to that year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug is approved under section 505(j) of the FD&C Act using the selected drug as the listed drug or at least one biological product is licensed under section 351(k) of the PHS Act using the selected drug as the reference product, and that such drug or biological product is marketed pursuant to such approval or licensure. Additionally, section 1192(c)(2) of the Act states that a negotiation-eligible drug shall not be subject to the negotiation process under section 1194 of the Act for the applicable negotiation period but shall continue to be considered a selected drug for purposes of the number of negotiation-eligible drugs published on the list with respect to such initial price applicability year if the Secretary determines that the criteria in section 1192(c)(1) of the Act are met before or during the negotiation period for that initial price applicability year. Therefore, in accordance with sections 1192(c)(1) and (2) of the Act, we propose in § 429.135 to codify provisions related to deselection of a selected drug subject to the timeline and situations proposed in § 429.135(b).

Specifically in proposed § 429.135(a), each drug selected for negotiation for an initial price applicability year would remain a selected drug, with respect to such initial price applicability year and each subsequent year beginning before the first year that begins at least 9 months after the date on which CMS determines that at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the selected drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the selected drug as the

reference product, and that such generic drug or biosimilar is subject to Bona Fide Marketing.⁴⁴ First, we would use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar is approved or licensed for any strength(s) or dosage form(s) of a selected drug as proposed in § 429.135(a)(1). Second, if we determine that a generic drug or biosimilar has been approved or licensed, we would consider whether such generic drug or biosimilar is subject to Bona Fide Marketing as proposed in 429.130(a) and consistent with proposed § 429.135(a)(2). For clarity, we note that a selected drug remains a selected drug unless and until it is deselected as proposed in § 429.135(a) without regard to whether the Primary Manufacturer decides to execute a Negotiation Program Agreement as proposed in § 429.200, to terminate a Negotiation Program Agreement as proposed in § 429.205, or to transfer the Negotiation Program Agreement to a new Primary Manufacturer as proposed in § 429.210.

Proposed § 429.135(b) clarifies that the circumstances described in § 429.135(b) would apply to such selected drug based on the date as of which we determine the conditions described in § 429.135(a) are met. As detailed in proposed § 429.135(b)(1), if we determine on a date during the period beginning on the selected drug publication date (as defined in § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation, that a selected drug has a generic drug that is approved or biosimilar that is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing, pursuant to section 1192(c)(2) of the Act, the selected drug ceases to be subject to the negotiation process under section 1194 of the Act; an MFP would not be published for, or apply to, such drug; and the selected drug would remain a selected drug only for that

initial price applicability year but would not be replaced by another selected drug. As discussed in proposed § 429.130(c)(7), after CMS determines a selected drug would cease to be a selected drug consistent with § 429.135(a), CMS would monitor whether the generic drug or biosimilar for the selected drug continues to be subject to Bona Fide Marketing.

If CMS makes such determination that a selected drug ceases to be a selected drug (consistent with the criteria in proposed § 429.135(a)) on a date during the period of time beginning on November 2 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation and ending on March 31 of that initial price applicability year, then the selected drug would cease to be a selected drug on January 1 of the year following the initial price applicability year for which such drug was selected for negotiation and the MFP would apply only for the initial price applicability year for which such drug was selected for negotiation (consistent with proposed § 429.135(b)(3)).

If the date CMS makes such a determination is during the selected drug's price applicability period after March 31 of the initial price applicability year for which the selected drug is selected for negotiation, then the selected drug would cease to be a selected drug on January 1 of the year that begins at least 9 months after the date that CMS determines the conditions are met (consistent with proposed § 429.135(a)) and the MFP would apply until such date that the selected drug ceases to be a selected drug (consistent with proposed § 429.135(b)(4)).

These different scenarios for the timing of deselection in accordance with proposed § 429.135(b) are summarized in Table 1 using a drug selected for negotiation for initial price applicability year 2029 as an illustrative example.

TABLE 1—DESELECTION OF A SELECTED DRUG FOLLOWING GENERIC DRUG OR BIOSIMILAR APPROVAL/LICENSURE AND MARKETING

Date on which CMS determines that a generic drug or biosimilar is approved/licensed and marketed	Result with respect to selected drug for the negotiation program
The selected drug publication date for initial price applicability year 2029 through November 1, 2027 (the end of the Negotiation Period for initial price applicability year 2029).	Selected drug remains a selected drug for initial price applicability year 2029, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2030.

⁴⁴ Such date of determination is distinct from, and prior to, the date of Primary Manufacturer notification.

TABLE 1—DESELECTION OF A SELECTED DRUG FOLLOWING GENERIC DRUG OR BIOSIMILAR APPROVAL/LICENSURE AND MARKETING—Continued

Date on which CMS determines that a generic drug or biosimilar is approved/licensed and marketed	Result with respect to selected drug for the negotiation program
November 2, 2027 through March 31, 2029	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029; selected drug ceases to be a selected drug on January 1, 2030.
April 1, 2029 through March 31, 2030	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar year 2030; selected drug ceases to be a selected drug on January 1, 2031.
April 1, 2030 through March 31, 2031	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar years 2030 and 2031; selected drug ceases to be a selected drug on January 1, 2032.
April 1, 2031 through March 31, 2032	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar years 2030, 2031 and 2032; selected drug ceases to be a selected drug on January 1, 2033.

As we propose at § 429.135(c), if CMS determines a generic drug is approved or biosimilar is licensed for a selected drug, and such generic drug or biosimilar is subject to Bona Fide Marketing prior to the selected drug publication date for the next initial price applicability year (including drugs previously selected for renegotiation), a drug selected for a prior initial price applicability year is not eligible for renegotiation for such next initial price applicability year consistent with section 1194(f)(5) of the Act.

C. Negotiation Program Agreement (§§ 429.200 Through 429.210)

1. Entrance Into an Agreement With CMS (§ 429.200)

Section 1193(a) of the Act directs CMS to enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date and provides for certain requirements of such agreements. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 40.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of “manufacturer” established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate, or renegotiate, as applicable, an MFP with “the manufacturer” of the selected drug. To the extent that more than one entity meets the definition of manufacturer for a selected drug for purposes of initial price applicability year 2029 and subsequent years, we would designate the entity that holds the NDA(s)/BLA(s) for the selected drug to be “the

manufacturer” of the selected drug, hereinafter referred to as the “Primary Manufacturer” (as defined in proposed § 429.20). We would refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on the NDA or BLA, as a Secondary Manufacturer (as defined in proposed § 429.20). Consistent with sections 1193(a)(4) and 1193(a)(5) of the Act, and as described in this proposed part 429, the Primary Manufacturer of a selected drug that enters into a Negotiation Program Agreement must collect and report all necessary information applicable to the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer. Likewise, as the entity that is party to the Negotiation Program Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Negotiation Program Agreement and will be accountable for ensuring compliance with respect to units of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 40.1 of the Negotiation Program Guidance, proposed § 429.200 establishes the Negotiation Program Agreement and the requirements of such which a willing Primary Manufacturer is subject to upon executing a Negotiation Program Agreement with CMS. We would not enter into a Negotiation Program Agreement with

any Secondary Manufacturer of a selected drug with respect to that selected drug. In accordance with section 1193(a) of the Act, as proposed in § 429.200(a)(1), the deadline for a Primary Manufacturer to enter into a Negotiation Program Agreement is 11:59 p.m. Pacific Standard Time (PST) on February 28 following the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation. We propose at § 429.200(a)(2) that the negotiation period would begin on the earlier of two dates: (1) February 28 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation; or, (2) the date that the Negotiation Program Agreement is fully executed by 11:59 p.m. PST. The Negotiation Program Agreement would be executed on the day that the last party to sign the Negotiation Program Agreement signs the Negotiation Program Agreement and would be in effect until terminated in accordance with proposed § 429.205(a).

We have established a model Negotiation Program Agreement in accordance with section 1193(a) of the Act. A Primary Manufacturer’s obligation to make the MFP available applies during the entirety of the selected drug’s price applicability period for which the manufacturer has a Negotiation Program Agreement in place. At proposed § 429.200(b), consistent with the provisions of such model Negotiation Program Agreement, we propose to codify requirements that a willing Primary Manufacturer will agree to comply with upon execution of the Negotiation Program Agreement, namely: (1) to comply with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance

and regulations, including in part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program; (2) to negotiate to determine an MFP for the selected drug with CMS, during the negotiation period for the initial price applicability year for the selected drug, in accordance with section 1194 of the Act, including as described in subpart F of this part (as described in II.F. of this proposed rule); (3) as applicable, to renegotiate to determine an MFP for the drug selected for renegotiation with CMS, during the renegotiation period for the initial price applicability year for the drug selected for renegotiation, in accordance with section 1194 of the Act, including as described in subpart G of this part (as described in II.G. of this proposed rule); (4) to provide access to the MFP, including as renegotiated, with respect to the selected drug, during the selected drug's price applicability period, in accordance with section 1193(a)(3), including as described in subpart B and subpart I of this part (as described in II.B. and II.I. of this proposed rule); (5) to submit to CMS, in a form and manner specified by CMS, the information specified in sections 1191 to 1198 of the Act, the Negotiation Program Agreement, or this part, including but not limited to, the information as specified at §§ 429.100(d), 429.405, 429.505(b), and, if applicable, § 429.615(b)(1) (as described in sections II.B.1, II.E.2, II.F.2, and if applicable, section II.G.4. of this proposed rule), in accordance with sections 1193(a)(4) and 1193(a)(5) of the Act; and (6) to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, in accordance with section 1193(a)(5) of the Act, including as described in subpart J of this part (as described in section II.J. of this proposed rule).

Consistent with policies for implementation as described in section 40.1 of the Negotiation Program Guidance, we propose in § 429.200(c) that the Negotiation Program Agreement must be signed by an authorized representative of the Primary Manufacturer as defined in proposed § 429.20 and by CMS. In § 429.20, we propose that an authorized representative of the Primary Manufacturer must be the Primary Manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), an individual with equivalent authority to a CEO or CFO, or an individual that has been granted delegation of signature authority on behalf of one of these

categories of individuals. The authorized representative(s) must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Negotiation Program Agreement, including any Addenda. CMS would specify a form and manner to access and sign the Negotiation Program Agreement as indicated in proposed § 429.200(c). Consistent with prior initial price applicability years, we intend to continue to use the CMS Health Plan Management System ("the CMS HPMS") for electronic access and signing of the Negotiation Program Agreement. Specifically, to make a request to obtain electronic signature access via the CMS HPMS, an authorized representative must prepare an official letter that states the user's name(s), role(s) (for example, Chief Executive Officer), CMS user ID, the P number that would be used for CMS and the Primary Manufacturer to interact for the purposes of the Negotiation Program related to the relevant selected drug, and that electronic signature access is required. We note that it is a requirement of the CMS HPMS that the person accessing the CMS HPMS have a Social Security Number (SSN), among other requirements, to meet the identity proofing requirements for system access.

Consistent with policies for implementation as described in section 40.1 of the Negotiation Program Guidance, we propose in § 429.200(d) that the Negotiation Program Agreement will take effect on the date that the Negotiation Program Agreement is signed both by an authorized representative of the Primary Manufacturer and by CMS. The term of the Negotiation Program Agreement shall be from the effective date until the Negotiation Program Agreement is terminated in accordance with § 429.205(a). As proposed in § 429.200(e), the Primary Manufacturer and CMS will formalize the agreement to an MFP through the execution of an Addendum to the Negotiation Program Agreement. The Addendum to the Negotiation Program Agreement will be made available to the Primary Manufacturer in a form and manner specified by CMS and must be signed by an authorized representative of the Primary Manufacturer and CMS. Instructions for completing the Negotiation Program Agreement and a template of the Negotiation Program Agreement are available on the CMS website.⁴⁵

⁴⁵ See "Instructions for this Agreement" and the "Medicare Drug Price Negotiation Program Agreement" at <https://www.cms.gov/priorities/>

2. Termination (§ 429.205)

Section 1193(b) of the Act requires that, when the Primary Manufacturer enters into the Negotiation Program Agreement described in proposed § 429.200, the Negotiation Program Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act (as described in proposed § 429.135 and section II.B.7. of this proposed rule). With respect to 2026 through 2028, CMS implemented these requirements in section 40.6 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 40.6 of the Negotiation Program Guidance, we are proposing at § 429.205 that when the Primary Manufacturer enters into the Negotiation Program Agreement described in proposed § 429.200, the Negotiation Program Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act (as described in proposed § 429.135 and section II.B.7. of this proposed rule) unless the Negotiation Program Agreement is terminated sooner by the Primary Manufacturer under the process established in proposed § 429.205(b).

Participation in the Negotiation Program is voluntary. And so, in accordance with section 1193(a)(5) of the Act, a Primary Manufacturer may terminate its Negotiation Program Agreement with respect to a selected drug with respect to a price applicability period, before reaching an agreement with CMS as to the MFP for the selected drug or after such an MFP is agreed to, if the Primary Manufacturer meets certain conditions for termination consistent with the provisions in 26 U.S.C. 5000D(c). Specifically, a Primary Manufacturer seeking to terminate its Negotiation Program Agreement with respect to a selected drug must submit to CMS a Request to Terminate, as defined in proposed § 429.20, that meets all requirements established in proposed § 429.205(b)(1). Section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid

[medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-negotiated-prices](https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-negotiated-prices).

Drug Rebate Program, the Coverage Gap Discount Program,⁴⁶ and the Manufacturer Discount Program. The provisions enacted in 26 U.S.C. 5000D give the Primary Manufacturer choices with regard to the Negotiation Program. One option is that the Primary Manufacturer may participate in the Negotiation Program. Another option is that the Primary Manufacturer may opt out of the Negotiation Program, and the excise tax may be imposed under 26 U.S.C. 5000D. Alternatively, the Primary Manufacturer may opt out of the Negotiation Program but avoid the excise tax on sales of the selected drug during periods for which the Primary Manufacturer does not have applicable program agreements, as defined in proposed § 429.20, with the aforementioned Medicare and Medicaid programs and none of its drugs are covered by an agreement under the Manufacturer Discount Program under section 1860D–14C of the Act. Promoting continuity in the administration of the Negotiation Program warrants extending parallel options to a Primary Manufacturer with respect to potential civil monetary penalty liability, as described in proposed subpart K and section II.C.10. of this proposed rule. A Primary Manufacturer with a Negotiation Program Agreement with respect to the price applicability period with respect to a selected drug may opt out of the Negotiation Program and pay civil money penalties associated with violations of program requirements. Alternatively, a Primary Manufacturer seeking to cease participation in the Negotiation Program through the end of the price applicability period for a selected drug may avoid civil monetary penalty liability by terminating its Negotiation Program Agreement if it also ceases participation in the Medicaid Drug Rebate Program and the Manufacturer Discount Program through the end of the price applicability period for the selected drug.

In proposed § 429.205(a)(1) and (a)(2), we propose the processes by which termination from the Negotiation Program may occur. Specifically, we propose that a Negotiation Program Agreement will terminate effective as of the date of the earlier of: (1) The first date that the selected drug covered by

the Negotiation Program Agreement is no longer a selected drug consistent with CMS's determination in accordance with section 1192(c) of the Act as described at § 429.135; or (2) The date of termination established in proposed § 429.205(b)(5) in connection with a Request to Terminate by the Primary Manufacturer submitted under proposed § 429.205(b), that is, absent a Primary Manufacturer request to rescind its Request to Terminate in accordance with proposed § 429.205(d), the first date following the receipt of a Request to Terminate that CMS determines none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with 42 CFR 423.2752(c)(1).

In proposed § 429.205(b)(1), in accordance with section 1193(a)(5) of the Act, CMS proposes that a Primary Manufacturer that wishes to terminate a Negotiation Program Agreement may submit in writing a Request to Terminate, in a form and manner specified by CMS, which must include both: (1) a request for termination of the Primary Manufacturer's applicable program agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. 5000D(c)(1)(A)(i); and, (2) an attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer: (i) shall not seek to enter into any subsequent applicable program agreement; and (ii) shall not seek coverage for any of its drugs under the Manufacturer Discount Program under section 1860D–14C of the Act, consistent with the requirements as set forth in 26 U.S.C. 5000D(c)(1)(B). In proposed § 429.205(f), CMS proposes that a Primary Manufacturer that terminates in accordance with proposed § 429.205(b) and later seeks to re-enter any applicable program agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program during the selected drug's price applicability period would be deemed to have provided an invalid attestation that was a condition of termination, and the Negotiation Program Agreement would once again become operative as of the date of re-entry into the applicable program agreement(s) or coverage for any of the Primary Manufacturer's drugs under the Manufacturer Discount Program. If a Primary Manufacturer terminated its Negotiation Program Agreement pursuant to the process described at § 429.205(b)(1) prior to completing the

negotiation process and agreeing to an MFP, and such Primary Manufacturer later sought to re-enter any applicable program agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program, the negotiation process would be initiated or resumed in accordance with the negotiation process proposed in subpart F and section II.C.6. of this proposed rule. In addition, the timing of the Primary Manufacturer's decision to resume participation in the Negotiation Program may implicate the renegotiation process described in proposed subpart G and section II.C.7. of this proposed rule.

We propose in § 429.205(b)(2) that if the Primary Manufacturer's notice of termination contains all required elements under proposed § 429.205(b)(1), CMS will confirm receipt of the Primary Manufacturer's notice and execute the actions with respect to termination of the Primary Manufacturer's applicable program agreements as described in the proposed § 429.205(b)(3), (b)(4), and (b)(5). As noted previously, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program and the Manufacturer Discount Program. As described in proposed § 429.205(b)(3), if a Primary Manufacturer determines after executing its Negotiation Program Agreement that it is unwilling to continue its participation in the Negotiation Program and provides a Request to Terminate that CMS determines complies with the requirements in proposed § 429.205(b)(1), the Primary Manufacturer's Request to Terminate will constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Manufacturer Discount Program, as applicable, in accordance with section 1860D–14C(b)(4)(B)(i) of the Act and 42 CFR 423.2752(c)(1) of this chapter, and to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with 42 CFR 423.2752(c)(1). CMS will automatically grant a Request to Terminate that complies with the requirements in proposed § 429.205(b)(1). Consistent with section 1860D–14C(b)(4)(B)(i) of the Act and 42 CFR 423.2752(c)(1) of this chapter, a termination of a Manufacturer Discount Program agreement by CMS will not be effective earlier than 30 calendar days

⁴⁶ The CGDP, established under section 1860D–14A of the Act, remained in place through December 31, 2024. Because the IRA sunset the CGDP effective December 31, 2024 and all manufacturer CGDP agreements automatically terminated as of such date, CMS has removed references to the CGDP in discussion of Primary Manufacturer termination. CGDP requirements are codified in subpart W of 42 CFR part 423.

after the date of notice from CMS to the manufacturer of such termination after CMS determines that the Primary Manufacturer's Request to Terminate complies with proposed § 429.205(b)(1). CMS has proposed codifying the established deadlines for the Negotiation Program in proposed subpart F, including the date by which CMS will provide the final offer to Primary Manufacturers, to provide a Primary Manufacturer with sufficient time to ensure all conditions for termination are met by the end of the negotiation period set forth in section 1191(b)(4)(B) of the Act.

As described in proposed § 429.205(b)(4), if CMS determines the Primary Manufacturer's Request to Terminate complies with the requirements in proposed § 429.205(b)(1), the Request to Terminate also will constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and the Medicaid National Drug Rebate Agreement (NDRA). CMS will automatically grant a Request to Terminate that complies with the requirements in proposed § 429.205(b)(1). The Primary Manufacturer's applicable program agreements include all the NDRA's of the Primary Manufacturer. Consistent with section 1927(b)(4)(B)(i) of the Act and the NDRA, such termination by CMS will not be effective earlier than 60 days after the date of CMS' notice to the Primary Manufacturer of such termination.

As discussed previously, in the proposed § 429.205(b)(5), unless a Primary Manufacturer rescinds its Request to Terminate in accordance with the proposed § 429.205(d), CMS will terminate the Negotiation Program Agreement effective on the first date following the receipt of a Request to Terminate that CMS determines complies with the requirements in proposed § 429.205(b)(1) on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with 42 CFR 423.2752(c)(1).

Consistent with policies as described in section 40.1 of the Negotiation Program Guidance, § 429.205(c) proposes the process by which a Primary Manufacturer may decide not to execute a Negotiation Program Agreement with CMS and expedite its exit from the Manufacturer Discount Program to meet the conditions of 26 U.S.C. 5000D(c). As described in

proposed § 429.200(a)(2), the negotiation period will begin on the earlier of two dates: (1) February 28 of the year of the selected drug publication date; or, (2) the date that the Negotiation Program Agreement is fully executed. If a Negotiation Program Agreement is not fully executed by February 28 following the publication of the selected drug list, a period will begin on March 1 of the year in which the selected drug list is published, during which the Primary Manufacturer could be exposed to potential excise tax liability, in accordance with 26 U.S.C. 5000D(b)(1). Section 429.205(c) proposes that a Primary Manufacturer that does not wish to participate in the Negotiation Program and that seeks to avoid potential excise tax liability may submit to CMS in writing a Request to Terminate, in a form and manner specified by CMS, that meets the requirements described in proposed § 429.205(b)(1), consistent with the requirements set forth in 26 U.S.C. 5000D(c). In response to such a Request to Terminate, we propose to take the steps described in § 429.205(b)(2) through (5), as applicable.

If a Primary Manufacturer decides not to execute a Negotiation Program Agreement with CMS, and follows the process proposed at § 429.205(c), and later enters into applicable program agreements or obtains coverage under the Manufacturer Discount Program for any of its drugs, but never executes a Negotiation Program Agreement, the tax suspension period described in 26 U.S.C. 5000D(c) will end. See 26 U.S.C. 5000D(c)(1)(B).

Section 429.205(d) proposes the process by which a Primary Manufacturer may rescind the Primary Manufacturer's Request to Terminate submitted pursuant to proposed § 429.205(b) or (c). A Primary Manufacturer may request to rescind the Request to Terminate by submitting to CMS a written request for a hearing, in a form and manner specified by CMS. If a Primary Manufacturer provides a Request to Terminate that complies with the requirements in proposed § 429.205(b)(1), in accordance with section 1860D–14C(b)(4)(B)(i) of the Act, upon written request to rescind from such Primary Manufacturer, we propose to provide a hearing concerning termination of the Primary Manufacturer's applicable program agreements under the Manufacturer Discount Program. Such a hearing would be held prior to the effective date of termination of the applicable program agreements with sufficient time for such effective date to be repealed. Such a hearing would be held solely on the

papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS intends to automatically grant a request from the Primary Manufacturer to rescind its Request to Terminate.

Likewise, as proposed at § 429.205(d), if a Primary Manufacturer submits a Request to Terminate that CMS determines complies with the requirements in proposed § 429.205(b)(1), in accordance with section 1927(b)(4)(B)(i) of the Act, upon written request to rescind from such Primary Manufacturer, we propose to provide a hearing concerning termination of the Primary Manufacturer's applicable NDRA(s) under the Medicaid Drug Rebate Program. Such a hearing would be held prior to the effective date of termination of the applicable program agreements with sufficient time for such effective date to be repealed. Such a hearing would be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. We intend to automatically grant a request from the Primary Manufacturer to rescind its Request to Terminate. If a Primary Manufacturer's request to rescind termination of the applicable program agreements under the Manufacturer Discount Program and the Medicaid Drug Rebate Program is granted, the Primary Manufacturer's Request to Terminate will also be rescinded.

In proposed § 429.205(e), CMS proposes requirements about the effect of termination and the Primary Manufacturer's continuing responsibilities under the Negotiation Program Agreement. That is, we propose that notwithstanding any termination of the Negotiation Program Agreement for a selected drug in accordance with either § 429.205(a)(1) or (a)(2), the Primary Manufacturer would continue to be responsible for making the MFP for the selected drug available, in accordance with subpart I, with respect to any unit of the selected drug

dispensed, administered, or furnished prior to the effective date of termination under § 429.205(a). Also, we propose that notwithstanding the termination of the Negotiation Program Agreement, any confidentiality, record retention, or data requirements and any requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities shall continue to apply.

3. Other Provisions of the Negotiation Program Agreement (§ 429.210)

With respect to initial price applicability year 2029 and subsequent years, consistent with policies for implementation as described in section 40.7 of the Negotiation Program Guidance, we propose at § 429.210(a) to codify that if any provision of the Negotiation Program Agreement is found to be invalid by a court of law with competent jurisdiction, the Negotiation Program Agreement would be construed in all respects as if any invalid or unenforceable provision(s) were eliminated, and without any effect on any other provision. Further, as proposed at § 429.210(b), CMS retains the authority to amend the Negotiation Program Agreement to reflect changes in law, regulations, or guidance as applicable. When possible, CMS would give the Primary Manufacturer at least 60 days of notice of any change to the Negotiation Program Agreement.

In accordance with section 1193(a)(5) of the Act, consistent with policies for implementation as described in section 40.7 of the Negotiation Program Guidance, we propose at § 429.210(c) to codify that if, after entering in a Negotiation Program Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs or BLAs, as applicable, of a selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Negotiation Program Agreement associated with the transferred NDA(s) or BLA(s), including the requirement to provide access to the MFP as described in proposed subpart I, unless and until the Primary Manufacturer transfers all the NDAs or BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer. CMS proposes in § 429.210(c)(1)(ii) that the acquiring entity's assumption of responsibility as the new Primary Manufacturer must be evidenced by a novation to the transferring Primary Manufacturer's original Negotiation Program Agreement, which, as discussed below, must be provided to CMS for review and approval at least 30

calendar days before the intended effective date of the proposed transfer. In proposed § 429.210(c)(1)(ii), CMS also requires that the novation be signed by the transferring Primary Manufacturer and the acquiring entity and must include, at minimum, the legal name of the acquiring entity (which would be the new Primary Manufacturer), the effective date of the transfer of ownership of all transferred NDAs or BLAs of the selected drug that the transferring Primary Manufacturer holds and of the transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, a list of all transferring NDAs or BLAs of the selected drug, and agreement that the acquiring entity assumes all obligations and liabilities under the transferring Primary Manufacturer's Negotiation Program Agreement as the successor in interest.

We propose at § 429.210(c)(2), that if the transferring Primary Manufacturer submits a novation agreement that meets the requirements proposed at § 429.210(c)(1)(ii), and is approved by CMS, the acquiring entity becomes the successor in interest to the transferring Primary Manufacturer's Negotiation Program Agreement and the Primary Manufacturer of the applicable selected drug as of the novation's effective date of the transfer of responsibility for all requirements of the Negotiation Program Agreement.

We propose at § 429.210(c)(1)(ii), that the transferring Primary Manufacturer must provide CMS with documentation of the intended transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, in the form of a novation, at least 30 calendar days before the intended effective date of any such transfer, for CMS review and approval. We encourage Primary Manufacturers to consult with CMS regarding their potential novation before submission of the novation to CMS at least 30 calendar days before the intended effective date of any such transfer.

We propose at § 429.210(c)(3) that the transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the Biosimilar Delay under section 1192(f) of the Act unless, and until, such liabilities are transferred to the acquiring entity as the new Primary Manufacturer.

If the Primary Manufacturer of a selected drug transfers all NDAs or BLAs of the selected drug, and the acquiring entity assumes responsibility as the new Primary Manufacturer of the selected drug for purposes of the Negotiation Program, we recognize that

this transfer of ownership could enable the original Primary Manufacturer to avoid potential excise tax liability for future sales, as well as render unnecessary the efforts by the original Primary Manufacturer to comply with the statutory suspension of the excise tax and the termination process for a Primary Manufacturer seeking to invoke the statutory suspension of the excise tax. We recognize that whether this transfer of ownership would have these impacts may depend on whether the transfer of the NDA(s) or BLA(s) was made to an entity that is not a related party and complied with relevant principles of tax law.

D. Program Administration (§ 429.300)

1. Confidentiality Policy and Data Use (§ 429.300)

Section 1193(c) of the Act directs CMS to consider manufacturer-submitted information that CMS deems proprietary to only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 40.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We are proposing at § 429.300(a) to codify the requirement that Primary Manufacturer submitted information that CMS deems proprietary would only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program and we are proposing at § 429.300(b) to establish a confidentiality policy that would deem proprietary information, as described in proposed § 429.300(a), including trade secrets and confidential commercial or financial information, as confidential information exempt from disclosure if the information meets the requirements set forth under Exemption 3 or Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(3), (4)). We would not disclose PHI or PII, except in accordance with applicable laws, where received by CMS as proposed in §§ 429.505 and 429.615 or information received by CMS in engagement with interested parties specified in §§ 429.515 and 429.620(e), as proposed in § 429.300(b)(1).

We are proposing at § 429.300(c) to codify certain data elements submitted by a Primary Manufacturer of a selected drug proposed in §§ 429.405 and 429.505(b), or of a drug selected for

renegotiation proposed in § 429.615(b)(1), as applicable, that shall be considered confidential information of the Primary or Secondary Manufacturer and would be deemed proprietary information by CMS, unless the information is publicly available. We propose at § 429.300(c)(1) through 429.300(c)(5) that CMS would consider non-FAMP and associated non-FAMP data collection, research and development costs of the Primary Manufacturer for the selected drug, current unit costs of production and distribution of the selected drug, data on pending patent applications for the selected drug, and market data and revenue and sales volume for the selected drug in the United States as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. We would consider prior Federal financial support, approved patent information, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available to be non-proprietary. Information submitted by a Primary Manufacturer to CMS on a particular data element as a part of the data submission in proposed §§ 429.405, 429.505, and 429.615, as applicable, and described in sections II.E.2., II.F.2., and II.G.4.b. of this proposed rule (which CMS anticipates collecting via the Drug Price Negotiation ICR) may include information that is non-proprietary because it is publicly available or does not represent trade secrets and confidential commercial or financial information, such as the introductory language within an explanation field of a data element. Additionally, we propose in § 429.300(c)(6) that if a Primary Manufacturer submits a Common Technical File/Drug Master File/“drug dossier” as a part of their submission, in accordance with proposed § 429.505(d)(3) or § 429.615(b)(1)(i) (if applicable), we would consider this to be proprietary information.

Finally, as a part of the Drug Price Negotiation ICR for data submissions in proposed §§ 429.505(b)(2) and (d)(3), and 429.615(b), as applicable, a Primary Manufacturer may indicate for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing Federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included under proposed § 429.300(c) as

data that must be deemed proprietary information by CMS.

A Primary Manufacturer may choose to publicly disclose information regarding its ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, we reserve the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. CMS would not publicly discuss ongoing negotiations with a Primary Manufacturer, otherwise. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS would no longer consider that specific material proprietary consistent with proposed § 429.300.

As proposed in § 429.705(b) (as described in section II.H.2. of this proposed rule), we propose to make public the explanation for the MFP, which includes: the narrative explanation of the MFP; redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable; and the redacted information submitted by a Primary Manufacturer in proposed in § 429.505(b)(2) or § 429.615(b)(1) (as described in section II.F.2. or II.G.4. of this proposed rule), as applicable, and the redacted information submitted by interested parties in proposed § 429.505(d)(3) or § 429.615(b)(2), as applicable. We propose at § 429.300(d) that CMS must redact any information deemed proprietary or covered by the confidentiality policy described in § 429.300(a) and 429.300(b), including the publication of the MFP. The narrative explanation of the negotiation process would not include any information that CMS deemed to be proprietary information of the Primary Manufacturer, PHI or PII (defined in proposed § 429.20), or information that is protected from disclosure under other applicable law that may have been submitted through a Primary Manufacturer's data submission or an individual's data submission. In advance of this public narrative, CMS may share certain aggregate or non-selected drug specific information, for example regarding status of the negotiation process or conclusion of negotiations without sharing any information that CMS deemed to be proprietary information of the Primary Manufacturer, PHI, PII, or information that is protected from disclosure under

other applicable law. If the Primary Manufacturer chooses to disclose proprietary information prior to the explanation of the MFP, then it would not be redacted in the explanation of the MFP.

Within the explanation of the MFP, CMS may also make public high-level comments about the data submitted to CMS, as proposed in § 429.405 and proposed in §§ 429.505 or 429.615 (as applicable) that are determined to be proprietary, without sharing any PHI/PII or any proprietary information reported to CMS under section 1193(a)(4) of the Act for purposes of the negotiation. For example, CMS will not make public the research and development costs reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say “the manufacturer has recouped its research and development costs.” Any proprietary information obtained during an audit will also remain confidential, except as necessary to use that information in the course of a judicial enforcement proceeding.

As proposed in § 429.515(a)(5) and described in section II.F.4.a. of this proposed rule, CMS would prohibit audio or video recording of any negotiation meetings between CMS and a Primary Manufacturer. We would maintain written records of the negotiation process, including negotiation meetings, in compliance with applicable Federal law, including the Federal Managers Financial Integrity Act and the Federal Records Act. A Primary Manufacturer may maintain its own written record of the negotiation process.

We would retain all records pertaining to the Negotiation Program, including but not limited to records submitted by a Primary Manufacturer, in compliance with the Federal Records Act, as implemented by the CMS Policy for Records and Information Management.⁴⁷ Data submitted by Primary Manufacturers, as described in proposed in §§ 429.405, 429.505, and 429.615 (as applicable) would be classified as Bucket 3: financial records in the CMS Records Schedule and would be managed in accordance with the CMS Records schedule.⁴⁸

⁴⁷ See: <https://www.cms.gov/files/document/cms-records-management-policy-2022.pdf>.

⁴⁸ See: <https://www.cms.gov/medicare/regulations-guidance/guidance>.

E. Establishment of a Single MFP and Determination of the Ceiling (§§ 429.400 Through 429.445)

1. Establishment of a Single MFP for Negotiation and Renegotiation Purposes (§ 429.400)

Section 1191(c)(3) of the Act states that an MFP means, with respect to a year during a price applicability period and with respect to a selected drug with respect to such period, the price negotiated under section 1194 of the Act, and updated under section 1195(b) of the Act, as applicable, for such drug and year. We interpret this language to refer to negotiation of a selected drug with respect to the price applicability period for that selected drug. Consistent with respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including for example, with respect to initial price applicability year 2028, section 60.1 of the Negotiation Program Guidance. Consistent with the policies for implementation as described in section 60.1 of the Negotiation Program Guidance, we propose in § 429.400 to identify a single price for each selected drug, including for selected drugs with multiple dosage forms and strengths. This single price would be used at each step in the negotiation process, as described in proposed §§ 429.510 through 429.535 and sections II.F.3. through II.F.8. of this proposed rule, and for each step in the renegotiation process, as described in proposed § 429.620 and section II.G.5. of this proposed rule. Accordingly, each offer and counteroffer, as described in proposed §§ 429.520 through 429.535 for negotiation and § 429.620(f) through (i) for renegotiation, would include a single price, including for a selected drug with multiple dosage forms, strengths, and formulations. We also propose in § 429.400(a)(1) to base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit—such as tablet, capsule, injection—or per volume or weight-based metric) for all formulations (including drugs payable under Part B, covered under Part D, or both, as applicable), weighted across dosage forms and strengths for the purposes of determining a single price included in an initial offer proposed in §§ 429.510(d) and § 429.520 and as described in sections II.F.3.c. through II.F.3.d. and section II.F.5. of this proposed rule and for the purpose of additional offers during the negotiation as proposed in §§ 429.525 through 429.535 and as described in sections II.F.4. and II.F.6. through II.F.8. of this proposed rule. This approach of

negotiating a single price across all dosage forms and strengths based on a 30-day equivalent supply of the selected drug both aligns with the statutory requirement at section 1194(a)(1) of the Act to negotiate a single MFP for each selected drug and would allow for a more direct comparison between the selected drug and its therapeutic alternative(s) (described in proposed § 429.510(b)), if any, which might also have different dosage forms, strengths, and treatment regimens (for example, daily consumption of tablets versus monthly injections of solutions) when developing the initial offer. The 30-day equivalent supply methodology is proposed in § 429.415 and described in section II.E.4. of this proposed rule.

2. Collection of Non-FAMP (§ 429.405)

Section 1193(a)(4)(A) of the Act establishes that a Primary Manufacturer that has entered into a Negotiation Program Agreement with CMS (proposed in § 429.200 and described in section II.C.1. of this proposed rule), in accordance with the requirements of its Negotiation Program Agreement, is required to submit, for the negotiation period for the price applicability period, and, if applicable, before any period of renegotiation, information on the non-FAMP (as defined in 38 U.S.C. 8126(h)(5)) for the selected drug for the applicable year or period. Section 1194(c)(1)(C)(ii) of the Act, with respect to a selected drug selected for initial price applicability year of 2027 or later, provides that the MFP negotiated for the selected drug shall not exceed the lower of the amount calculated pursuant to section 1194(c)(1)(B) of the Act or section 1194(c)(1)(C) of the Act, where the calculation pursuant to section 1194(c)(1)(C) of the Act requires identifying the lower of: (1) the average non-FAMP price for the selected drug for 2021 (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, for the first full calendar year following the market entry for such drug), as adjusted for inflation; or (2) the average non-FAMP for the selected drug for the calendar year prior to the selected drug publication date for the selected drug. Section 1194(c)(6) of the Act further provides that the term “average non-Federal average manufacturer price” means the average of the non-Federal average manufacturer price (as defined in 38 U.S.C. 8126(h)(5)) for the four calendar quarters of the year involved.

With respect to initial price applicability years 2027 and 2028, CMS implemented these requirements through guidance, including, for example, with respect to initial price

applicability year 2028, section 50.1.1 of the Negotiation Program Guidance. Consistent with the policies implemented through section 50.1.1 of the Negotiation Program Guidance, we are proposing at § 429.405(a) to codify the requirement that, in accordance with the requirements of its Negotiation Program Agreement, a Primary Manufacturer of a selected drug must submit to CMS, in a form and manner specified by the agency, by 11:59 p.m. PST on March 1 of the calendar year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, the non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug for all quarters of the four quarters of calendar year 2021 in which the selected drug was sold and non-FAMP data was reported (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, the non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug for the four quarters of the first full calendar year following the market entry for such drug), and for the calendar year prior to the selected drug publication date with respect to the initial price applicability year for which the selected drug, was selected for negotiation. This requirement to submit information is not inclusive of NDC–11s of the selected drug that are not manufactured, marketed, controlled, or sold by the Primary Manufacturer or a Secondary Manufacturer, or NDC–11s to which the MFP would not apply, such as sample packages, inner packages, and discontinued products. We intend to consider the average non-FAMP to be available for a selected drug for calendar year 2021 if non-FAMP data has been reported for at least one NDC–11 of the selected drug for at least one quarter in calendar year 2021. For a given NDC–11 of a selected drug, when there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) or the calendar year prior to the selected drug publication date for the selected drug, the non-FAMP reported by the Primary Manufacturer to CMS for that calendar quarter should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated

following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2025 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102–585 (including any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA).

In accordance with sections 1193(a)(4)(A), 1194(b)(2)(A), 1194(c)(1)(C)(ii), 1194(c)(6), and 1193(a)(5) of the Act, as described in proposed § 429.405(a)(1), we propose that this data collection would be mandatory for Primary Manufacturers and would be due by March 1 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation. This due date also aligns with the due date for submission of information related to the factors listed at section 1194(e) of the Act (further described in proposed § 429.505 and II.F.2. of this proposed rule). We intend to collect the non-FAMP through an Information Collection Request (ICR), which will include additional parameters for this data collection.

Additionally, in accordance with section 1193(a)(5) of the Act, we propose at § 429.405(b) that if the non-FAMP is restated due to requirements of 38 U.S.C. 8126 and implementing regulations and guidance issued by the VA, then in accordance with the requirements of its Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer is required to update the submission of non-FAMP to CMS for the selected drug.

3. Determination of the Ceiling (§ 429.410)

a. Limitations on Offer Amount (§ 429.410(a))

Section 1194(b)(2)(F) of the Act states the limitations on an offer amount and requires that in negotiating the MFP of a selected drug, including during renegotiation, we will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling as determined in section 1194(c) of the Act or, if applicable, is less than the Temporary Floor for Small Biotech Drugs as determined in section 1194(d) of the Act. Consistent with section 60.2.1 of Negotiation Program Guidance, we propose at § 429.410(a) to codify the requirement that CMS would not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling amount

under section 1194(c) of the Act. We also propose at § 429.440(a) that CMS would not make an offer or agree to a counteroffer for an MFP that is less than the Temporary Floor for Small Biotech Drugs, if applicable.

b. Determination of the Ceiling (§ 429.410(b))

Section 1194(c)(1)(A) of the Act states that the MFP negotiated for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under section 1194(c)(1)(B) of the Act or the amount under section 1194(c)(1)(C) of the Act. In section 60.2.1 of the Negotiation Program Guidance, CMS developed a process to calculate the amounts described in section 1194(c)(1)(B) and (c)(1)(C) of the Act. We propose to codify that process at § 429.410(b). Provisions regarding the ceiling calculation for drugs selected for renegotiation are proposed at § 429.620(b) and discussed at section II.G.5.a. of this proposed rule. The process we propose to codify at § 429.410(b) provides for a single ceiling amount to apply for each selected drug, in accordance with the references in sections 1194(b)(2)(F) and 1194(c)(1)(A) of the Act to “the ceiling” or “the lower of the amount under subparagraph (B) or the amount under subparagraph (c),” respectively, both in the singular.

In proposed § 429.410(b)(1), we propose to identify the amount under section 1194(c)(1)(B) of the Act, consistent with section 60.2.1 of the Negotiation Program Guidance, as one of the following amounts, as applicable to the selected drug:

- As described in proposed § 429.410(b)(1)(i), for a selected drug that is covered under Part D but is not payable under Part B, the sum of the plan-specific enrollment weighted amounts, described in section 1194(c)(1)(B)(i) of the Act and as determined under proposed § 429.420 and discussed in section II.E.5. of this proposed rule.

- As described in proposed § 429.410(b)(1)(ii), for a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, but is not covered under Part D, the payment amount under section 1847A(b)(4) of the Act for the year prior to the year of that selected drug’s publication date with respect to the initial price applicability year for that selected drug, described in section 1194(c)(1)(B)(ii) of the Act and as determined under proposed § 429.425 and discussed in section II.E.6. of this proposed rule.

- As described in proposed § 429.412(b)(1)(iii), for a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, and covered under Part D, an amount equal to the combined Part B and Part D amount, as determined under proposed § 429.430 and discussed in section II.E.7. of this proposed rule.

- As described in proposed § 429.410(b)(1)(iv), for a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act,⁴⁹ and is covered under Part D, an amount based on the sum of the plan-specific enrollment weighted amounts, described in section 1194(c)(1)(B)(i) of the Act and as determined under proposed § 429.420 and discussed in section II.E.5. of this proposed rule.

- As described in proposed § 429.410(b)(1)(v), for a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and is not covered under Part D, there is no amount as determined under proposed paragraph § 429.410(b)(1).

The previous two bullet points describe scenarios where a selected drug is payable under Part B but is not paid according to the methodology provided in section 1847A(b)(4) of the Act. Since such selected drugs would not have a “payment amount” determined under such section, we propose that the ceiling amount described under section 1194(c)(1)(B)(ii) of the Act would not be applicable to the determination because no such amount exists. In such instances, we propose to calculate and consider the other ceiling amounts specified under section 1194(c)(1) of the Act for such drugs, as applicable. When such a selected drug is payable under Part B but not paid according to section 1847A(b)(4) of the Act and is covered under Part D, we propose to use the sum of the plan-specific enrollment weighted amount. However, for a selected drug that is payable under Part B but not paid according to section 1847A(b)(4) of the Act and is not covered under Part D, there would be no applicable ceiling amount described in section 1194(c)(1)(B) of the Act, and so we propose to use only the applicable percent of average non-FAMP described in section 1194(c)(1)(C) of the Act and determined as proposed in § 429.410(b)(2) to calculate the ceiling.

⁴⁹ When discussing a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act in § 429.410(b)(1)(iv) and (v), an example would be a selected drug which is paid on the basis of 95 percent of Average Wholesale Price (AWP).

Section 1194(c)(1)(C)(ii) of the Act requires that for initial price applicability year 2027 and subsequent years, the lower of two different average non-FAMP amounts described in sections 1194(c)(1)(C)(ii)(I) and 1194(c)(1)(C)(ii)(II) of the Act be used as the amount described under section 1194(c)(1)(C) of the Act. CMS implemented these requirements through guidance, including, for example, section 60.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We propose in § 429.410(b)(2), that the applicable percent, as applicable to the selected drug, will be the lower of the average non-FAMP amounts described in section 1194(c)(6) of the Act. We will compare the amounts described in § 429.410(b)(2) to determine which is lower and serve as the payment amount to compare the amount described in § 429.410(b)(1). In accordance with 1194(c)(1)(A) of the Act, the selected drug's ceiling is the lower of the amount determined under § 429.410(b)(1) or (b)(2).

The amounts determined under proposed § 429.410(b)(2) would be the lower of the average non-FAMP for each selected drug for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year that is 3 years prior to the initial price applicability year of the selected drug proposed in § 429.410(b)(2)(i) and the average non-FAMP for such selected drug for the calendar year prior to the selected drug publication date proposed in § 429.410(b)(2)(ii). Regarding the first referenced amount, we interpret section 1194(c)(1)(C)(i) of the Act to indicate that if there is no non-FAMP for any of the NDCs for the selected drug for calendar year 2021, then we would use the first full year following market entry of the selected drug. Similarly, regarding the second referenced amount, in a situation where none of the NDCs for the selected drug are reported in the calendar year prior to the selected drug publication date, we would then apply the average non-FAMP reported for such NDCs from the first full year prior to the year of the selected drug publication date.

We propose at § 429.410(b)(3), to calculate a single amount, a 30-day equivalent supply as described in § 429.415, across all dosage forms and strengths of the selected drug for the

amounts calculated in §§ 429.420 through 429.435 to determine which of these amounts is the lowest and would serve as the ceiling for the MFP for the selected drug. We solicit comments on recommended approaches for CMS to our proposals throughout this section, including calculation of the 30-day equivalent supply, the determination of the different ceiling amounts, and the temporary floor for small biotech drugs.

4. Calculation of the 30-Day Equivalent Supply (§ 429.415)

Consistent with the policies for implementation as described in section 60.2.1.1 of the Negotiation Program Guidance, we propose at § 429.415 a methodology for determining the 30-day equivalent supply for a selected drug and therapeutic alternative(s), as applicable. The price per 30-day equivalent supply methodology facilitates the determination of a single ceiling price, and the negotiation of a single MFP, across dosage forms and strengths of a selected drug where units (for example, milligrams versus milliliters) and treatment regimens (for example, daily consumption of tablets versus monthly injections of solutions) differ. The proposed 30-day equivalent supply methodology also provides a standardized methodology to calculate a price for a standardized treatment duration for all dosage forms and strengths of selected drugs and its therapeutic alternative(s), if any; gives a more complete picture of beneficiary utilization when compared to a unit-based approach; and allows for comparison across the selected drug and the respective therapeutic alternative(s), if any.

We considered several alternatives, including those submitted through public comment for the Negotiation Program Guidance for initial price applicability year 2028. The alternatives that we considered included a per-unit approach; price per course of treatment; consulting with the Primary Manufacturer of each selected drug to determine a methodology; and a flexible methodology to accommodate the clinical disease state and treatment landscape. We do not believe these alternatives provide for the standardization needed across different formulations, dosage forms, and strengths of a selected drug and its therapeutic alternative(s), if any, necessary to consider the selected drug as described in section 1194(e) of the Act and apply a single ceiling and a single MFP across dosage forms and strengths of the selected drug as required in section 1191(c)(3) of the Act. In addition, using a different

methodology for selected drugs that are covered under Part D from selected drugs that are payable under Part B or for selected drugs that are both covered under Part D and payable under Part B could lead to inconsistencies and issues with comparing the selected drug to therapeutic alternative(s), if any.

Using a per-unit price approach, particularly for drugs payable under Part B, would not provide the standardization necessary to compare a selected drug with a therapeutic alternative nor to apply a single ceiling and a single MFP for a selected drug. This is because for drugs payable under Part B, unit type may differ both across HCPCS codes within a selected drug and across therapeutic alternatives payable under Part B, especially if a drug is both payable under Part B and covered under Part D. Using a price-per-course of treatment approach to creating a 30-day equivalent supply is time and resource intensive because treatment duration and dosing may be specific to individual patients and can also differ due to factors such as individual adherence, delays due to adverse events, or expected gaps due to adjuvant therapy or procedures. The option wherein we would work with the Primary Manufacturer on an individual methodology for each selected drug would be time and resource intensive and potentially not lead to a standardized approach and methodology that could be used for selected drugs and its therapeutic alternative(s), if any. This approach would also create inconsistency across selected drugs. We also believe that a flexible 30-day equivalent supply methodology to accommodate the clinical disease state and treatment landscape, wherein we would use FDA labeling and treatment guidelines to tailor the methodology, would not capture patient-specific dosing regimens whereas the proposed approach using days between services approach would capture such patient-specific variation.

After considering these alternatives, we propose at § 429.415(a)(1), that for selected drugs that are covered under Part D, we would use the methodology as described at 42 CFR 423.104(d)(2)(iv)(A)(2) which relies on the "days' supply" field in PDE records to calculate the 30-day equivalent supply for each PDE record associated with the selected drug.

Consistent with the policies for implementation as described in section 60.2.1.1 of the Negotiation Program Guidance, we propose at § 429.415(a)(2) that CMS will use a different methodology to calculate the 30-day

equivalent supply for selected drugs payable under Part B because Part B data does not contain a “days’ supply” field like the PDE records for selected drugs that are covered under Part D. The methodology we propose to use for calculating the 30-day equivalent supply for drugs payable under Part B involves calculating a “days between services” amount for each instance of Part B data associated with the selected drug. As an example of the approach proposed at § 429.415(a)(2)(ii), consider if the date of service for the first instance of Part B data is January 12, 2025, and the immediately subsequent instance of Part B data with the same active moiety/active ingredient has a date of service of March 12, 2025, then the first claim or record’s “days between services” amount would be calculated as 59 days. If the beneficiary’s third instance of Part B data was August 1, 2025, the number of “days between services” amount, for days between March 12, 2025, and August 1, 2025, would be calculated as 142 days for the second claim or record. The resulting “days between services” amounts in this example would be the same amount if the subsequent claim was a PDE record rather than an instance of Part B data. We propose at § 429.415(a)(2)(i)(B) that the subsequent instance of Part B data or any PDE record be for a drug or biological product with the same active moiety/active ingredient identified as set forth at § 429.125(b), as the selected drug.⁵⁰ We propose at § 429.415(a)(2)(ii)(A) if the beneficiary has an instance Part B data that does not have a subsequent instance of Part B data or PDE record with the same active moiety/active ingredient, identified as set forth at § 429.125(b), CMS would assign a “days between services” amount equal to the median “days between services” amount for all prior instances of Part B claims or records or PDE records for that selected drug associated with that beneficiary during the applicable claims period. Thus, if the beneficiary’s last instance of Part B data was August 1, 2025, and there is no subsequent instance of Part B data or PDE record of the same active moiety/active ingredient, it would be assigned a median of 59 days and 142 days, which is 100.5 days. We propose at § 429.415(a)(2)(ii)(B) that if there is only one instance of Part B data for the selected drug and there are no other instances of Part B data or PDE records

with the same active moiety/active ingredient associated with the beneficiary during the applicable claims period then we would not assign a “days between services” amount and furthermore not include the single instance of Part B data in the calculation of 30-day equivalent supply. The proposal at § 429.415(a)(2)(ii)(B) would not apply for drugs typically administered one time because there would most likely never be subsequent instances of Part B data. We discuss our proposed approach for drugs typically administered one time later in this section.

We understand that drugs payable under Part B often have recurrent administrations and variable dosing depending on body weight, indication, treatment phase, or response to treatment. The proposed “days between services” methodology addresses these concerns by using observed data from individual patients, which can potentially capture if providers are using patient-specific dosing regimens which can cause the variations. The “days between services” methodology would reduce the possibility of undervaluing the costs of drugs payable under Part B when attempting to determine the cost per 30-day equivalent supply.

Part B data is billed at the HCPCS code level, and some calculations using the 30-day equivalent supply of the selected drug require NDC-level 30-day equivalent supply amounts, so we propose at § 429.415(a)(2)(iv) to allocate a portion of the 30-day equivalent supply calculated at the level of each HCPCS code to each NDC within the HCPCS code that includes a selected drug to calculate a 30-day equivalent supply at the NDC level. We propose at § 429.415(a)(2)(v) steps to determine the total Part B 30-day equivalent supply at the NDC level.

We propose at § 429.415(a)(2)(v)(E)(2) to assign a value of “12” for the 30-day equivalent supply for drugs that are typically administered one time (for example, some vaccines and cancer therapies), by identifying HCPCS codes that generally have a median of one claim per calendar year. This value would apply to any selected drug and therapeutic alternative(s) of the selected drug, if any, for purposes of determining the initial offer as described in § 429.510, that are typically administered one time and payable under Part B. However, unlike for claims described in § 429.415(a)(2)(ii)(B), the reason for a lack of a second claim for these drugs is because these drugs are typically administered once for the lifetime of a

patient. A “days between services” amount would therefore generally not be calculated for any claim associated with such drugs under the proposed methodology at § 429.415(a)(2)(ii) without this second claim. To calculate a single amount for the ceiling and for offers and counteroffers for the MFP under the methodologies proposed under this subpart E, a value for the 30-day equivalent supply needs to be assigned for these drugs in order to be included in the calculation. We propose that assigning a value of “12” as a 30-day equivalent supply facilitates the necessary calculations in a manner that reasonably and accurately reflects such drugs usage. This proposal would also be consistent with our policy of developing a standardized methodology to calculate a price for all dosage forms and strengths of selected drugs and its therapeutic alternative(s).

We considered an alternative approach to the proposed 30-day equivalent supply methodology for drugs typically administered one time described previously, wherein we would use a price-per-administration or price per HCPCS billing unit for such drugs. Under this alternative approach, instead of calculating a 30-day equivalent supply and price per 30-day equivalent supply, we would instead calculate a price-per-administration or price-per-HCPCS billing unit for a selected drug. However, if such selected drug includes multiple HCPCS codes, calculating a single price per administration across HCPCS codes may not be appropriate (for example, if the existing price-per-administration differs significantly across HCPCS codes due to different treatment patterns). Calculating a price-per-administration would also not account for different volumes of the drug used in different instances of administration, which would conflict with our typical use of a payment limit per HCPCS billing unit for payment under Part B.

5. Determination of the Sum of the Plan-Specific Enrollment Weighted Amounts (§ 429.420)

Section 1194(c)(2) of the Act describes the calculation for the sum of the plan-specific enrollment weighted amount for prescription drug plan or an MA-PD plan with respect to a covered Part D drug for purposes of section 1194(c)(1)(B)(i) of the Act. Consistent with the policies for implementation as described in section 60.2.2.1 of the Negotiation Program Guidance, we propose at § 429.420(b) to use a 30-day equivalent supply methodology to calculate the sum of the plan-specific enrollment weighted amounts.

⁵⁰ CMS did not use the term “selected drug” in this proposal because there could be a shared HCPCS code or different NDA/BLA holders, especially for therapeutic alternative(s) of the selected drug.

Plan sponsors report Part D PDE data to CMS at the NDC–11 level and report direct and indirect remuneration data to CMS at the NDC–11 level in the annual Detailed Direct and Indirect Remuneration (DIR) Report. As directed by statute, and proposed at § 429.420(a) and (b)(1), we propose to use plan sponsors' reported Part D PDE data and DIR data for the year that is 4 years prior to the initial price applicability year of the selected drug, which would be the most recent year for which data would be available, for purposes of determining the sum of the plan-specific enrollment weighted amounts for selected drugs that are covered under Part D. As proposed at § 429.420(a), we would include all Part D plans found in the PDE data that meet the inclusion criteria described in the definition of "total expenditures under Part D" at proposed § 429.20. We intend to identify Part D plans based on the combination of the Part D contract identifier and the plan benefit package identifier.

We propose at § 429.420(a)(1) to use the list of NDC–11s of the selected drug (as determined in proposed § 429.100(c) and discussed in section II.B.1. of this proposed rule), to determine which NDC–11s of the selected drug are included in this ceiling calculation.

We note that because we would not have PDE data for Part D plans in the following circumstances, such Part D plans would, by definition, be excluded from the calculation proposed at § 429.420(b):

- Plans that have no utilization of the selected drug; and
- Plans that have no enrollment for the year that is 4 years prior to the initial price applicability year of the selected drug.⁵¹

We propose at § 429.420(b)(1) to use the most recent year for which all data is available, which is generally the year that is 4 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation. We propose at § 429.420(b)(2) for each Part D plan and each NDC–11 we would sum the total direct and indirect remuneration amounts found in the DIR Report for the year that is 4 years prior to the initial price applicability year of the selected drug and subtract the total ERPOSA calculated in proposed § 429.420(b)(3) to avoid double counting price concessions applied at the point of sale. The amount calculated under proposed

§ 429.420(b)(4) is the NDC–11 price per unit, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan. To determine which month(s) of enrollment to include in our analysis, we conducted an analysis of monthly Part D plan enrollment changes during 2022 and determined that monthly enrollment changes were the lowest from November to December, so we propose at § 429.420(b)(5) that December would be the most stable month to identify Part D plan enrollment. The choice of one month to identify enrollment, rather than an average annual enrollment, also allows the weights calculated at proposed § 429.420(b)(6) to sum to one.

6. Determination of the Payment Amount Under Section 1847A(b)(4) of the Act (§ 429.425)

Section 1194(c)(1)(B)(ii) of the Act provides for the use of an amount equal to the payment amount under section 1847A(b)(4) for a selected drug that is payable under Part B for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the selected drug. Consistent with the policies for implementation as described in section 60.2.2.2 of the Negotiation Program Guidance and in accordance with section 1194(c)(1)(B)(ii) of the Act, CMS proposes at § 429.425 to calculate for a selected drug payable under Part B and paid under section 1847A(b)(4) of the Act, an amount equal to the payment amount under section 1847A(b)(4) of the Act for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for that drug or biological product (that is, 3 years prior to the initial price applicability year of the selected drug). We interpret "payment amount under section 1847A(b)(4)" under section 1194(c)(1)(B)(ii) of the Act to refer to an amount calculated for such year calculated using the methodology specified in section 1847A(b)(4) of the Act which is, for single source drugs and biological products, separately calculating the annual ASP and WAC described at proposed § 429.425(a)(2)(i) and taking the lesser of, as proposed at § 429.425(a)(2)(ii). When calculating this amount, we propose at § 429.425(a)(1) to use the list of NDC–11s of the selected drug (as determined in proposed § 429.100(c) and discussed in section II.B.1. of this proposed rule).

Additionally, as directed by statute, we propose to calculate the payment amount under section 1847A(b)(4) of the Act by using the quarterly reported ASP

and WAC data for the calendar year 3 years prior to the initial price applicability year of the selected drug, for the purpose of determining the payment amount under section 1847A(b)(4) of the Act. This calculated amount proposed in § 429.425(a)(2) would apply for only selected drugs that are payable under Part B and paid according to section 1847A(b)(4) of the Act. When calculating the payment amount under 1847A of the Act for each HCPCS code we would use NDC-level data from the ASP Data Collection System (that is, the ASP portal). ASP data are required to be submitted to the ASP portal within 30 days after the close of each calendar quarter, and CMS uses that data to calculate payment amounts under section 1847A of the Act for the subsequent quarter, which results in a two-quarter lag between the quarter of ASP data used and when the Part B payment limits apply. We would apply this two-quarter lag when conducting all relevant calculations of the ceiling and application of MFP that rely on data from the ASP portal. For example, when calculating the annual ASP to determine the "payment amount under section 1847A(b)(4)" of the Act for calendar year 2028, CMS would use ASP portal data reported for the third quarter of 2027 through the second quarter of 2028.

To calculate a payment amount under section 1847A(b)(4) of the Act as described in section 1194(c)(1)(B)(ii) of the Act for a 30-day equivalent supply across all dosage forms and strengths of a selected drug, we propose at § 429.425(a)(2) to calculate such amount for each HCPCS code to which NDC–11s of the selected drug are assigned using data from manufacturers of all NDC–11s that are assigned to the HCPCS code and are part of the selected drug, and then assign such payment amount to each NDC–11 of the selected drug within such HCPCS code. We propose at § 429.425(a)(3) to allocate HCPCS code-level utilization from Part B data across each NDC–11 assigned to such HCPCS code, so that we may then use the NDC-level utilization as weights when calculating a single payment amount under section 1847A(b)(4) of the Act, across all dosage forms and strengths of the selected drug. We would achieve this allocation by using the proportion of ASP units reported by manufacturers to CMS for each NDC–11 that is assigned to the HCPCS code.

We propose at § 429.425(a)(2)(i) to convert the quarterly ASP and WAC reported by the manufacturer for the year as set forth in § 429.425(a) for each NDC–11 for a selected drug that is associated with a HCPCS code to an

⁵¹ Employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage would not be included because they are not Part D plans.

annual calendar year ASP or WAC amount for each HCPCS code. We propose to do so by taking an average of the reported ASP or WAC amounts for the HCPCS code across all four quarters of such calendar year, weighted by the total number of billing units in the Part B data within that HCPCS code each quarter.

We propose at § 429.425(a)(2)(i)(A), that if the total number of billing units in the Part B data within the HCPCS code are zero for a given quarter, we would assign that quarter the lowest positive total units from among the other quarters in the same calendar year for that HCPCS code.

We propose at § 429.425(a)(2)(i)(B), that for each of the separate ASP and WAC calculations, if the reported price is negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code in a given quarter for the calendar year as set forth in § 429.405(a), we would exclude that quarter from the applicable calculation.

We propose at § 429.425(a)(2)(i)(C), that if the WAC reported to the ASP portal is negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code for all four quarters for the calendar year as set forth in § 429.405(a), then we would use the WAC reported by the Primary Manufacturer of the selected drug to CMS under section 1194(e)(1) of the Act as described in § 429.505(b)(2)(v).

We propose at § 429.425(a)(2)(iii), if ASP, WAC reported to the ASP payer portal, and WAC reported by the Primary Manufacturer pursuant to section 1194(e)(1) of the Act as described in § 429.505(b)(2) are all negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code for all four quarters of the calendar year as set forth in § 429.405(a), we would calculate the payment amount under section 1847A(b)(4) of the Act by taking the average of the published payment limits in the ASP pricing file (or in the OPBS Addendum B file, if it is not available in the ASP pricing file) for the HCPCS code across all four quarters, weighted by the total number of billing units in the Part B data for that HCPCS code for the four quarters of the calendar year as set forth in § 429.415(a)(2)(i) (including the adjustments made when billing units are zero). We believe this approach is appropriate because the prices in these files are typically calculated following the methodology described in section 1847A(b)(4) of the Act but may be adjusted as necessary to accommodate the underlying data (for example, negative, zero, or missing ASP and/or WAC). This amount would apply

to all applicable NDC-11s assigned to the associated HCPCS code.

We propose at § 429.425(a)(2)(ii) that we would use the lesser of the annual ASP and the annual WAC as determined under proposed § 429.425(a)(2)(i) to yield the payment amount under section 1847A(b)(4) of the Act for the associated HCPCS code. As proposed at § 429.425(a)(1)(iv), we propose to exclude from the determination of the payment amount under section 1847A(b)(4) NDC-11s of the selected drug that are self-administered drugs. Self-administered drugs that are adjudicated through pharmacy claims are not used in the CMS calculation of the payment amounts under section 1847A(b)(4) of the Act for drugs that are not selected for negotiation. Therefore, we believe the exclusion of self-administered drugs from the determination of the payment amount for selected drugs under section 1847A(b)(4) of the Act is appropriate since self-administered drugs are not factored into payment amounts under section 1847A(b)(4) for drugs that are not selected for negotiation.

We propose at § 429.425(a)(3) the steps for allocating HCPCS code-level utilization from Part B data for Part B services. For the steps proposed at § 429.425(a)(3)(ii), we have streamlined the steps given our experiences from previous initial price applicability years, specifically initial price applicability year 2028. The units, measured as the Part B data converted to the NCPDP level units that are used in PDE records, are used in cases where we need to sum together the Part D quantity dispensed and the Part B quantity administered, (*i.e.*, for non-FAMP proposed at § 429.435 and application of MFP proposed at § 429.700). To do so, we need the Part B billing units to be converted to the NCPDP level to match the units on PDE records. We recognize that the Part B data converted to the NCPDP level to match the units in PDE records are not needed for the calculation of the payment amount under section 1847A(b)(4) of the Act as we weight across the Part B and Part D amounts of the selected drug using the 30-day equivalent supply (as set forth in § 429.430), if applicable; however, we still conduct the NCPDP unit conversion to calculate the PDE equivalent number of units here for later use in the non-FAMP ceiling and MFP calculations.

We propose at § 429.425(a)(4) how we would calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug.

We propose at § 429.425(b), that the sequestration payment adjustment is not applied to the amount described under section 1847A(b)(4) of the Act. The amount described under section 1847A(b)(4) of the Act is not adjusted to account for sequestration. Therefore, we do not intend to apply sequestration to the payment amount under section 1847A(b)(4) of the Act as part of the methodology to calculate the payment amount under section 1847A(b)(4) of the Act.

7. Determination of the Combined Part B and Part D Amount (§ 429.430)

Section 1194(c)(1)(B) of the Act provides for the calculation of “an amount,” in the singular, under such subparagraph for each selected drug. Section 1194(c)(1)(B)(ii) of the Act then specifies the payment amount under section 1847A(b)(4) of the Act as an amount to be used under section 1194(c)(1)(B) of the Act for selected drugs that are payable under Part B and paid under section 1847A(b)(4) of the Act and separately specifies at section 1194(c)(1)(B)(i) of the Act the sum of the plan-specific enrollment weighted amounts as an amount to be used for under section 1194(c)(1)(B) of the Act for selected drugs covered under Part D. It does not specify that we should select only one of these two different amounts when calculating the amount for under section 1194(c)(1)(B) of the Act for a selected drug is both covered under Part D and payable under Part B.

For such selected drugs, we interpret section 1194(c)(1)(B) of the Act, which states “. . . an amount equal to . . .” when referring to calculating a single amount under such subparagraph for each selected drug, to mean that we should calculate an amount that captures both the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amounts, where both amounts are available for such drug (that is, where such drug is payable under Part B and is paid according to section 1847A(b)(4) of the Act). Our proposed interpretation gives effect to the entirety of section 1194(c)(1)(B) of the Act for such drugs when both amounts described thereunder are applicable. In contrast, we do not believe section 1194(c)(1)(B) of the Act is best read as permitting the selection and use of just one of the two applicable amounts under such subparagraph. Such subparagraph offers no criteria by which CMS would choose which of the amounts described thereunder to apply for selected for which both amounts are applicable. Moreover, we do not believe section 1194(c)(1) of the Act is best read

as permitting CMS to use only the amount described in section 1194(c)(1)(C) of the Act for such drugs, because both amounts described under section 1194(c)(1)(B) of the Act are applicable to such drugs and CMS can calculate a single amount that accounts for both such amounts.⁵²

To calculate the amount specified at section 1194(c)(1)(B) of the Act for such selected drugs, we propose at § 429.430, consistent with the policies for implementation as described in section 60.2.2.3 of the Negotiation Program Guidance, a methodology to calculate a weighted average of the payment amount under section 1847A(b)(4) of the Act, proposed at § 429.425 and discussed at section II.E.6. of this proposed rule, and the sum of the plan-specific enrollment weighted amounts, proposed at § 429.420 and discussed at section II.E.5. of this proposed rule. We propose at § 429.430(a) that this proposed amount be referred to as the combined Part B and Part D amount. The combined Part B and Part D amount would be for all dosage forms and strengths of a selected drug that are payable under Part B and paid according to section 1847A(b)(4) of the Act and covered under Part D as proposed at § 429.410(b)(2)(iii) and discussed at section II.E.3. of this proposed rule. We propose at § 429.430 how the 30-day equivalent supply will be calculated for the combined Part B and Part D amount.

For the utilization weighting proposed at § 429.430(a)(2), we would treat the NDC-11s of drugs payable under Part B and covered under Part D as having two distinct versions and keep those versions separate in the utilization weighting so that the NDC-11s of drugs payable under Part B and covered under Part D contribute separately to the single amount, based on their applicable proportions to the total. We believe this step is necessary to account for differences in the pricing data between Part D and Part B.

8. Determination of the Applicable Average Non-FAMP Amounts and Applicable Percent of the Average Non-FAMP (§ 429.435)

Section 1194(c)(1)(C)(ii) of the Act requires that for initial price applicability year 2027 and subsequent

years, that the lower of the average non-FAMP amounts described in sections 1194(c)(1)(C)(ii)(I) and 1194(c)(1)(C)(ii)(II) of the Act is used as the average non-FAMP amount. Section 1194(c)(1)(C)(ii)(I) of the Act describes the first amount as the average non-FAMP for such drug for 2021 (or, in the case that there is not an average non-FAMP available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year. Section 1194(c)(1)(C)(ii)(II) of the Act describes the second amount as the average non-FAMP for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year. Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance and in accordance with section 1194(c)(1)(C)(ii) of the Act, we propose at § 429.435(a) to use the methodology and comparison described to determine the lower of the two applicable non-FAMP amounts and apply the applicable percent described in section 1194(c)(3) of the Act.

We propose at § 429.435(a)(1)(i) to use the list of NDC-11s of the selected drug (as determined in proposed § 429.100(c) and discussed in section II.B.1. of this proposed rule), to determine which NDC-11s of the selected drug are included in this ceiling calculation.

Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance, we propose at § 429.435(a)(2)(ii) to use the same methodology for calculating the average non-FAMP for the calendar year 3 years prior to the initial price applicability year of the selected drug as used for the calculation proposed at § 429.435(a)(1)(ii) through (iv) for calendar year 2021, noting that the set of NDCs used to calculate the annual average non-FAMP calculation for each may differ.

To directly compare the amount calculated based on the applicable percent of average non-FAMP proposed in § 429.435 to the amount calculated based on the sum of the plan-specific enrollment weighted amounts proposed in § 429.420, the payment amount under section 1847A(b)(4) of the Act § 429.425, and the combined Part B and Part D amount described in proposed § 429.430, as applicable, we propose to

base the average non-FAMP calculations on a 30-day equivalent supply. We propose to use the approach set forth in proposed § 429.435(a)(3) to calculate the average non-FAMP for a 30-day equivalent supply because it is necessary for the calculated non-FAMP amounts to account for different units and treatment regimens across dosage forms and strengths.

We propose at § 429.435(a)(4) to determine the average non-FAMP across all NDC-11s of the selected drug by conducting the steps outlined in this section separately for the average non-FAMP in calendar year 2021 (or for the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated) and for the calendar year that is 3 years prior to the initial price applicability year of the selected drug. Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance, we propose at § 429.435(a)(4) to calculate an average non-FAMP that is comparable to the sum of the plan-specific enrollment weighted amount (as set forth in § 429.420), the payment amount under section 1847A(b)(4) of the Act (as set forth in § 429.425), or the combined Part B and Part D amount (as set forth in § 429.430), as applicable, and determine the total number of NCPDP units per NDC-11 package. We propose at § 429.435(a)(4)(i) and (ii) the calculations to account for non-FAMP unit volume fluctuations that may occur across quarters.

Consistent with policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance and in accordance with section 1194(c)(1)(C)(ii)(I) of the Act, we propose at § 429.435(a)(4)(v) to increase the average non-FAMP per unit for calendar year 2021 (or for the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated), which would be calculated in § 429.435(a)(4)(iv) by the percentage increase in CPI-U from September 2021 to September of the calendar year that is 3 years prior to the initial price applicability year of the selected drug.

Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance and in accordance with section 1194(c)(3) of the Act, we propose at § 429.435(a)(4)(vi) to apply the applicable percent to the average non-FAMP associated with the monopoly type for the selected drug that is described in section 1194(c)(3)(A) through (C) of the Act. The applicable

⁵² In contrast, for selected drugs not covered under Part D but which are payable under Part B and not paid according to section 1847A(b)(4) of the Act, we do not believe any of the amounts described in section 1194(c)(1)(B) of the Act are applicable, so we propose that section 1194(c)(1) of the Act is best read as permitting the agency to apply only the amount described under section 1194(c)(1)(C) of the Act for such drugs.

percent is determined based on the initial approval date, as set forth in § 429.125(a)(1)(i), of the selected drug and the initial price applicability year for which the drug is selected for negotiation. We note that applying the applicable percent at proposed § 429.435(a)(4)(vi) results in the same ultimate amount calculated at proposed § 429.435(a)(4)(viii) as it would if we were to apply the applicable percent to the average non-FAMP per 30-day equivalent supply for the selected drug at proposed § 429.435(a)(4)(viii). Consistent with section 1194(c)(3)(A) of the Act, short monopoly drugs and vaccines with respect to a selected drug (other than an extended-monopoly drug and long-monopoly drug), will be 75 percent. Consistent with section 1194(c)(3)(B) of the Act, the applicable percent with respect to an extended-monopoly drug will be 65 percent. Consistent with section 1194(c)(4)(C) of the Act, the applicable percent with respect to long-monopoly drug will be 40 percent.

We propose at § 429.435(a)(4)(vii) and (viii) the steps that we would take for each NDC–11 to calculate the average non-FAMP per 30-day equivalent supply. We propose at § 429.435(a)(4)(ix) the method to compare the amounts calculated for the two separate applicable percent of the average non-FAMP amounts and to determine the lower amount.

9. Temporary Floor for Small Biotech Drugs (§ 429.440)

a. Definitions

In proposed § 429.440, we propose to codify the following definitions applicable to § 429.440 based on policies detailed in this proposed rule.

(1) “Part B 2021 Manufacturer”

We propose to define “Part B 2021 Manufacturer” to mean the NDA holder or the BLA holder for the qualifying single source drug on December 31, 2021.

(2) “Part D 2021 Manufacturer”

We propose to define “Part D 2021 Manufacturer” as the entity that either (1) had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D–14A of the Act in effect for the qualifying single source drug on December 31, 2021, or (2) had an arrangement whereby the manufacturer’s labeler codes were listed on another manufacturer’s Medicare CGDP Agreement, consistent with section 1860D–14A of the Act, in effect on December 31, 2021.

(3) “Part B 2021 Manufacturer and Its Controlled Group”

We propose to define “Part B 2021 Manufacturer and its controlled group” as comprising all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer.

(4) “Part D 2021 Manufacturer and Its Controlled Group”

We propose to define “Part D 2021 Manufacturer and its controlled group” as comprising all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021.

b. Implementation of the Temporary Floor for Small Biotech Drugs

Section 1192(d)(2) of the Act established the Small Biotech Exception (SBE), which states that a negotiation eligible drug shall not include, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either the criteria at section 1192(d)(2)(A)(i) or section 1192(d)(2)(A)(ii) of the Act. With respect to initial price applicability years 2026 through 2028, CMS implemented the requirements set forth in section 1192(d)(2) of the Act for a qualifying single source drug to be determined a Small Biotech Drug and therefore eligible for the SBE through guidance, including for example, section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

Section 1194(d) of the Act requires that for a selected drug that is a qualifying single source drug that meets the requirements set forth in section 1192(d)(2) of the Act to be determined a Small Biotech Drug, and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, CMS will not offer or agree to a counteroffer for an MFP that is lower than the Temporary Floor for Small Biotech Drugs. To fulfill the statutory obligation at section 1194(f)(4)(B) of the Act, which states that reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to renegotiation

applies, drugs selected for renegotiation also would be eligible to be considered for the Temporary Floor for Small Biotech Drugs described in section 1194(d). Section 1194(d) of the Act states that the Temporary Floor for Small Biotech Drugs shall be equal to 66 percent of the average non-FAMP for such drug for 2021 (or, in the case that there is not an average non-FAMP available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

With respect to a drug selected for negotiation for initial price applicability year 2029 and 2030, or a drug selected for renegotiation for initial price applicability year 2029 or 2030, for which the Primary Manufacturer submits information in accordance with § 429.440(b)(1), we propose at § 429.440(b) to establish the Temporary Floor for Small Biotech Drugs for selected drugs that are determined to be a Small Biotech Drug based on the criteria that were used and implemented with respect to the SBE for initial price applicability year 2028, as proposed in § 429.440(b)(2). We will not make an offer or agree to a counteroffer for an MFP (as proposed in § 429.500(b) and described in section II.F.1. of this proposed rule) that is lower than the Temporary Floor for Small Biotech Drugs, which shall be equal to the amount specified in proposed § 429.440(b)(3). A determination by CMS that a given selected drug is eligible for the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030 is not based on whether or not CMS previously determined that the qualifying single source drug was eligible or not eligible for the SBE for initial price applicability years 2026, 2027, or 2028.

We propose at § 429.440(b)(1) to establish a process whereby a Primary Manufacturer that would like its selected drug to be considered eligible for the Temporary Floor for Small Biotech Drugs must submit information to allow CMS to determine whether its selected drug meets the requirements of a Small Biotech Drug. This submission is a prerequisite for the Temporary Floor for Small Biotech Drugs to apply to a selected drug. We are proposing at § 429.440(b)(2) to establish requirements for determining whether a selected drug is a Small Biotech Drug that are

consistent with the eligibility requirements for the SBE for initial price applicability year 2028, which were implemented through section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028. If a selected drug is determined to be a Small Biotech Drug, CMS would then calculate the Temporary Floor for Small Biotech Drugs, as proposed at § 429.440(b)(3). We propose at § 429.440(b)(4) to establish a stepwise approach to adjust the ceiling for a selected drug in the event that the ceiling identified in § 429.410(b) (or § 429.620(b) as applicable) is below the Temporary Floor for Small Biotech Drugs, if applicable.

As discussed in further detail in section IV. of this proposed rule, for a Primary Manufacturer to be considered for the Temporary Floor for Small Biotech Drugs, we propose revisions to a currently approved information collection request, titled the Negotiation Program Drug Price Negotiation for Initial Price Applicability Year 20XX under Section 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10849, OMB 0938–1452) (hereinafter, the “Drug Price Negotiation ICR”), for a 60-day public comment period concurrently with this proposed rule. A form and manner for submitting an application for the Temporary Floor for Small Biotech Drugs, consistent with proposed § 429.440(b)(1), would be specified in the ICR for initial price applicability year 2029 and initial price applicability year 2030. Information submitted in an application for the Temporary Floor for Small Biotech Drugs that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3), (4)).

In accordance with section 1194(d) of the Act, to determine eligibility for the Temporary Floor for Small Biotech Drugs, and proposed at § 429.440(b)(2), we would determine whether the selected drug meets the criteria set forth in section 1192(d)(2)⁵³ of the Act.

⁵³ Section 1192(d) of the Act implemented the SBE for initial price applicability years 2026, 2027, and 2028, which included criteria for determining if a qualifying single source drug was a Small Biotech Drug. Section 1194(d) of the Act directs CMS to use the same criteria when determining whether a selected drug is a Small Biotech Drug. Section 1194(f)(4)(B) extends the Temporary Floor for Small Biotech Drug provisions to certain drugs selected for renegotiation. Therefore, when discussing the criteria to determine a Small Biotech Drug to determine the eligibility of the Temporary

Section 1192(d)(2)(A)(i) of the Act establishes that for a selected drug that is covered under Part D to be considered a Small Biotech Drug, the Total Expenditures under Part D during 2021 for such drug must be: equal to or less than 1 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and equal to or greater than 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer had a Coverage Gap Discount Program Agreement in effect during 2021. Section 1192(d)(2)(A)(ii) of the Act establishes that for a selected drug that is payable under Part B to be considered a Small Biotech Drug, the Total Expenditures under Part B for such drug during 2021 must be: equal to or less than 1 percent of the Total Expenditures under Part B for all qualifying single source drugs for which payment may be made under Part B during 2021; and equal to or greater than 80 percent of the Total Expenditures under Part B for all qualifying single source drugs of the manufacturer for which payment may be made under Part B during 2021. A selected drug that meets either the criteria set forth in section 1192(d)(2)(A)(i) of the Act or the criteria set forth in section 1192(d)(2)(A)(ii) of the Act will qualify as a Small Biotech Drug. Section 1192(d)(2)(B)(i) of the Act establishes the aggregation rule, which establishes that all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer when determining whether a selected drug is a Small Biotech Drug. Additionally, section 1192(d)(2)(B)(ii) of the Act establishes that a selected drug shall not be considered a Small Biotech Drug if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025. With respect to initial price applicability years 2026 through 2028, CMS implemented the requirements set forth in sections 1192(d)(2)(A)(i), 1192(d)(2)(A)(ii), 1192(d)(2)(B)(i), and 1192(d)(2)(B)(ii) of the Act through guidance, including, for example, section 30.2.1 of the

Floor for Small Biotech Drugs, we use the term “selected drug” as defined in proposed § 429.20 and “drug selected for renegotiation” in lieu of “qualifying single source drug”.

Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability years 2029 and 2030, and consistent with the policies for implementation of the SBE through section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028, we propose at § 429.440(b)(2)(i) to establish the Part D Track, which outlines the criteria for determining whether a selected drug covered under Part D qualifies as a Small Biotech Drug in accordance with section 1192(d)(2)(A)(i) of the Act. In our assessment, we would consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the selected drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer (as defined in proposed § 429.440(a)(2)) and its controlled group (as defined in proposed § 429.440(a)(4)) had a CGDP Agreement in effect on December 31, 2021, as calculated using the methodology proposed in § 429.120(a) and described section in II.B.5.a. of this proposed rule, except the date of service as described in § 429.120(a)(1) is during 2021. Specifically, we would consider whether, for dates of service in calendar year 2021, the Total Expenditures during 2021 under Part D for the selected drug were: (1) equal to or less than 1 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and (2) equal to or greater than 80 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021. For the purpose of performing the calculations described at proposed § 429.440(b)(2)(ii), CMS would identify the NDC–11s of the selected drug determined under § 429.100(d) with respect to the initial price applicability year for which the Primary Manufacturer of the selected drug applied for the Temporary Floor for Small Biotech Drugs in accordance with proposed § 429.440(b)(1). We would identify the drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021 as the NDC–11s corresponding to the labeler codes of the Part D 2021 Manufacturer and its controlled group.

For the purposes of determining whether a selected drug qualifies as a Small Biotech Drug via the Part D Track, we need to collect information to

accurately identify the Part D 2021 Manufacturer, which is the entity that had the CGDP Agreement under section 1860D–14A of the Act in effect for the selected drug on December 31, 2021. In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we propose at § 429.440(a)(4) that the Part D 2021 Manufacturer and its controlled group comprise all persons that, as of December 31, 2021, were treated as a single employer with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021. However, CMS does not have information about which entities were treated as a single employer with the Part D 2021 Manufacturer under the applicable IRC provisions and the Treasury regulations thereunder. Therefore, we propose that a Primary Manufacturer that seeks the Temporary Floor for Small Biotech Drugs for its selected drug covered under Part D would be required to submit information to CMS about the Part D 2021 Manufacturer and its controlled group to be considered for the Part D Track.

With respect to initial price applicability years 2029 and 2030, and consistent with the policies for implementation of the SBE, we propose at § 429.440(b)(2)(ii) to establish the Part B Track, which outlines the criteria for determining whether a selected drug payable under Part B qualifies as a Small Biotech Drug in accordance with section 1192(d)(2)(A)(ii) of the Act. In our assessment, we would consider Total Expenditures under Part B during 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the selected drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer (as defined in proposed § 429.440(a)(1)) and its controlled group (as defined in proposed § 429.440(a)(3)), calculated using the methodology proposed in § 429.120(b) and described in II.B.5.b. of this proposed rule, except the date of service as described in § 429.120(b)(1)(i) and (b)(2)(i) is during 2021. We would consider whether, for Part B data, as defined in § 429.20, with dates of service during 2021, the Total Expenditures under Part B during 2021 for the selected drug were: (1) equal to or less than 1 percent of the Total Expenditures under Part B for all qualifying single source drugs payable under Part B during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its

controlled group for which payment may be made under Part B. For the purpose of performing the calculations described at proposed § 429.440(b)(2)(ii), CMS would identify the NDC–11s of the selected drug determined under § 429.100(d) with respect to the initial price applicability year for which the Primary Manufacturer of the selected drug applied for the Temporary Floor for Small Biotech Drugs in accordance with proposed § 429.440(b)(1). CMS would identify the NDC–11s of other applicable qualifying single source drugs using the policies for identifying qualifying single source drugs proposed in § 429.125. Accordingly, we would identify the qualifying single source drug(s) payable under Part B for the Part B 2021 Manufacturer and its controlled group using the NDC–11(s) associated with the qualifying single source drug(s) that correspond to the NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer or any member of its controlled group on December 31, 2021. For the purposes of determining whether a selected drug qualifies as a Small Biotech Drug via the Part B Track, we need to collect information to accurately identify the Part B 2021 Manufacturer, which is the entity that is the NDA(s) holder or BLA(s) holder for the selected drug on December 31, 2021. In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we propose at § 429.440(a)(3) that the Part B 2021 Manufacturer and its controlled group comprise all persons that, as of December 31, 2021, were treated as a single employer with the Part B 2021 Manufacturer. However, CMS does not have information about which entities were treated as a single employer with the Part B 2021 Manufacturer under the applicable IRC provisions and the Treasury regulations thereunder. Therefore, we propose that a Primary Manufacturer that seeks the Temporary Floor for Small Biotech Drugs for its selected drug covered under Part B would be required to submit information to CMS about the Part B 2021 Manufacturer and its controlled group to be considered for the Part B Track.

In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we propose at § 429.440(b)(2)(iii) to preclude a selected drug from being eligible for the Temporary Floor for Small Biotech Drugs if the Primary Manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act,

effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.⁵⁴ For purposes of implementing this limitation, we would use the determinations of the Manufacturer Discount Program as to whether the acquiring entity met the definition of specified manufacturer in the applicable period. We would consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount Program as either a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act or a specified small manufacturer under section 1860D–14C(g)(4)(C)(ii) of the Act.⁵⁵ For an acquisition of a Primary Manufacturer to be relevant to the limitation, and therefore to potentially preclude a selected drug from being considered a Small Biotech Drug, we propose that the transaction must occur after 2021 and must involve the acquisition of the Primary Manufacturer after it held the NDA(s) or BLA(s) for the drug.

In accordance with section 1194(d) of the Act, we propose at § 429.440(b)(3) to calculate the Temporary Floor for Small Biotech Drugs for each Small Biotech Drug as 66 percent of the average non-FAMP in calendar year 2021, calculated using the methodology set forth in § 429.435, increased by the percentage increase in the CPI–U from September 2021 to September of the year prior to the selected drug publication date for which the drug is selected for negotiation or, as applicable, renegotiation. If a selected drug did not have a non-FAMP for 2021, we would use the average non-FAMP for the first full year following the market entry, increased by the percentage increase in the CPI–U from December of the first full year following market entry to September of the year prior to the selected drug publication date for which

⁵⁴ See 42 CFR 423.2724.

⁵⁵ For purposes of the Temporary Floor for Small Biotech Drugs and implementing section 1192(d)(2)(B)(ii) of the Act, to determine whether the acquiring entity meets the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, CMS will use the determination made by CMS under the Manufacturer Discount Program as to whether the acquiring entity is a “specified manufacturer.” The Part D Manufacturer Discount Program ICR (CMS–10846, OMB control no. 0938–1451) is available for viewing at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003 (select “all” to see full details).

the drug is selected for negotiation or, as applicable, renegotiation.

In accordance with section 1194(b)(2)(F)(ii) of the Act and as proposed in § 429.410(a), we would not offer or agree to a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs. However, we note that there is a possibility under the statute that the ceiling calculated as described in proposed § 429.410(b) (or § 429.620(b), as applicable) is below the Temporary Floor for Small Biotech Drugs. The statute does not expressly address how to apply section 1194(b)(2)(F)(ii) of the Act in such cases, though such a scenario is possible under the statute—for example, if a selected drug is eligible for the Temporary Floor for Small Biotech Drugs in initial price applicability year 2030 and is an extended-monopoly drug, the applicable percent of average non-FAMP for 2021 used in the ceiling calculation for an extended-monopoly drug under proposed § 429.435(a)(4)(vii)(A)(2) would be less than that of the Temporary Floor for Small Biotech Drugs under proposed § 429.440(b)(3) (65 percent and 66 percent, respectively).

Additionally, as proposed in § 429.620(b) and further described in section II.G.5. of this proposed rule, for the purpose of calculating the ceiling for renegotiation, we propose to determine the ceiling applicable to renegotiation using the ceiling amounts determined with respect to the selected drug's original negotiation, with limited updates, including to account for the statutory directive to update the applicable percent for certain renegotiation-eligible drugs. However, for drugs selected for renegotiation that are eligible for the Temporary Floor for Small Biotech Drugs, the ceiling determined under § 429.620(b) may be lower than the Temporary Floor for Small Biotech Drugs.

To address such a scenario, and to ensure the negotiation process gives effect to the Temporary Floor for Small Biotech Drugs provision at section 1194(d) of the Act that establishes a specific limitation to the general rules for MFP negotiations, we are proposing at § 429.440(b)(4) a stepwise approach to calculate an adjusted ceiling that would apply to the negotiation, or renegotiation, process for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs. We would first determine if an adjusted ceiling is needed by calculating the unadjusted ceiling as described at proposed § 429.410(b) or the renegotiated unadjusted ceiling as described in § 429.620(b) (as applicable), as well as

the Temporary Floor for Small Biotech drugs as described at proposed § 429.440(b)(3), and then would determine if the unadjusted ceiling is below the Temporary Floor for Small Biotech Drugs. If the unadjusted ceiling is greater than or equal to the Temporary Floor for Small Biotech Drugs, then this ceiling would apply, and we would not offer or accept a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs or greater than the ceiling for the selected drug. If, however, such ceiling is below the Temporary Floor for Small Biotech Drugs, we would calculate an adjusted ceiling, as described in proposed § 429.440(b)(4)(i) or (ii), as applicable. To calculate an adjusted ceiling, we propose in § 429.440(b)(4)(i) that, for purposes of determining the potential ceiling amount described under section 1194(c)(1)(C) of the Act, rather than selecting the lower of the average non-FAMP available for such drug in 2021 (or the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated), as described in section 1194(c)(1)(C)(i) or section 1194(c)(1)(C)(ii)(I) of the Act and proposed § 429.435(a)(1) or § 429.620(b) (as applicable), or the average non-FAMP for such drug for the year prior to the selected drug publication date, as described in section 1194(c)(1)(C)(ii)(II) of the Act and proposed § 429.435(a)(2) or § 429.620(b) (as applicable), to calculate the lower amount of the applicable percent of the average non-FAMP, as described in proposed § 429.410(b) (or § 429.620(b) for both non-FAMPs as applicable), we would only consider the average non-FAMP for such drug for the prior year to the selected drug publication date (that is, the amount described in section 1194(c)(1)(C)(ii)(II) of the Act). Therefore, the adjusted ceiling proposed in § 429.440(b)(4)(i) would determine the ceiling as described in § 429.410(b) (or § 429.620(b) as applicable) except that the lower amount of the applicable percent of the average non-FAMP, as proposed in § 429.435 (or § 429.620(b) as applicable), would consider only the average non-FAMP for such drug for the prior year to the selected drug publication date, as described in § 429.435(a)(2) (or § 429.620(b), as applicable). We believe that removing the average non-FAMP available for such drug in 2021 from the calculation of the lower amount of the applicable percent of the average non-FAMP allows for the implementation of the Temporary Floor for Small Biotech

Drugs while preserving the ceiling calculation, giving effect to both provisions, and is the most appropriate and narrowly tailored way to reconcile cases where the Temporary Floor for Small Biotech Drugs exceeds the ceiling for a selected drug, as the average non-FAMP available for such drug in 2021 may be in direct tension when calculating the ceiling and the Temporary Floor for Small Biotech Drugs, due the applicable percent being applied in contradictory ways in the ceiling and the Temporary Floor for Small Biotech Drugs. If this adjusted ceiling is greater than or equal to the Temporary Floor for Small Biotech Drugs, then such adjusted ceiling would be used as the ceiling for the negotiation between CMS and the Primary Manufacturer, and we would not offer or agree to a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs or greater than this adjusted ceiling for the selected drug.

If this adjusted ceiling is still below the Temporary Floor for Small Biotech Drugs, then, as described in proposed § 429.440(b)(4)(ii), we would raise the ceiling to be equal to the Temporary Floor for Small Biotech Drugs. We believe that raising the ceiling to be equal to the Temporary Floor for Small Biotech Drugs appropriately balances the statutory requirements to establish a ceiling for a selected drug while ensuring the negotiation process also gives full effect to the Temporary Floor for Small Biotech Drugs provision at section 1194(d) of the Act. We note that the Temporary Floor for Small Biotech Drugs provision applies only with respect to negotiations and renegotiations that occur for initial price applicability years 2029 and 2030 for eligible drugs, and it would not apply to any subsequent renegotiations of drugs selected for renegotiation with respect to an initial price applicability year after initial price applicability year 2030. We considered disregarding the ceiling entirely, but we do not believe this approach would align with the statutory requirements for both a ceiling and a Temporary Floor for Small Biotech Drugs. We also considered using the amount calculated in section 1194(c)(1)(B) of the Act (as proposed in § 429.410(b)(1) or § 429.620(b)) as the sole amount for the ceiling, however we do not believe this approach would align with the statutory requirements to apply an applicable percent in section 1194(c)(1)(C) of the Act, and would result in a ceiling that would not distinguish between a short-monopoly drug, a long-monopoly drug, and an extended-monopoly drug (beginning in

initial price applicability year 2030). In accordance with section 1194(b)(2)(F) of the Act, because the ceiling and the Temporary Floor for Small Biotech Drugs for a selected drug would equal the same price, we would only offer or agree to a counteroffer for an MFP that is equal to such price. We believe that this stepwise approach addresses circumstances in which the ceiling is below the Temporary Floor for Small Biotech Drugs while maintaining the integrity of the negotiation process and implementing the statutory responsibility to not offer or accept a counteroffer of an MFP that is above the ceiling or below the Temporary Floor for Small Biotech Drugs.

As proposed in § 429.440(b)(5), if a Primary Manufacturer submits an application for the Temporary Floor for Small Biotech Drugs, we would provide a notice in writing to the Primary Manufacturer, alongside the calculation information provided as set forth in § 429.445(a), which would include: a determination of whether the selected drug is a Small Biotech Drug; and, if the selected drug is eligible for the Temporary Floor for Small Biotech Drugs, the calculation of the Temporary Floor for Small Biotech Drugs as proposed in § 429.440(b)(3) (or adjusted ceiling, if applicable, as proposed in § 429.440(b)(4)). We propose in § 429.440(b)(6) to allow a Primary Manufacturer that believes in good faith that CMS has made an error in calculations pertaining to the calculation of the Temporary Floor for Small Biotech Drugs, as proposed in § 429.440(b)(3), or the adjusted ceiling, if applicable, calculated for a drug that receives the Temporary Floor for Small Biotech Drugs, as proposed in § 429.440(b)(4), to submit a Suggestion of Error as proposed in § 429.445(c).

10. Calculation Information and Suggestion of Error (§ 429.445)

In implementing the statutory provisions of the Negotiation Program, CMS is required to execute a number of multi-step calculations. Section 1194(b)(2)(F)(i) of the Act requires that, in negotiating the MFP of a selected drug, including during renegotiation, CMS would not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. Section 1196(a) of the Act describes certain of CMS' administrative duties, including section 1196(a)(2) of the Act, which requires CMS to establish procedures to compute and apply the MFP across dosage forms and strengths of a selected drug and not based on the specific formulation or package size or package type of such

drug. Section 1194(d) of the Act requires that for a selected drug that is a qualifying single source drug that meets the requirements set forth in section 1192(d)(2) of the Act to be determined a Small Biotech Drug, and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, CMS will not offer or agree to a counteroffer for an MFP that is lower than the Temporary Floor for Small Biotech Drugs. With respect to initial price applicability years 2026 through 2028, we implemented a suggestion of error process for Primary Manufacturers if they believe in good faith that CMS has made an error in calculating the ceiling or in applying the MFP across dosage forms and strengths of a selected drug, including, for example, in section 40.5 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 40.5 of the Negotiation Program Guidance, as revised based on the proposed modifications discussed in this section, we propose in § 429.445 to provide a Primary Manufacturer the opportunity to submit a suggestion of error if they believe in good faith that CMS has made an error in the calculation of the ceiling or the computation of how CMS intends to apply a single MFP across dosage forms and strengths of the selected drug.

We propose at § 429.445(a) to provide a Primary Manufacturer with the following information, as applicable: information on CMS' calculation of the ceiling, as described in §§ 429.410 through 429.435; the computation of how we will apply a single MFP across dosage forms and strengths of the selected drug, as described in § 429.700(b) and (c); and information on CMS' calculations of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable), as described in § 429.440(b)(3) and (b)(4). The information on CMS' calculations of the ceiling would include each intermediate step in the calculation of the section 1847A(b)(4) of the Act payment amount as described in § 429.425, and the non-FAMP amounts as described in § 429.435. The plan-specific enrollment weighted amount as described in § 429.420 would also be included in the information on CMS' calculations of the ceiling but the intermediate steps that make up the plan-specific weighted amount would not, as the plan sponsor's reported Part

D PDE data is proprietary data of the plan sponsors and is protected from disclosure, as described in the confidentiality policy proposed in § 429.300(b). The computation of how we will apply a single MFP across dosage forms and strengths of the selected drug would include each intermediate step in our calculation for all applicable NDCs associated with a selected drug, as described in § 429.700 to demonstrate how we will apply a single MFP across dosage forms and strengths. If a selected drug is eligible for the Temporary Floor for Small Biotech Drugs, the information on the calculations of the Temporary Floor for Small Biotech Drugs would include each intermediate step in the calculation of the Temporary Floor for Small Biotech Drugs as described in § 429.440(b)(3). We would also include the information on CMS' calculation of the ceiling, as described previously, and information on CMS' calculation of the adjusted ceiling, if applicable. The information on CMS' calculations of the alternative ceiling will include a modified version of the ceiling calculations, based on whether the selected drug's adjusted ceiling is calculated using proposed § 429.440(b)(4)(i) or (ii).

We propose in § 429.445(b)(1) to provide the information on CMS' calculation of the ceiling, the computation of how we will apply a single MFP across dosage forms and strengths of the selected drug, and, as applicable, information on CMS' calculations of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable) following the Primary Manufacturer's submission of the section 1194(e)(1) data described in proposed §§ 429.100(d), 429.405(a), 429.440(b)(1), and 429.505(b)(2) and following the Primary Manufacturer's submission of the section 1194(e)(1) data described in proposed § 429.615(b)(1). Additionally, in proposed § 429.445(b)(2), we would also provide the computation of how we will apply a single MFP across dosage forms and strengths of the selected drug following the Primary Manufacturer's submission of any updates to the list of NDC-11s, as proposed in § 429.100(e) and following the determination that an NDC with insufficient data, as described in section II.H.1. of this proposed rule and proposed in § 429.700(c)(3) has sufficient data, as proposed in § 429.700(c)(4)(i)(B)(2).

Further, we propose in § 429.445(c) that Primary Manufacturers would have 10 days to submit a suggestion of error with respect to these calculations if they believe that CMS has made a calculation

error. A calculation error is any error related to the mathematical equations that make up the calculation of the ceiling, the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug, or the calculations of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, if applicable) for a selected drug eligible for the Temporary Floor for Small Biotech Drugs. This includes errors in the sums, products, and quotients of values in the mathematical equations. In contrast, objections to policies and methodologies for implementing the relevant calculations would not be considered a relevant suggestion of error.

Under the applicable guidance for initial price applicability years 2027 and 2028, Primary Manufacturers have 21 days to submit a suggestion of error. We propose to change the length of time that a Primary Manufacturer has to submit a suggestion of error with respect to the information provided under proposed § 429.445(a)(1) and (a)(3) in order to ensure we can meet deadlines for the negotiation process established in statute. As described in section II.C.1. of this proposed rule, in accordance with section 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug must submit, no later than March 1 of the year of the selected drug publication date, with respect to the selected drug, certain information, including non-FAMP data and other information required to carry out the negotiation process, including the information specified at section 1194(e)(1) of the Act. In accordance with section 1194(b)(2)(B) of the Act, and as proposed at § 429.520(a), CMS would provide the Primary Manufacturer with the written initial offer no later than June 1 following the selected drug publication date. Therefore, CMS has only 3 months to process and analyze Primary Manufacturer data that the agency must consider when preparing the written initial offer. Our experience implementing the Negotiation Program to date has demonstrated that a suggestion of error period of 21 days (or more) impedes our ability to perform the analysis necessary to meet the June 1st statutory deadline. In particular, we have found that additional time is needed beyond March 1st to engage with Primary Manufacturers regarding their required data submissions to ensure that they have submitted the data necessary for us to perform the required calculations and that such information is presented with sufficient clarity for us

to be able to use it, in accordance with their obligations under the Negotiation Program Agreement. We cannot provide the ceiling calculation information described in proposed § 429.410 through § 429.435, until we have engaged in this process. Reducing the time for Primary Manufacturers to submit a suggestion of error to 10 days will allow for a timely review of Primary Manufacturer submissions of the section 1194(e)(1) factors, the opportunity for Primary Manufacturers to supplement and clarify submissions in accordance with agency requests in accordance with proposed § 429.900(b), and allow for the delivery of the information to the Primary Manufacturer and the suggestion of error window to be complete prior to the June 1st statutory deadline for written initial offers.

Additionally, we propose to change the length of time that a Primary Manufacturer has to submit a suggestion of error with respect to the information provided under proposed § 429.445(a)(2) in order to incorporate Primary Manufacturer feedback to the extent practicable and as appropriate, into MFP application calculations prior to the MFP going into effect. As described in section II.B.1. of this proposed rule, a Primary Manufacturer of a selected drug has an ongoing obligation to report, at least 30 calendar days prior to the change taking effect, any changes to the list of NDC-11s provided in proposed § 429.100(d) to ensure the list of NDC-11s of the selected drug remains complete and accurate. Our experience implementing the Negotiation Program to date has demonstrated that a suggestion of error period of 21 days does not leave the agency sufficient time to consider Primary Manufacturer feedback prior to implementation of revised MFPs and MFPs for new NDCs. Reducing the time for Primary Manufacturers to submit a suggestion of error to 10 days will allow for CMS to consider, and incorporate, to the extent practicable and as appropriate, Primary Manufacturer feedback prior to implementation of revised MFPs and MFPs for new NDCs.

As further specified in proposed § 429.445(c), the suggestion of error process would not affect a Primary Manufacturer's obligation to comply with Negotiation Program requirements and would not alter or change any timelines or requirements of the Negotiation Program.

A Primary Manufacturer must submit any suggestion of error on the calculation of the ceiling, the computation of how CMS would apply a single MFP across dosage forms and

strengths, and information on CMS' calculation of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable) of the selected drug in a form and manner specified by CMS, as proposed in § 429.445(d).

We solicit comments on our proposed approach for the suggestion of error process. In addition, we solicit comment on whether the regulatory text should expressly identify each of the calculations for which this suggestion of error process would be available. *F. Negotiation Process (§§ 429.500 through 429.535)*

1. General Rule (§ 429.500)

Section 1194 of the Act describes the process that CMS must follow when conducting negotiation and renegotiation. Specifically, section 1194(b)(2) of the Act directs CMS to use a consistent methodology and process for negotiation that aims to achieve the lowest MFP for each selected drug. Further, section 1194(e) of the Act requires CMS to consider section 1194(e)(1) factors and section 1194(e)(2) factors as the basis for determining offers and counteroffers. CMS proposes to codify these provisions at § 429.500(a). We also propose in § 429.500(b) that to formalize an agreed-upon MFP, CMS and the Primary Manufacturer must sign an Addendum to the Negotiation Program Agreement, as described in proposed § 429.200(e) and discussed in section II.C.1. of this proposed rule.

With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, sections 60.3 and 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, we are proposing in §§ 429.500 through 429.535 to codify the negotiation process consistent with the requirements of the IRA and such prior guidance, with proposed revisions noted in these sections.

2. Negotiation Factors (§ 429.505)

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining offers and counteroffers, as described at proposed § 429.505(a) and further discussed at proposed § 429.510(e) and (f) and section II.F.3. of this proposed rule. These factors include data submitted by the Primary Manufacturer, as specified in section

1194(e)(1) of the Act and evidence about alternative treatments, as specified in section 1194(e)(2) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, with respect to initial price applicability year 2028, section 50 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 50 of the Negotiation Program Guidance, proposed § 429.505, as described more fully below, codifies our collection of data related to the factors listed at section 1194(e) of the Act, the process for such data collection, the timing of such data collection, and requirements for the Primary Manufacturer to update submitted data. This section also discusses how we propose to consider evidence from comparative clinical effectiveness research in accordance with section 1194(e)(2) of the Act.

a. Information Related to Section 1194(e)(1) Factors

As noted previously, section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining offers and counteroffers, including data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Further, section 1194(b)(2)(A) requires that, not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the Primary Manufacturer shall submit the information described in section 1193(a)(4) of the Act, including but not limited to, information required to carry out the negotiation or renegotiation process. Accordingly, in accordance with the requirements of its Negotiation Program Agreement (proposed in subpart C and described in section II.C.3. of this proposed rule) and in accordance with sections 1193(a)(4) and 1194(b)(2)(A) of the Act, we propose to codify at § 429.505(b) that the Primary Manufacturer of a selected drug is required to submit, among other information, information required to carry out the Negotiation Program, including but not limited to, information related to the factors listed in section 1194(e)(1) of the Act, inclusive of NDC-11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, by 11:59 p.m. PST on March 1 of the year of the selected drug

publication date (described in proposed § 429.100(c) and section II.B.1. of this proposed rule). We propose that such information would be submitted through the Drug Price Negotiation ICR.

Specifically, in accordance with sections 1193(a)(4), 1194(b)(2)(A), and 1194(e)(1) of the Act, we propose at § 429.505(b)(1) to codify that a Primary Manufacturer is required to submit the following information with respect to its selected drug, inclusive of NDC-11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, by 11:59 p.m. PST on March 1 of the year of the selected drug publication date: (1) R&D costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs; (2) current unit costs of production and distribution of the selected drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug; (4) data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and (5) market data and revenue and sales volume data for the selected drug in the United States.

When determining what information we require to carry out the statutory obligation to consider the section 1194(e)(1) factors, we considered the operational and financial burden to the Primary Manufacturer alongside the importance of collecting sufficient information to inform determination of offers and counteroffers, including development of the initial offer. Specifically for the section 1194(e)(1) factors, we do not believe that we are able to obtain this information from sources other than the Primary Manufacturer of the selected drug per statute regardless of whether alternative sources for this information may exist, whether publicly available or available within CMS. Likewise, in accordance with section 1194(e)(1) of the Act, the Primary Manufacturer will be required to submit information for the section 1194(e)(1) factors for renegotiation, as proposed in § 429.615(b)(1) and discussed further in II.G.4 of this proposed rule.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200(b)), we propose in § 429.505(c) that a Primary Manufacturer has an ongoing obligation to report any updates to the information provided in proposed § 429.505(b) if the

Primary Manufacturer becomes aware that any of such information has changed or is otherwise inaccurate. CMS will provide the Primary Manufacturer with a method to report any updates to the information provided in proposed § 429.505(b). For example, under proposed § 429.505(c), Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under proposed § 429.505(b) if the data was restated due to requirements of the Federal government entity that initially receives and oversees processing of such data. For example, under the Medicaid program, manufacturers must report revisions to best price under 42 CFR 447.510. The Primary Manufacturer must timely notify CMS if any such updates are applicable to the selected drug. This ongoing obligation to update the Primary Manufacturer's original data submissions is separate both from any voluntary submission of data from a Primary Manufacturer of a selected drug to inform renegotiation eligibility and selection (described at proposed § 429.615(a) and section II.G.4. of this proposed rule) and the required submission of data related to section 1194(e)(1) factors to CMS for drugs selected for renegotiation (described at proposed § 429.615(b)(1) and section II.G.4. of this proposed rule), which cover different reporting periods. As discussed further in section II.G.4.a. of this proposed rule, we may consider the Primary Manufacturer's prior data submission(s) under proposed § 429.505(b), including any updates to such information, to inform renegotiation eligibility and selection, and may use such information during renegotiation if a drug is selected for renegotiation.

b. Information Related to Section 1194(e)(2) Factors

Section 1194(e)(2) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as described at proposed § 429.510 and section II.F.3. of this proposed rule. These factors, listed at sections 1194(e)(2)(A) through (D) of the Act, include: (1) the extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives; (2) FDA-approved prescribing information for the selected drug and its therapeutic alternatives; (3) comparative effectiveness of the selected drug and its

therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations as described in section 1194(e)(2)(C) of the Act); and (4) the extent to which the selected drug and the therapeutic alternatives to the selected drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy. Section 1194(e)(2) of the Act does not require the information listed to come from any specific source. As such, we considered various options for obtaining information related to the factors listed in section 1194(e)(2) of the Act, including an internal CMS analysis, obtaining the information from the Primary Manufacturer, obtaining information from the public, or some combination of these options. We believe that obtaining input from multiple perspectives, including but not limited to manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties will provide the most comprehensive understanding of the selected drug and its therapeutic alternatives.

For section 1194(e)(2) factors, we propose to take a two-pronged approach consistent with policies for implementation for initial price applicability year 2028 as described in section 50.2 of Negotiation Program Guidance. In this approach, we would evaluate existing literature and real-world evidence, conduct internal analytics, and consult subject matter experts and clinicians, whether within CMS or external to CMS, when considering available evidence about alternative treatments to the selected drug (per the process proposed at § 429.510(b) and (c) and described in section II.F.3.c. of this proposed rule). We also intend to provide for a voluntary submission of information related to section 1194(e)(2) factors from manufacturers and the public through the Drug Price Negotiation ICR. Accordingly, consistent with policies for implementation for initial price applicability year 2028 as described in section 50.2 of the Negotiation Program Guidance, we propose at § 429.505(d) to codify that the submission of information related to section 1194(e)(2) of the Act will be open to the public and voluntary. We propose at § 429.505(d)(1) that any interested party, including the Primary Manufacturer of a selected drug, may submit information on

selected drugs and their therapeutic alternatives (consistent with policies for implementation for initial price applicability year 2028 as described in section 60.3 of Negotiation Program Guidance) including information on whether the selected drug represents a therapeutic advance over its therapeutic alternative(s), prescribing information for the selected drug and its therapeutic alternative(s), comparative effectiveness data for the selected drug and its therapeutic alternative(s), information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, information about patient experience, information on whether the selected drug addresses unmet medical need, or any combination thereof, as described in section 1194(e)(2) of the Act.

In accordance with section 1196(a)(4) of the Act, we also propose at § 429.505(d)(2) that the deadline for submission of information related to the factors listed in section 1194(e)(2) of the Act be the same date and time as the deadline for the Primary Manufacturer to submit non-FAMP and information related to factors listed in section 1194(e)(1) of the Act, that is by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the selected drug (described in proposed § 429.100(c) and section II.B.1. of this proposed rule). This serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer.

Section 1194(e)(2) of the Act also requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Accordingly, consistent with policies for implementation for initial price applicability year 2028 as described in section 50.2 of the Negotiation Program Guidance, we propose to codify at § 429.505(e), that we will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Specifically, we propose to codify at § 429.505(e)(1) that we will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the use of the measure is permitted in accordance with section 1194(e)(2) of the Act as described at § 429.505(e), as well as section 1182(e)

of the Act and other applicable law, including section 504 of the Rehabilitation Act. We also propose at § 429.505(e)(2) that we may use content in a study that uses a cost-effectiveness measure if we determine that the cost-effectiveness measure used is permitted in accordance with section 1194(e)(2) of the Act as described at proposed § 429.505(e), as well as section 1182(e) of the Act and other applicable law, including section 504 of the Rehabilitation Act. In proposed § 429.505(e)(2), we propose that in instances where some, but not all, content in a study is excluded, we may still consider content that is relevant and allowable (for example, clinical effectiveness, risks, harms) under section 1194(e)(2) of the Act and section 1182(e) of the Act.

3. Methodology for Developing the Initial Offer (§ 429.510)

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternative(s) as the basis for determining offers and counteroffers in the negotiation process. Further, section 1194(b)(2)(B) of the Act requires CMS to provide the manufacturer of a selected drug with a written initial offer and a concise justification based on the factors described in section 1194(e) of the Act that were used in developing the offer. However, the statute does not specify how and to what degree each factor should be considered, thereby providing CMS with the discretion to determine how each factor is considered.

Consistent with section 1194(e) of the Act and with policies for implementation as described in section 60.3 of Negotiation Program Guidance, we propose in § 429.510 that for purposes of determining the initial offer, we would: (1) identify conditions for which the selected drug is used, as described in proposed § 429.510(a); (2) identify the therapeutic alternative(s), if any, for the selected drug, as described in proposed § 429.510(b) and (c) and consistent with policies for implementation as described in section 60.3.1 of Negotiation Program Guidance; (3) determine the starting point for the initial offer based on the price(s) of the therapeutic alternative(s) for the selected drug, if any, or an alternative price if there is no therapeutic alternative, as described in § 429.510(d) and consistent with policies for implementation as described in section 60.3.2 of Negotiation Program Guidance; (4) consistent with policies for implementation as described in section 60.3.3 of Negotiation Program Guidance

and as proposed at § 429.510(e), evaluate the selected drug, including compared to its therapeutic alternative(s), for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2) of the Act, which would result in the preliminary price as defined at proposed § 429.20; and (5) adjust the preliminary price based on the negotiation factors outlined in section 1194(e)(1) of the Act and consistent with policies for implementation as described in section 60.3.4 of Negotiation Program Guidance as described in proposed § 429.510(f) to determine the initial offer price. In accordance with section 1194(b)(1) of the Act, this process will be conducted with the aim of achieving the lowest MFP for each selected drug.

In accordance with section 1194(b)(2)(F) of the Act we would not make any offers or accept any counteroffers for the MFP that are above the statutorily defined ceiling as indicated in proposed § 429.410 nor below the temporary floor for small biotech drugs, if applicable, as indicated in § 429.440.

a. Identifying Conditions for Which the Selected Drug Is Used (§ 429.510(a))

To identify conditions for which the selected drug is used, we propose at § 429.510(a)(1) to identify the FDA-approved indication(s) of the selected drug covered under Part D, payable under Part B, or both using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act and consistent with policies for implementation as described in section 60.3.1 of Negotiation Program Guidance. In § 429.510(a)(2), we propose to consider off-label use to identify conditions for which the selected drug is used, if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically accepted indication, as defined in section 1927(k)(6) of the Act, payable under Part B, covered under Part D, or both, taking into consideration the major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof.

In proposed § 429.510(a)(3), we propose to exclude from our analysis for development of the initial offer any FDA-approved indication(s) or off-label uses for which we believe that utilization of the selected drug within such indication(s) and for such uses is intended solely for use in a setting in which the selected drug is not payable under Part B and not covered under Part

D. Since the MFP resulting from a negotiation may only be applied for drugs payable under Part B, covered under Part D, or both, it is consistent for CMS to exclude from its analysis these FDA-approved indications or off-label uses. The MFP would not be applied unless payable under Part B or covered under Part D, so excluding such FDA-approved indications or off-label uses from CMS' analysis provides the opportunity to focus on indications for which the MFP would be applied when developing the initial offer. For example, we may not include an FDA-approved indication or off-label use in our analysis for the initial offer if such indication or off-label use is recommended for use in clinical practice guidelines only in inpatient hospital settings. We note that a Primary Manufacturer may suggest in its response to the initial offer that use within an FDA-approved indication or an off-label use that was not included in the initial offer is relevant for negotiating an MFP for the selected drug, in which case we may include such indication or off-label use in our consideration of any counteroffers or revised offers.

b. Identifying Therapeutic Alternatives for Each Condition (§ 429.510(b) and (c))

For each condition for which the selected drug is used, we would use the information identified in proposed § 429.510(b) and would follow the steps defined in proposed § 429.510(c) and consistent with policies for implementation as described in section 60.3.1 of Negotiation Program Guidance to identify a pharmaceutical therapeutic alternative(s), if any, for purposes of developing the initial offer. To identify potential therapeutic alternatives for the condition(s) for which a selected drug is used, we propose in § 429.510(b)(1) to use data submitted by the Primary Manufacturer and the public, prescribing information approved by the FDA, drug classification systems commonly used in the public and private sector for formulary development, major drug compendia, widely accepted clinical practice guidelines, evidence identified through the CMS-led literature review, published drug or drug class reviews, peer-reviewed studies, and Medicare claims or other data sets. In addition to brand name drugs and biological products, we propose to consider generic drugs and biosimilars, including specific formulations or dosage forms and strengths of a brand name drug, brand name biological product, generic drug, or biosimilar, as applicable, when identifying a potential therapeutic

alternative(s) to a selected drug as described in proposed § 429.510(b)(2).

We considered evaluating non-pharmaceutical interventions as potential therapeutic alternatives to the selected drug, including requesting public comment on the use of health care services during the 45-day public comment period on the draft guidance for initial price applicability year 2028. Considering non-pharmaceutical interventions as a therapeutic alternative poses several challenges. First, from a clinical perspective, non-pharmaceutical interventions are not exclusively used as alternatives to drugs, or vice versa. For example, non-pharmaceutical interventions may serve as a complementary component of treatment provided at the same time as treatment with a drug. In other situations, such as cancer care, the standard of care may recommend the sequential use of non-pharmaceutical interventions and drugs, with the non-pharmaceutical intervention (for example, surgery) provided as a first-line treatment and then a drug that is used as the second-line treatment (for example, oral chemotherapy) or vice versa. Should a non-pharmaceutical intervention be considered a therapeutic alternative, such intervention must be an alternative to the drug rather than a complementary or sequential component of care, which may be difficult to clearly determine given the complex nature of treatment for many disease states and conditions. It may also be difficult to assess the comparative effectiveness of a non-pharmaceutical intervention and a drug. As a result of these considerations, we are not proposing to use non-pharmaceutical interventions as a therapeutic alternative for selected drugs in this proposed rule. As we continue to gain experience with the Negotiation Program, we may continue to evaluate approaches to the identification of therapeutic alternatives.

Section 1194(e)(2)(A) of the Act directs CMS to consider "[t]he extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives." As such, we also considered how to understand this directive from statute if non-pharmaceutical interventions were included as therapeutic alternatives, including how to consider differential pricing between drugs and non-pharmaceutical interventions. Pricing and payment for drugs and services often differ substantially, not only within Medicare but also across other

payer types, and non-pharmaceutical interventions may not have similar periodicity or frequency of administration as drugs, which could make comparisons challenging. If CMS were to consider non-pharmaceutical interventions as therapeutic alternatives, we would be required to adopt or create a methodology for determining the 30-day equivalent supply of a non-pharmaceutical intervention, which could include or exclude many components of a service. For example, if physical therapy could potentially serve as a therapeutic alternative to the use of a selected drug, we would need to determine how many and what types of physical therapy services and what duration of those services should be compared to the selected drug and over what time frame. Also, if a type of surgery could potentially serve as a therapeutic alternative to the use of the selected drug, we would need to determine what bundle of services from that surgery would be included in the therapeutic alternative. We believe that general rules would likely be insufficient to capture the heterogeneity of possible non-pharmaceutical interventions available and that specific analyses would be needed in each case. Therefore, we do not believe this is feasible at this time given the statutory timelines provided for negotiation and renegotiation.

Given these challenges, we believe that pharmaceutical therapeutic alternatives would be the most analogous alternative to the selected drug. By comparing a selected drug to a pharmaceutical therapeutic alternative, we would be able to consider the treatment effect and costs as directed by the statute in section 1194(e) of the Act while also operating within statutorily determined timeframes for the negotiation and renegotiation periods. We propose at § 429.510(c)(1) that we may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same condition. We may also consult with clinicians, patients or patient organizations, researchers, or any combination thereof to ensure that appropriate therapeutic alternatives are identified. We propose in § 429.510(c)(2)(i) to consider off-label use when identifying conditions for therapeutic alternatives if such use is included in evidence-based clinical practice guidelines and the off-label use is medically accepted and covered under Part D, payable under Part B, or both, taking into consideration the major drug compendia, authoritative

medical literature, accepted standards of medical practice, or some combination thereof, as defined in proposed § 429.20.

We propose at § 429.510(c)(2)(ii) to identify potential therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action and also propose at § 429.510(c)(2)(iii) to consider potential therapeutic alternatives in different pharmacologic classes based on our evaluation of the sources noted previously and in proposed § 429.510(b)(1). Where appropriate, only certain formulations or dosage forms and strengths of a brand name drug, brand name biological product, generic drug, or biosimilar (as described in § 429.510(b)(2)) would be identified as the therapeutic alternative to the selected drug as specified in proposed § 429.510(c)(2)(iv), for example, when one formulation of a drug meets the criteria for a therapeutic alternative, but other formulations do not.

In proposed § 429.510(c)(3), we propose that, in cases where there are many potential therapeutic alternatives for a given condition for which the selected drug is used, we may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug for the purpose of developing the initial offer. We note that when referencing a “therapeutic alternative” this may refer to one or more therapeutic alternative(s) or a subset of therapeutic alternatives that are clinically comparable. For example, for a potential therapeutic alternative, we may consider the place in therapy based on evidence-based clinical practice guidelines, pharmacologic and therapeutic characteristics, utilization in the Medicare population, and the availability of direct and indirect comparative evidence relative to the selected drug. In § 429.510(c)(4), we propose to prioritize clinical appropriateness in the selection of therapeutic alternatives.

c. Developing a Starting Point for the Initial Offer (§ 429.510(d))

To fulfill the statutory requirement to develop the initial offer per section 1194b(2)(B) of the Act in accordance with section 1194(e) of the Act, we propose at § 429.510(d) to determine a numerical starting point that would be adjusted based on the section 1194(e)(2) factors to determine a preliminary price (as described in § 429.510(e) and section II.F.3.d.1. of this proposed rule) which would then be adjusted based on the section 1194(e)(1) factors (as described in § 429.510(f) and section II.F.3.d.2. of

this proposed rule). We considered several options for what price should be used as the starting point for developing the initial offer. Options considered included the use of the Part D net price(s), the ASP/WAC(s) of therapeutic alternative(s) for drugs covered under Part D or payable under Part B, respectively, or both; the unit cost of production and distribution for the selected drug; the ceiling for the selected drug (as described in proposed § 429.440(a)); a domestic reference price for the selected drug (for example, the Federal Supply Schedule⁵⁶ (FSS) price); a “fair profit” price for the selected drug based on whether R&D costs have been recouped and margin on unit cost of production and distribution; Net Part D Plan Payment and Beneficiary Liability for drugs covered under Part D; the MFP, if available; a starting point between: (a) the Part B ASP/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and D amount discussed previously for the therapeutic alternatives; and (b) the statutory ceiling; or considering a starting point between (a) the Part B ASPs/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and Part D amount discussed previously for therapeutic alternatives and (b) unit cost of production and distribution of the selected drug; or some combination thereof. Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling as required by section 1194(c) of the Act and proposed at § 429.440(b).

After considering these options and based on experience from implementation of the Negotiation Program for initial price applicability years 2026 through 2028, in accordance with section 1194(e)(2)(A) of the Act, which directs CMS to consider the cost of therapeutic alternative(s), we propose at § 429.510(d)(1) to use the price of the therapeutic alternative(s) to determine the starting point for developing the initial offer. We propose at § 429.510(d)(1)(i) that the price of a therapeutic alternative covered under Part D would be the lower of: the Net Part D Plan Payment and Beneficiary Liability, WAC, or the MFP for a selected drug negotiated for a prior

⁵⁶ The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: <https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government.>

initial price applicability year (regardless of whether the agreed-upon MFP for such selected drug has become effective). We propose at § 429.510(d)(1)(ii) that the price of a therapeutic alternative payable under Part B would be the lower of: ASP, the MFP for a selected drug negotiated for a prior initial price applicability year (regardless of whether the agreed-upon MFP for such selected drug has become effective), or WAC. We propose at § 429.510(d)(1)(iii) that for a therapeutic alternative that is both payable under Part B and covered under Part D, the price would be equal to a combined amount based on the price of the therapeutic alternative under Part D and the price under Part B (as determined under proposed § 429.510(d)(1)(i) and (ii)). We propose that the combined amount would be determined using an approach similar to the methodology used to combine the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act; this single combined amount would then be weighted by utilization of the drug across Part B and Part D.

For a selected drug with no therapeutic alternative or for a selected drug where the price(s) of the therapeutic alternative(s) determined under proposed § 429.510(d)(1)(i) and (iii) are above the ceiling, we propose at § 429.510(d)(1)(iv) to use an alternative price equal to the lower of: the pharmaceutical price for the selected drug as included in the FSS as managed by the Department of Veterans Affairs per 48 CFR part 38 as most recently submitted by the Primary Manufacturer; or the maximum price a manufacturer can charge for the selected drug under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacturer.

When determining the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative, as defined in § 429.20, we would exclude PDE records for which a compound code indicates the PDE record is for a compounded drug as described in section II.B.5.a. of this proposed rule. We also believe it is important to reduce the total gross covered prescription drug costs by both DIR and Manufacturer Discount Program payments to permit an appropriate accounting of the price paid by the plan and beneficiary net of price concessions received by Part D plan or pharmacy benefit managers on behalf of a Part D plan. When assessing a therapeutic alternative(s) payable under Part B to determine a starting point for the initial offer, we believe using the lesser of ASP or WAC aligns with the payment amount under section

1847A(b)(4) of the Act, including in circumstances where the WAC of a therapeutic alternative is lower than its ASP. We also believe that considering the agreed-upon MFP for a selected drug that is payable under Part B, covered under Part D, or both, is also appropriate since the agreed-upon MFP may be the lowest available pricing metric for certain drugs.

In proposing this approach, we acknowledge that the therapeutic alternative(s) may not be priced to reflect the clinical benefit of the selected drug; however, using existing prices for therapeutic alternatives, including Net Part D Plan Payment and Beneficiary Liability, MFP, or WAC for a drug covered under Part D, or ASP, MFP, or WAC for a drug payable under Part B, enables CMS to start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), we would be able to focus the adjustments on section 1194(e)(2) factors by adjusting this starting point (as described in proposed § 429.510(e)(4)) based on the overall evidence of benefits and harms offered by the selected drug as compared with its therapeutic alternative(s). The other options considered do not provide a starting point that reflects the cost of therapeutic alternatives in the current market, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries relative to the other drug(s) available to treat the patient's disease or condition.

We propose at § 429.510(d)(2) that the prices determined under § 429.510(d)(1) and the starting point would be expressed as a 30-day equivalent supply. We propose at § 429.510(d)(2)(i) to use the same methodology described in proposed § 429.410(b)(1) to calculate the 30-day equivalent supply for drugs covered under Part D, as appropriate, unless we determine it is appropriate to apply an alternative methodology as described further below. We propose at § 429.510(d)(2)(ii) to use the same methodology described in proposed § 429.410(b)(2) to calculate the 30-day equivalent supply for drugs payable under Part B, as appropriate, unless we determine it is appropriate to apply an alternative methodology as described further below. We propose at § 429.510(d)(2)(iii) to calculate the 30-day equivalent supply of a therapeutic alternative that is both covered under Part D and payable under Part B separately (as determined in proposed § 429.510(d)(1)(i) and (ii)), unless we

determine it is appropriate to apply an alternative methodology as discussed below. We also propose in § 429.510(d)(2)(iii) that we would determine the 30-day equivalent supply for the price of the therapeutic alternative that is payable under Part B and, separately determine the 30-day equivalent supply for the therapeutic alternative that is covered under Part D prior to combining these amounts using the methodology described in proposed § 429.415(d)(1)(iii) to result in a single combined price expressed as a 30-day equivalent supply.

In certain circumstances it may be necessary to use an alternative methodology to calculate a 30-day equivalent supply, for example, if a therapeutic alternative for a condition is typically prescribed for a period meaningfully shorter than 30 days (for example, for a two-week period, meaning that one fill would be defined as a 30-day equivalent supply despite lasting only two weeks), and the selected drug does not have a similar prescribing pattern, we may use an alternative methodology to calculate 30-day equivalent supply for the therapeutic alternative to ensure that its price is expressed on comparable terms to a 30-day equivalent supply. In circumstances such as these, we propose at § 429.510(d)(4)(iv) to use a tailored alternative methodology to calculate the 30-day equivalent supply for therapeutic alternative(s) covered under Part D, payable under Part B, or both, when appropriate. The tailored methodology would promote comparability between the therapeutic alternative(s) and the selected drug.

We propose in § 429.510(d)(3) to use the price(s) identified under proposed § 429.510(d)(1) to determine the starting point for developing the initial offer. We propose at § 429.510(d)(3)(i) that if there is no therapeutic alternative for a selected drug or there is no price of the therapeutic alternative(s) determined under proposed § 429.510(d)(1)(i) through (iii) that are below the ceiling, then the starting point for developing the initial offer is the lower of the prices listed at proposed § 429.510(d)(3)(i)(A) through (C). That is, we propose to use the lower of the maximum price a manufacturer can charge under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacturer, the pharmaceutical price for the selected drug as included in the FSS as managed by the Department of Veterans Affairs per 48 CFR part 38 (hereinafter the "FSS price") as most recently submitted by the Primary Manufacturer, or the ceiling.

If there are multiple therapeutic alternatives and at least one therapeutic alternative price identified is below the ceiling, we propose at § 429.510(d)(3)(ii) to determine a starting point for developing the initial offer within a range based on the lower of the prices of the therapeutic alternatives determined under § 429.510(d)(1) and the ceiling. In implementing this proposal, we may weigh prices used to determine the range based on utilization, for example, by the utilization of therapeutic alternatives within and across multiple conditions or other patterns of use for the therapeutic alternatives or the selected drug. When determining the starting point within this range, we may consider the therapeutic alternative prices for each condition if such prices are available and if such prices are different across conditions.

Finally, we propose at § 429.510(d)(3)(iii) that if there is one therapeutic alternative for the selected drug with a price that is below the ceiling, the price of such therapeutic alternative is the starting point. In all cases, the starting point would not exceed the statutory ceiling and would be subject to adjustments as described further in proposed § 429.510(e) and section II.F.3.d. of this proposed rule.

d. Adjusting the Starting Point and Preliminary Price Based on the Factors Listed at Section 1194(e) of the Act (§ 429.510(e) and (f))

Section 1194(e) of the Act directs CMS to consider the factors listed at section 1194(e)(1) and 1194(e)(2) of the Act as the basis for any offers and counteroffers and, in accordance with section 1194(b)(1) of the Act, CMS must develop and use a consistent methodology and process for negotiations to achieve the lowest MFP for each selected drug. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, sections 60.3.3 and 60.3.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in sections 60.3.3 and 60.3.4 of the Negotiation Program Guidance, we are proposing at § 429.510(e) to adjust the starting point determined under proposed § 429.510(d), based on the section 1194(e)(2) factors to determine the preliminary price and then adjusting the preliminary price based on the section 1194(e)(1) factors, as described in § 429.510(f), to

determine the initial offer. This approach ensures that we consider each section 1194(e) factor while also providing a consistent methodology for doing so.

(1) Adjusting the Starting Point Based on Section 1194(e)(2) Factors (§ 429.510(e))

To evaluate the section 1194(e)(2) factors, including the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), we propose at § 429.510(e)(1) to use a qualitative approach to broadly evaluate the body of available evidence, including information received from the public and the Primary Manufacturer as described in proposed §§ 429.505(b), 429.505(d), and 429.515(b), evidence identified through a CMS-led literature review, Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug versus its therapeutic alternative(s), clinical data, or other information relevant to the selected drug and its therapeutic alternative(s). We also propose at § 429.510(e)(2) that we may consult with clinicians, patients or patient organizations, researchers, and/or FDA. This review would be complementary to additional engagement opportunities for interested parties—specifically, meetings with the Primary Manufacturer and public events as proposed in § 429.515 and described in section II.F.4.b. of this proposed rule—after the March 1 deadline described at proposed § 429.505(d)(2) for submission of section 1194(e)(2) data.

As a complement to the public submission of information on section 1194(e)(2) factors and consistent with policies for implementation as described in section 50.2 of Negotiation Program Guidance, we propose at § 429.510(e)(1) to additionally evaluate existing literature and real-world evidence, conduct internal analytics, and consult subject matter experts and clinicians on these topics when considering available evidence about alternative treatments to the selected drug. When evaluating the literature from the public and manufacturer submissions as well as literature from CMS' review, we intend to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the

negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. We also propose to prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (that is, has sufficient sample size) to answer the primary question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses. We propose to consider research and real-world evidence relating to Medicare populations, including individuals with disabilities, patients with end-stage renal disease, and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, we intend to prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

This approach would provide a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or white papers, clinician expertise, real-world evidence, and patient experience. This approach also would provide us with the flexibility to consider a variety of aspects in our evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to use of the selected drug or therapeutic alternatives.

To consider comparative effectiveness of a selected drug and its therapeutic alternative(s) as required by section 1194(e)(2)(C) of the Act, we propose at § 429.510(e)(3) to identify outcomes to evaluate for each identified condition for which the selected drug is used. Outcomes of interest may include direct clinical outcomes (for example, cure, mortality) or validated or reasonably likely surrogate endpoints (for example, serum hemoglobin A1c) or both. In determining outcomes of interest, we would consider patient-reported outcomes and outcomes of importance to patients, if available. We would consider the identified outcomes of interest, including patient-centered outcomes, and patient experience data, when evaluating the clinical benefit of the selected drug and its therapeutic alternative(s) for those conditions. In addition, we propose at § 429.510(e)(3)(i)(C) that outcomes and contextual factors such as health-related

quality of life or patient and caregiver preferences would also be considered to the extent these outcomes and factors correspond with benefits or harms to the individuals taking the selected drug or therapeutic alternative(s) and are appropriately measurable and quantifiable.

We propose at § 429.505(e) that when evaluating such information we would not, per section 1194(e)(2) of the Act, use evidence in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and would not, per section 1182(e) of the Act, use QALYs. Outcomes of interest may include direct clinical outcomes (for example, cure, mortality) and/or validated or reasonably likely surrogate endpoints (for example, serum hemoglobin A1c). In determining outcomes of interest, we would consider patient-reported outcomes and outcomes of importance to patients, if available. We may also consider additional outcomes and contextual factors, such as health-related quality of life or patient/caregiver preferences regarding treatment, to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternatives. In proposed § 429.510(e)(3)(i)(D), we propose to also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug. As described in proposed § 429.510(e)(3)(ii), relevant outcomes would be identified using the CMS-led literature review and information submitted by manufacturers and the public, including patients and caregivers, as well as in the public events described in proposed § 429.515(b).

In all cases, we propose to consider applicable evidence and other input collectively, within the context of the course of care for each condition for which the selected drug is used. As noted previously, we believe this approach would provide flexibility to consider a variety of aspects in our evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to the use of the selected drug or its therapeutic alternative(s) for a given condition.

Once the starting point for the initial offer has been established and evidence on section 1194(e)(2) factors has been considered, we would consider the

information regarding the four factors outlined in section 1194(e)(2) of the Act collectively and within the context of the course of care for each condition for which the selected drug is used as described at proposed § 429.510(e)(4) and apply an upward adjustment, downward adjustment, or no adjustment to the starting point to determine the preliminary price as described at proposed § 429.510(e)(5). In accordance with section 1194(b)(1) of the Act, consideration and adjustment for the section 1194(e) factors will be made with the aim of achieving the lowest MFP for each selected drug. We considered employing both a qualitative approach (for example, adjusting the starting point upward or downward relative to the section 1194(e)(2) factors offered by the selected drug compared to its therapeutic alternative(s)) and a more thoroughly pre-specified quantitative approach. Consistent with the first three cycles of negotiation, we are proposing to use a qualitative approach to consider nuanced differences between drugs, for example, interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

(a) Analysis for Selected Drugs With Therapeutic Alternative(s)

For each condition for which we identify a therapeutic alternative, we propose to consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively. As described at proposed § 429.510(e)(4)(i), we propose that such review would include, but is not limited to, examining improvements (as described at proposed § 429.510(e)(4)(i)) in outcomes (as determined in proposed § 429.510(e)(3)) to determine the extent to which a selected drug represents a therapeutic advance (as defined at proposed § 429.20) as compared to its therapeutic alternative(s) (as defined at proposed § 429.20) (for example, if selected drug is curative versus a therapeutic alternative that delays progression) and would consider the costs of the selected drug and its therapeutic alternative(s) as described at proposed § 429.510(e)(4)(i)(A).

We propose at § 429.510(e)(4)(i)(B) to consider the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for each condition in which we identify a therapeutic alternative, when determining the extent to which a selected drug represents a therapeutic

advance. We understand that a selected drug can be first in class.⁵⁷ However, other drugs may have become available since the selected drug's initial approval and therefore we propose in the definition of "therapeutic advance" at proposed § 429.20 to consider the extent to which a selected drug represents a therapeutic advance for a condition at the time the section 1194(e)(2) data is submitted, which is the date specified in proposed § 429.505(d)(2). In accordance with section 1194(e)(2)(A) of the Act, we propose to review the analyses detailed previously for each identified condition of the selected drug and its therapeutic alternative(s) to determine the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) as described in proposed § 429.510(e)(4)(i). For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS proposes to consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

In accordance with section 1194(e)(2)(C) of the Act, we would also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations, such as individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations. To do so, we propose to identify studies, if available, focused on the conditions for which each selected drug is used and the impact of the selected drug and its therapeutic alternative(s) on such specific populations. Further, per section 1194(e)(2)(D) of the Act, for each condition in which CMS has identified a therapeutic alternative, we would consider the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need for each condition for which the selected drug is used. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration. When considering unmet medical need (see proposed § 429.20), we propose to consider the selected drug, its therapeutic alternative(s), if

⁵⁷ For purposes of this discussion, first in class drugs are those that have a new mechanism of action, defined by the National Cancer Institute as "a term used to describe how a drug or other substance produces an effect in the body." See: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action>.

any, and any existing treatment options, which may include pharmacologic or non-pharmacologic treatments. We may consider the nonbinding recommendations in the FDA's "Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics,"⁵⁸ as well as any updates that may be issued by FDA in the future, when determining the extent to which a selected drug addresses an unmet medical need for a condition.

(b) Analysis for Conditions of Selected Drugs Without Therapeutic Alternatives

For conditions of selected drugs without therapeutic alternatives, we would consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively. We propose at § 429.510(e)(4)(ii) certain parameters for our review of conditions of selected drugs where we need to account for the lack of therapeutic alternatives for such conditions. Specifically, we propose at § 429.510(e)(4)(ii)(A) that for each condition for which a selected drug is used but does not have a therapeutic alternative, we would consider the totality of available information relevant to the section 1194(e)(2) factors as detailed previously and in proposed § 429.510(e)(1), including information received from Primary Manufacturers and the public as described in proposed § 429.505(d), and evidence identified through a CMS-led literature review. We also propose at § 429.510(e)(4)(ii)(B) to consider the selected drug and any existing treatment options, which may include pharmacologic or non-pharmacologic treatments, to determine the extent to which the selected drug addresses an unmet medical need (as defined in § 429.20) at the condition level. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration. We would consider unmet medical need in the same manner as discussed in section II.F.3.a. of this proposed rule. At proposed § 429.20, we propose to define unmet medical need as a circumstance in which the relevant condition is one for which no treatment options exist, or existing treatments do not adequately address the condition. As noted

previously, we may consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics," as well as any updates that may be issued by FDA in the future, when considering the extent to which a drug addresses an unmet medical need for the purpose of the Negotiation Program.

Finally, as described at proposed § 429.510(e)(4)(ii)(C), we propose to examine improvements in outcomes, such as the magnitude of differences in outcomes of interest conferred by the selected drug, for a condition wherein CMS has not identified a therapeutic alternative to determine the extent to which a selected drug represents a therapeutic advance. For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS would consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration

(c) Preliminary Price

As noted in section II.F.3.d.(1).(a). of this proposed rule, we propose to take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s), if any, as well as the patient population(s) taking the selected drug. For each selected drug, we propose to adjust the applicable starting point (as determined in proposed § 429.510(d)) upward or downward or to not adjust (as described in proposed § 429.510(e)(5)) based on the totality of the relevant information and evidence submitted and gathered through our analysis based on section 1194(e)(2) factors. We may adjust the starting point based on how the section 1194(e)(2) factors apply with respect to individual condition(s) in cases where there are notable differences relative to the therapeutic alternative(s).

After the starting point is adjusted, if applicable, as described in proposed § 429.510(e)(4), as appropriate, based on section 1194(e)(2) factors, evaluated using data submitted by the Primary Manufacturer and the public through the Drug Price Negotiation ICR and gathered through our analyses and literature review, the resulting price is referred to as "the preliminary price" (defined in proposed § 429.20).

We propose to adjust the preliminary price, as appropriate, based on data submitted by the Primary Manufacturer in accordance with section 1194(e)(1) of the Act, as described in detail in section II.F.3.d.(2). of this proposed rule and proposed § 429.510(f).

(2) Adjusting the Preliminary Price Based on Consideration of Section 1194(e)(1) Factors

Section 1194(e)(1) of the Act directs CMS to consider certain factors, which must be reported by each Primary Manufacturer, when determining offers and counteroffers. To fulfill this requirement, we propose at § 429.510(f) to adjust the preliminary price based on the factors listed at section 1194(e)(1) of the Act. The preliminary price may be adjusted upward, adjusted downward, or not adjusted to account for these manufacturer-specific data elements. In accordance with section 1194(b)(1) of the Act, this process would be conducted with the aim of achieving the lowest MFP for each selected drug. The section 1194(e)(1) factors are listed at proposed § 429.505(b)(2) and include: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

We propose to consider the five factors outlined in section 1194(e)(1) of the Act in totality at proposed § 429.510(f)(1) and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price as described at proposed § 429.510(f)(2). We provide illustrative examples of how we might adjust, or not adjust, the preliminary price based on evaluation of a manufacturer-specific data element later in this section. However, the overall adjustment, inclusive of all five elements taken together, may differ from the example adjustment for any single element viewed in isolation.

Section 1194(e)(1)(A) of the Act requires CMS to consider the extent to which the Primary Manufacturer has recouped its R&D costs. As an example of how we could approach this consideration, CMS could compare the R&D costs with the global and U.S. net revenue for the selected drug reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its R&D costs. For example, if a Primary Manufacturer has not recouped its R&D costs, we may consider adjusting the preliminary price upward. Conversely,

⁵⁸ FDA Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics, May 2014. See: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics>.

if a Primary Manufacturer has recouped its R&D costs, we may consider adjusting the preliminary price downward or apply no adjustment. We may use the R&D costs reported by the Primary Manufacturer and the calculated recouped costs, including the assumptions and calculations in the accompanying narrative text, and/or other factors as described in proposed § 429.505(b)(2) to adjust the preliminary price.

As an example for how we may consider the relationship between the preliminary price and the unit costs of production and distribution (the factor listed at section 1194(e)(1)(B) of the Act), we may consider adjusting the preliminary price downward if the unit costs of production and distribution are lower than the preliminary price, or upward if the unit costs of production and distribution are greater than the preliminary price. Again, we may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug as described in proposed § 429.505(b) to determine if an adjustment is appropriate.

As an example of how we may consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug (the factor listed at section 1194(e)(1)(C) of the Act), we may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

We would also review the patents and exclusivities reported as we develop our initial offer, consistent with section 1194(e)(1)(D) of the Act. We believe that this information would support CMS' consideration of the factors listed at section 1194(e) of the Act and in proposed § 429.505(b)(2) and (d)(3). For instance, patents and exclusivities may inform our understanding of therapeutic alternatives and other available therapy for the purposes of adjusting for clinical benefit, including consideration of the extent to which the selected drug represents a therapeutic advance or the extent to which the selected drug addresses an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a disease or condition, and consideration of such information would be relevant to our consideration of the extent to which the selected drug addresses an unmet medical need for that disease or condition.

Finally, we would consider how the market data and revenue and sales volume data compare to the preliminary price in accordance with section 1194(e)(1)(E) of the Act. For example, if the average commercial net price is lower than the preliminary price, we may consider adjusting the preliminary price downward. If the average commercial net price is greater than the preliminary price, we may consider adjusting the preliminary price upward.

We propose in § 429.510(f)(3) that after any adjustments to the preliminary price are made as described in paragraphs (f)(1) and (f)(2), the result is the initial offer unless paragraph (f)(3)(i) applies. As proposed in § 429.510(f)(3)(i), if the resulting amount is above the ceiling (as determined in § 429.410), then the initial offer will be equal to the ceiling, and if the amount is below the temporary floor for small biotech drugs (as determined in proposed § 429.440), if applicable, then the initial offer will be equal to the temporary floor.

4. Engagement With Primary Manufacturers and Interested Parties (§ 429.515)

a. Engagement With Primary Manufacturers

Consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we propose in § 429.515 to hold up to four, optional meetings in a form and manner specified by CMS with Primary Manufacturers of selected drugs that have submitted the information set forth in proposed § 429.505. As proposed in § 429.515(a)(1), the first meeting that we would offer Primary Manufacturers to attend would be intended for the Primary Manufacturer to provide additional context on their data submission of the section 1194(e)(1) factors and section 1194(e)(2) factors described in proposed § 429.505(b)(2) and (d)(3), respectively, as we begin evaluating the data submission and developing an initial offer as described in proposed § 429.510. We would also offer Primary Manufacturers the opportunity to attend up to three optional meetings that would focus on the section 1194(e)(1) factors and section 1194(e)(2) factors, and other topics aimed at working toward an agreement on an MFP. During these meetings, discussion of disputes and program policies regarding the negotiation process would be considered out of scope. As proposed in § 429.515(a)(2), meetings would be attended solely by representatives of the Primary Manufacturer and of CMS. The

number of attendees would be limited as specified by CMS via future communications with the Primary Manufacturer specific to each initial price applicability year. For example, as described in section 60.4.4 of the Negotiation Program Guidance, CMS and the Primary Manufacturer were permitted to bring up to eight meeting attendees and both parties would share their participant lists ahead of each meeting. We determined this meeting attendee number after considering the roles from each party that would be critical to the conversation while ensuring that the meeting is sized appropriately to encourage active discussion. Given these considerations, we propose at § 429.515(a)(2) to continue to limit the number of meeting attendees.

We propose at § 429.515(a)(3)(i) that Primary Manufacturers may share new information on section 1194(e)(2) factors during meetings. The Primary Manufacturer may bring materials to facilitate discussion which must comply with limits on the amount and format of such materials as specified by CMS, and we may request that the Primary Manufacturer provide copies of any presented or discussed materials after the meeting in which they are presented or discussed, as proposed in § 429.515(a)(3)(ii). For example, for initial price applicability year 2028, if a Primary Manufacturer is interested in sharing materials at a negotiation meeting, such materials are limited to 15 pages (or a combination of pages, slides, and/or charts and graphs totaling 15 pages) and no more than 30 citations, to focus the discussion on issues that can reasonably be discussed within the scope of the meeting. We would specify the limits on the amount and format of materials specific to each initial price applicability year via future communications with the Primary Manufacturer. We propose at § 429.515(a)(1)(ii) that new data related to section 1194(e)(1) factors, as described in proposed § 429.505(b), would not be considered. Rather, any information shared during these meetings and materials shared afterwards should only contextualize the Primary Manufacturer's submission of data related to section 1194(e)(1) factors specified in proposed § 429.505(b).

We propose at § 429.515(a)(4) for the first optional meeting that CMS would offer to Primary Manufacturers to attend would occur, at a time to be specified by CMS, after the data submission deadline specified in section II.F.2. of this proposed rule and in proposed § 429.505(b)(1) and (d)(2) and before the

provision of CMS' initial offer, as set forth in proposed § 429.520. We would offer up to three additional optional meetings to occur after the provision of CMS' initial offer. If accepted by the Primary Manufacturer, such meeting(s) would occur, at a time to be specified by CMS, after the provision of CMS' initial offer as set forth in proposed § 429.520 and before the provision of CMS' final offer, if applicable, as specified in proposed § 429.535. A written record of these meetings would be developed and retained by CMS in compliance with applicable Federal laws, including the Federal Managers' Financial Integrity Act and the Federal Records Act, and would be subject to the confidentiality policy described in section II.D.1. of this proposed rule and in proposed § 429.300. The Primary Manufacturer may also develop and retain its own written record. As proposed in § 429.515(a)(5), audio or video recording of the meetings would not be permitted.

As described in section II.D.1. of this proposed rule regarding proposed § 429.300, we would not publicly discuss ongoing negotiations with a Primary Manufacturer, including details of the negotiation meetings. A Primary Manufacturer may publicly disclose information regarding ongoing negotiations with CMS at their discretion. If a Primary Manufacturer discloses information regarding any aspects of the negotiation process prior to the explanation for the MFP being released by CMS, we reserve the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

b. Engagement With Interested Parties

At proposed § 429.515(b), we are proposing to codify the policy as described in section 60.4.1 of the Negotiation Program Guidance to hold events in a form and manner and at times to be specified by CMS with interested parties to seek input from patients and other interested parties about selected drugs and therapeutic alternatives. These public engagement events are intended to bring together patient-focused interested parties to share feedback with us on patient experiences with the conditions or diseases treated by the selected drug, as well as with the selected drugs and therapeutic alternatives to the selected drugs, and other information as we review data related to section 1194(e)(2) factors and develop an initial offer for each selected drug. These public engagement events allow us to hear from patients and other stakeholders close to the patient experience—directly

and in their own words—about patients' personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions. This type of information helps inform CMS' understanding of what matters to patients. We would use the information shared during these patient-focused events to better understand patients' experiences with the conditions and diseases treated by the selected drug and their experiences with the selected drugs themselves, as well as to inform CMS' identification of therapeutic alternatives, key outcomes, and adjustment of the starting point to develop the initial offer. These events would be held annually in the Spring.

Public engagement events for each initial price applicability year may include, for example, patient-focused roundtable events that would be open to patients, patient advocacy organizations, and caregivers and would allow for discussion among speakers. These patient-focused roundtable events may focus on one selected drug or group selected drugs by condition when appropriate as determined by CMS.

The public engagement events also may include one town hall meeting for all selected drugs that would be focused on the clinical considerations related to the selected drugs and would be open to practicing clinicians and researchers, as well as other interested parties. This town hall meeting may be divided into multiple sessions and may be held across multiple days. We may have the opportunity to ask follow-up questions of participants at the town hall meeting.

Lastly, we may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for negotiation or we may hold separate events specifically for drugs selected for renegotiation.

5. Provision of CMS' Initial Offer and Concise Justification (§ 429.520)

Section 1194(b)(2)(B) of the Act requires that, not later than June 1 following the selected drug publication date with respect to the initial price applicability year, CMS shall provide the Primary Manufacturer of the selected drug with a written initial offer that contains the proposal for the MFP of the drug and a concise justification based on the factors described in section 1194(e) that were used in developing such offer. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we are proposing in § 429.520(a) that the written initial offer from CMS would be provided to the Primary Manufacturer no later than June 1 following the selected drug publication date as defined in proposed § 429.20. We propose at § 429.520(a)(1) that this written initial offer would be accompanied by an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP for CMS and the Primary Manufacturer to formalize agreement upon the MFP if such agreement is reached at this stage. Consistent with proposed § 429.410(a), no written initial offer can exceed the statutorily determined ceiling as defined in section 1194(c) of the Act and proposed in section II.E.3. of this proposed rule and in proposed § 429.410(b). Consistent with proposed in § 429.440(b), no written initial offer can be less than the Temporary Floor for Small Biotech Drugs, if applicable, as defined in section 1194(d) of the Act and proposed in section II.E.9. of this proposed rule.

With respect to initial price applicability year 2029 and subsequent years, we are proposing in § 429.520(b) that CMS would include a concise justification for the written initial offer based on the data set forth in proposed § 429.505. Consistent with proposed § 429.505(a), CMS considers the Primary Manufacturer-required data specified in § 429.505(b)(2) and evidence about the selected drug and therapeutic alternatives specified in § 429.505(d)(3), as applicable to the drug, as the basis for determining the offers and counteroffers for the selected drug. As proposed in § 429.520(b)(1), the concise justification would include a qualitative description of the factors from section 1194(e) of the Act as proposed in § 429.505(b) and (d) and a description of the methodology that CMS used to develop the written initial offer as proposed in section II.F.3. of this proposed rule and under proposed subpart F. As proposed in § 429.520(b)(2), the information contained in the concise justification would provide the Primary Manufacturer with information on the range of evidence and other information considered under section 1194(e) of the Act that CMS found compelling during the development of the written initial offer, and may include information obtained through events with interested parties as proposed in § 429.520(b)(3). We believe the information in the

concise justification would provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the written initial offer.

The written initial offer and concise justification would not include information that we determine to be third-party proprietary pricing information, information that could lead to the calculation of a third-party's proprietary pricing information, PHI/PII, other information that is protected from disclosure under other applicable law in accordance with the confidentiality policies described in section II.D.1. of this proposed rule and in proposed § 429.300, or the starting point.

6. Statutory Written Counteroffers (§ 429.525)

Section 1194(b)(2)(C) of the Act requires that the Primary Manufacturer shall either accept the written initial offer under section 1194(b)(2)(B) of the Act, or propose a counteroffer, within 30 days of receipt of the written initial offer. If a Primary Manufacturer proposes a counteroffer, such counteroffer shall be in writing and shall be justified based on the factors described in section 1194(e) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we are proposing in proposed § 429.525(a) that the Primary Manufacturer would have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a statutory written counteroffer and providing a justification for such counteroffer based on the data described in proposed § 429.505(b) and (d). As proposed in § 429.525(b)(1)(ii), any statutory written counteroffer must respond to the concise justification provided in CMS' written initial offer, and the Primary Manufacturer's response must focus on the factors described in section 1194(e) of the Act, as set forth in proposed § 429.505(b) and (d). We propose at § 429.525(b)(1)(iii) that the statutory written counteroffer justification must indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the section

1194(e)(1) factors or section (e)(2) factors, or other available data related to the selected drug and its therapeutic alternative(s), as described in section 1194(e)(2) of the Act, supports the Primary Manufacturer's statutory written counteroffer or otherwise does not support CMS' written initial offer. Primary Manufacturers may also include in their statutory written counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) of the Act that supports the counteroffer.

We propose at § 429.525(b)(1)(i) that the Primary Manufacturer must provide a proposal for the MFP for the selected drug in its statutory written counteroffer. The proposal for the MFP must be a single price for the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. For a statutory written counteroffer to be considered complete, we propose at § 429.525(b)(2) that a Primary Manufacturer must complete an Addendum to the Negotiation Program Agreement, as described in section II.C.1. of this proposed rule and in proposed § 429.200(e), in the CMS HPMS and must submit the statutory written counteroffer in a form and manner specified by CMS as part of the Drug Price Negotiation ICR. A completed Addendum to the Negotiation Program Agreement would include, but is not limited to, the proposal for the MFP the Primary Manufacturer is counteroffering and a signature by an authorized representative.

Section 1194(b)(2)(D) of the Act requires that, after receiving a counteroffer under section 1194(b)(2)(C) of the Act, CMS must respond in writing to such counteroffer. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, we are proposing in § 429.525(c) that we would respond in writing to a statutory written counteroffer made by the Primary Manufacturer. Although the statute does not specify a timeframe for CMS' response to the Primary Manufacturer's statutory written counteroffer, in accordance with section 1194(b)(2)(E) of the Act and as proposed in § 429.535(b), negotiations must end prior to November 1 following the selected drug publication date to avoid

potential excise tax liability under 26 U.S.C. 5000D(b)(2).

As proposed in § 429.525(c)(1), in the case CMS' written initial offer is not accepted and the Primary Manufacturer submits a statutory written counteroffer, we would consider the statutory written counteroffer and either accept or reject it in writing within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later. When considering a statutory written counteroffer, we would evaluate whether accepting the counteroffer is consistent with the statutory directive to aim to arrive at an agreement that achieves the lowest possible MFP for the selected drug.

Section 1194(b)(2)(F) of the Act requires that CMS cannot offer a proposal for the MFP or agree to a Primary Manufacturer's proposal for the MFP for a selected drug, with respect to the initial price applicability year for the selected drug, that exceeds the ceiling determined under section 1194(c) for the selected drug and year. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, consistent with proposed § 429.410(a), CMS cannot accept a statutory written counteroffer from a manufacturer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section II.E.3. of this proposed rule and in proposed § 429.410(b). Consistent with proposed § 429.440(b), CMS cannot agree to any Primary Manufacturer proposal for the MFP that is less than the Temporary Floor for Small Biotech Drugs, if applicable, as defined in section 1194(d) of the Act and proposed in section II.E.9. of this proposed rule.

7. Additional Price Exchange Opportunities (§ 429.530)

Consistent with policies for implementation in section 60.4 of Negotiation Program Guidance, we propose in § 429.530(a) to provide additional price exchange opportunities through which CMS and Primary Manufacturers can initiate additional written offers and counteroffers via the CMS HPMS during the period between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the

MFP, or at least 8 business days before CMS issues the final offer, whichever is earlier. We believe this functionality would enable both parties to have additional flexibility to extend and consider offers and counteroffers during this time period.

We propose at § 429.530(a)(1) that the functionality for additional price exchange opportunities in the CMS HPMS would allow for the optional upload of materials which must comply with limits on the amount and format of such materials as specified by CMS, and include an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer. As proposed in § 429.530(a)(2), only one offer or counteroffer per selected drug may be active at a time in the CMS HPMS as part of the functionality for additional price exchange opportunities. Proposed § 429.530(a)(3) states an offering/counteroffering party may revise its offer/counteroffer in the period before the other party accepts or rejects it but not afterwards. We propose at § 429.530(a)(4) that parties would not need to alternate making offers and counteroffers. Consistent with proposed § 429.410(a), CMS cannot propose an MFP or agree to any Primary Manufacturer proposal for the MFP that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and as set forth in section II.E.3. of this proposed rule and in proposed § 429.410(b). Consistent with proposed § 429.440(b), CMS cannot propose an MFP or agree to any Primary Manufacturer proposal for the MFP that is less than the Temporary Floor for Small Biotech Drugs, if applicable, as defined in section 1194(d) of the Act and proposed in section II.E.9. of this proposed rule. Lastly, as proposed in § 429.530(a)(5), to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in section II.C.1. of this proposed rule and in proposed § 429.200(e) that sets forth the agreed-upon MFP.

8. Notification of Final Offer and Conclusion of Negotiations (§ 429.535)

Section 1194(b)(2)(E) of the Act requires that all negotiations between CMS and the Primary Manufacturer of the selected drug shall end prior to November 1 following the selected drug publication date, with respect to the initial price applicability year. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example,

section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we are proposing in proposed § 429.535(b) that all negotiations between CMS and the Primary Manufacturer of the selected drug must end prior to November 1 following the selected drug publication date, with respect to the initial price applicability year, to avoid potential excise tax liability. As proposed in § 429.535(a), in the event neither CMS' initial offer nor the Primary Manufacturer's statutory written counteroffer were accepted, and an MFP was not agreed to during the negotiation meetings or via the additional price exchange functionality, we would send the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" and an Addendum with the final offer MFP by September 30 following the selected drug publication date defined in proposed § 429.20. This would serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. This final offer would be sent only if, by September 30 following the selected drug publication date neither CMS nor the Primary Manufacturer has accepted the latest offer or counteroffer made in writing or agreed upon an MFP during the negotiation meeting process or via the additional price exchange functionality. We propose at § 429.535(a)(1), that if a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by October 31 following the selected drug publication date.

As proposed at § 429.535(a)(2), to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in section II.C.1. of this proposed rule and in proposed § 429.200(e) that sets forth the agreed-upon MFP. For example, when CMS prepares a written offer, we would also populate an Addendum to the Negotiation Program Agreement with the offered MFP and send that Addendum to the Negotiation Program Agreement with the written offer to the Primary Manufacturer via the CMS HPMS. If the Primary Manufacturer accepts the written offer, it would sign the Addendum to the Negotiation Program Agreement after which CMS

would countersign the Addendum to the Negotiation Program Agreement.

If CMS and the Primary Manufacturer do not agree to an MFP by the deadline set forth in paragraph (b) of this section, the Primary Manufacturer would enter a period during which the excise tax may be imposed on certain sales of the selected drug. As described in 26 U.S.C. 5000D(b)(2) and 5000D(c), the Primary Manufacturer can end the period during which the excise tax may apply by agreeing to an MFP; meeting the statutory criteria for the suspension of tax; or terminating its Negotiation Program Agreement in the manner described in section II.C.2. of this proposed rule and in proposed § 429.205.

G. Renegotiation of an MFP (§§ 429.600 Through 429.620)

1. General Rule (§ 429.600)

Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs, the selection of drugs for renegotiation, and the renegotiation process. With respect to initial price applicability year 2028, the first year in which renegotiation could occur per section 1194(f) of the Act, we implemented policies for renegotiation in section 130 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, and consistent with the policies described in section 130 of the Negotiation Program Guidance, we propose to identify renegotiation-eligible drugs in accordance with section 1194(f)(2) of the Act, as described in proposed § 429.605. Next, we would select certain renegotiation-eligible drugs for renegotiation in accordance with section 1194(f)(3) of the Act, as described in proposed § 429.610. Finally, we would renegotiate MFPs for such drugs selected for renegotiation, in accordance with section 1194(f)(4) of the Act, as described in proposed § 429.620. Figure 2 depicts an overview of this proposed process.

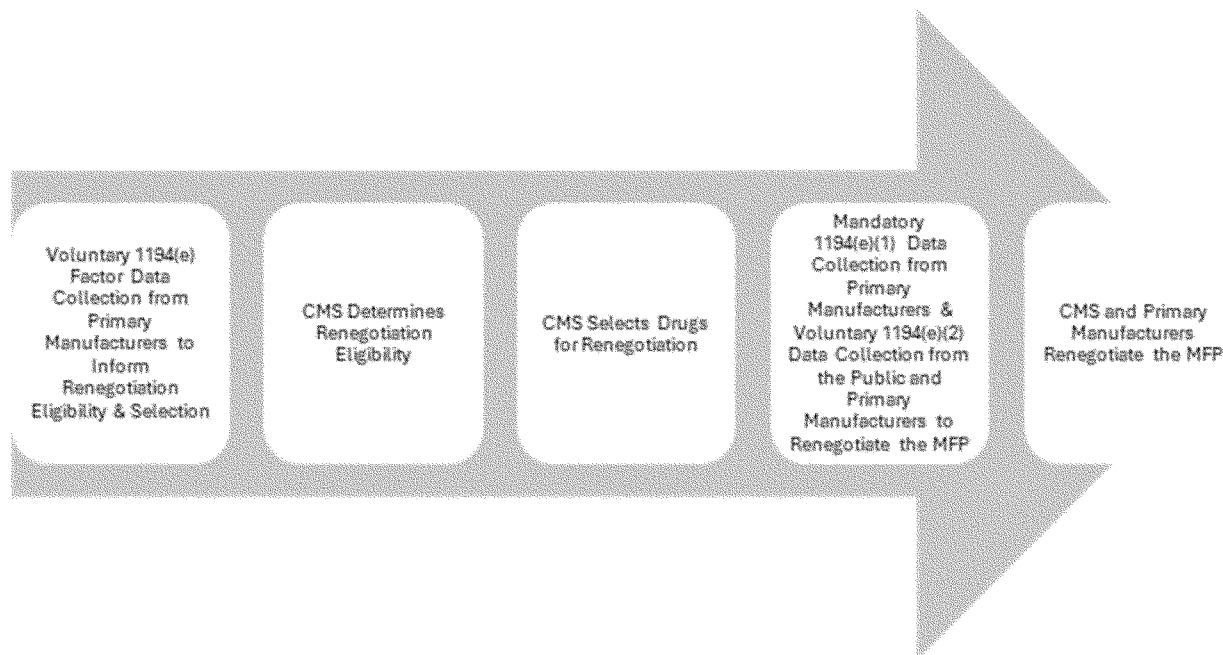
We note that renegotiation is a component of the Negotiation Program. A Primary Manufacturer that has a Negotiation Program Agreement in effect, as discussed in proposed subpart C and section II.C. of this proposed rule, would be required to adhere to the process and deadlines described throughout this proposed rule. For example, the policies described in proposed subparts F and H (described in sections II.F. and II.H. of this proposed rule) are applicable to renegotiation unless otherwise specified herein. The

renegotiation process would conclude with an agreed-upon MFP, unless the Primary Manufacturer chooses not to participate or chooses not to agree upon a new MFP (or CMS determines that a generic drug is approved or a biosimilar is licensed for the selected drug is

subject to Bona Fide Marketing during the renegotiation period consistent with proposed § 429.130(c)(5), in which case it will no longer be subject to the renegotiation process in accordance with section 1194(f)(5) of the Act and proposed § 429.135(c)(2)). To meet their

MFP effectuation obligations, Primary Manufacturers must make any agreed-upon MFP available as set forth in proposed § 429.200(b)(4).

Figure 2: Overview of Renegotiation Process Steps



If the Primary Manufacturer and CMS agree upon an MFP through the renegotiation process set forth under § 429.620, we propose at § 429.600(b)(1) that the renegotiated MFP would apply starting January 1 of the initial price applicability year for which the drug was selected for renegotiation. We also propose at § 429.600(b)(3) and consistent with the requirement in proposed § 429.200(b)(4), that to meet their MFP effectuation obligations, Primary Manufacturers of a selected drug with a renegotiated MFP must provide access to the selected drug's initial agreed-upon MFP in accordance with subpart I for all dispenses, administrations, and furnishings of the selected drug prior to such effective date for the renegotiated MFP. Additionally, we propose at § 429.600(b)(2) that the MFP that is agreed upon following renegotiation would apply to all formulations across dosage forms and strengths of the selected drug by applying the methodology set forth at proposed § 429.700. Information on MFP effectuation for 2029 and subsequent years will be included in future rulemaking.

Finally, we propose at § 429.600(c) that we would publish the list of drugs selected for renegotiation no later than

the selected drug publication date (consistent with § 429.100(b)(2)).

2. Eligibility of Drugs for Renegotiation (§ 429.605)

Section 1194(f)(2) of the Act establishes the definition of a "renegotiation-eligible drug" as a selected drug for which (1) a new indication is added to the drug; (2) the drug monopoly status was not that of an extended-monopoly or a long-monopoly drug and changes to that of an extended-monopoly drug; (3) the drug monopoly status was not that of a long-monopoly drug; and changes to that of a long-monopoly drug; or (4) the Secretary determines there has been a material change to any section 1194(e)(1) or (e)(2) factor.

In accordance with section 1194(f)(1) of the Act, we propose to identify renegotiation-eligible drugs from selected drugs negotiated, or renegotiated, if applicable, with respect to prior initial price applicability years. We interpret section 1194(f)(1) of the Act to mean that the Secretary must provide for a process of renegotiation for years during the selected drug's price applicability period. For example, because calendar year 2029 will be a year within the price applicability

period for drugs selected for initial price applicability years 2026, 2027, and 2028, these selected drugs may be eligible for renegotiation with respect to initial price applicability year 2029 (which would involve a renegotiation taking place in calendar year 2027) if these drugs meet any of the eligibility criteria set forth in section 1194(f)(2) of the Act and proposed § 429.605.

As a matter of operations, first, we propose in § 429.605(a) that the scope of selected drugs that would be considered for renegotiation eligibility and selection with respect to initial price applicability years beginning with initial price applicability year 2029 would include any selected drugs with an agreed-upon MFP from a prior initial price applicability year, which would include a selected drug that has an agreed-upon MFP from a prior renegotiation. A selected drug would not be subject to renegotiation if CMS determines prior to the selected drug publication date for the relevant initial price applicability year that the manufacturer of any generic drug or biosimilar, as applicable, of the selected drug is engaging in Bona Fide Marketing of such generic drug or biosimilar, based on CMS' consideration of the information set forth at proposed

§ 429.130(a). That is, for any selected drugs with an agreed-upon MFP from a prior initial price applicability year where CMS has not yet determined that Bona Fide Marketing exists, we would proceed to review such drugs for renegotiation eligibility. If CMS determines based on consideration of the information set forth at proposed § 429.130(a) in accordance with the timing in proposed § 429.135(b)(2) and section II.B.6.d. of this proposed rule, that one or more manufacturers of an approved generic drug or licensed biosimilar, as applicable, of the selected drug, including a drug selected for renegotiation, is engaging in Bona Fide Marketing of such generic drug or biosimilar then the selected drug ceases to be subject to the renegotiation process.

Among such selected drugs, we propose to identify selected drugs which are renegotiation-eligible drugs due to a change in monopoly status as described in proposed § 429.605(b). Then, we propose to review the remaining selected drugs and identify those which are renegotiation-eligible drugs due to the addition of a new indication as described in proposed § 429.605(c) or due to a material change in any section 1194(e) factor as described in proposed § 429.605(d).

Selected drugs negotiated in initial price applicability years 2026 and 2027 were limited to those covered under Part D per section 1192(d)(2)(A) of the Act. In proposed § 429.610(a)(2), we propose to consider any selected drugs from initial price applicability years 2026 and 2027, including those with Part B utilization, for renegotiation eligibility under section 1194(f)(2) of the Act. If such drugs meet the eligibility criteria described in proposed § 429.605, they may be selected for renegotiation under section 1194(f)(3) of the Act and as described in proposed § 429.610; and may have an agreed-upon MFP after renegotiation. For such renegotiation-eligible drugs that are selected for renegotiation and for which a renegotiated MFP is agreed upon, the renegotiated MFP would apply as described in proposed § 429.600(b) and would apply to claims payable under Part B and dispenses covered under Part D, as applicable. The MFP that is agreed upon following the renegotiation process would apply to all formulations across dosage forms and strengths of the selected drug as specified in proposed § 429.600(b)(2), which would include when the selected drug is payable under Part B only, covered under Part D only, and when the drug is payable under Part B and covered under Part D. Proposed § 429.600(b)(3) would require the

Primary Manufacturer of a selected drug with a renegotiated MFP to make the prior agreed-upon MFP available as set forth in proposed subpart I for all dispenses, administrations, and furnishings of the selected drug prior to the effective date of the renegotiated MFP as specified in proposed § 429.600(b)(1).

a. Selected Drugs for Which There Is a Change in Status to an Extended-Monopoly Drug

To meet the definition of an extended-monopoly drug proposed in § 429.20, the initial approval date under section 505(c) of the FD&C Act or the initial licensure date under section 351(a) of the PHS Act, as applicable, associated with the earliest-approved FDA application containing the active moiety/active ingredient (or in the case of a potential qualifying single source drug identified under § 429.125(b)(4), the distinct combination of active moieties/active ingredients)⁵⁹ must be on or before January 1 of the year 12 years prior but no more than 16 years prior. In accordance with section 1194(f)(2)(C) of the Act, we propose in § 429.605(b)(1) that a selected drug that meets the definition of an extended-monopoly drug with respect to initial price applicability years beginning with initial price applicability year 2029, and that did not qualify as an extended-monopoly drug when the drug was selected for negotiation or a prior renegotiation would be determined to be renegotiation-eligible due to a change in status to an extended-monopoly drug.⁶⁰

b. Selected Drugs for Which There Is a Change in Status to a Long-Monopoly Drug

To meet the definition of a long-monopoly drug, the initial approval date under section 505(c) of the FD&C Act or the initial licensure date under section 351(a) of the PHS Act, as applicable, associated with the earliest-approved

FDA application containing the active moiety/active ingredient (or in the case of a potential qualifying single source drug identified under § 429.125(b)(4), the distinct combination of active moieties/active ingredients)⁶¹ must be on or before January 1 of the year 16 years prior. In accordance with section 1194(f)(2)(C) of the Act and the existing policy established in section 130.1.2 of the Negotiation Program Guidance, we propose at § 429.605(b)(2) that a selected drug that meets the definition of a long-monopoly drug (as proposed in § 429.20) and that did not qualify as a long-monopoly drug when the drug was selected for negotiation or a prior renegotiation would be determined to be renegotiation-eligible due to a change in status to a long-monopoly drug.

c. Selected Drugs for Which a New Indication Is Added

Section 1194(f)(2)(A) of the Act identifies a selected drug for which a new indication is added as a renegotiation-eligible drug. As described in proposed § 429.615(a), we propose to collect voluntary information submissions from Primary Manufacturers of selected drugs to inform renegotiation drug eligibility and selection.

To identify whether a new indication has been added to the FDA-approved labeling⁶² for a selected drug, we propose at § 429.605(c) to use a number of sources, for example the *Drugs@FDA database*.⁶³ We also propose at § 429.605(c)(2)(ii) to review voluntary submissions from Primary Manufacturers, if any, are submitted. We propose at § 429.605(c)(2)(ii)(A) that we may review off-label use for the purpose of determining whether such off-label use is a new indication for renegotiation eligibility determinations only if voluntarily submitted by the Primary Manufacturer. At § 429.605(c)(1), we propose that we would determine a drug to be renegotiation-eligible based on the addition of a new indication if the FDA-

⁵⁹ For biological products with approved applications under section 505 of the FD&C Act as of March 23, 2020, that were deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, under section 7002(e)(4)(A) of BPCI Act, and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

⁶⁰ As we propose to codify in § 429.20, section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a Primary Manufacturer has entered into a Negotiation Program Agreement with CMS with respect to an initial price applicability year that is before 2030 from the definition of an "extended-monopoly drug". Therefore, the proposal at § 429.605(b)(1) would apply to drugs selected for negotiation in initial price applicability year 2030 or later.

⁶¹ For biological products with approved applications under section 505 of the FD&C Act as of March 23, 2020, that were deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, under section 7002(e)(4)(A) of BPCI Act, and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

⁶² Such additions to the FDA approved labeling include new indications approved in both new NDAs/BLAs and supplements to previously approved NDAs/BLAs.

⁶³ Available at www.fda.gov/drugsatfda, <https://www.fda.gov/vaccines-blood-biologics/cber-regulated-products-supporting-documents>.

approved labeling has been updated to include treatment or prevention of a new disease or condition. In the renegotiation context, “new” means not considered in the previous negotiation process or renegotiation process. For example, we would not determine a selected drug to be renegotiation-eligible under section 1194(f)(2)(A) of the Act based on FDA labeling updates within a previously indicated disease or condition.

In proposed § 429.605(c)(2)(ii)(A), we propose that if the Primary Manufacturer of a selected drug submits the off-label use through the voluntary information submission process then CMS may review off-label uses when identifying new indications for renegotiation eligibility. We would apply the definition proposed at § 429.20 when reviewing an off-label use submitted by a Primary Manufacturer for consideration as a new indication for the purpose of renegotiation eligibility. Voluntary submissions from a Primary Manufacturer of an off-label use for a selected drug would not be regarded as a “new indication” for renegotiation eligibility under section 1194(f)(2)(A) of the Act if such off-label use is for a previously indicated disease or condition. For example, in the event we previously considered an off-label use during negotiation and the Primary Manufacturer later received FDA approval for that off-label use, we would not consider the new on-label use to be a new indication in accordance with section 1194(f)(2)(A) of the Act. We may consider such off-label use that is for a previously indicated disease or condition as part of the evaluation of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act, as described in proposed § 429.605(d).

To ensure we have appropriate time to consider applicable data, we propose at § 429.610(c)(3) that the new indication must be added to the FDA-approved labeling for the selected drug by the date of the voluntary submission as proposed at § 429.615(b). That is, the new indication must be added to the FDA-approved labeling for the selected drug on or before March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug would be selected for renegotiation. The Primary Manufacturer may voluntarily submit data on a new indication, including an indication added to the FDA label or an off-label use, through the due date of the Drug Selection ICR to be specified by CMS upon approval of the Drug

Selection ICR by the OMB and prior to the selected drug publication date for which the drug would be selected for renegotiation. If a Primary Manufacturer chooses to submit information on new indication, we would update the review of available indications for that selected drug, including incorporating the Primary Manufacturer’s submission. We expect that there would be a low likelihood of new indications being available for selected drugs whose negotiation or renegotiation period ends on November 1 immediately prior to the Primary Manufacturer submission deadline of November 30.

d. Selected Drugs for Which There Is a Material Change in a Section 1194(e) Factor

Section 1194(f)(2)(D) of the Act directs CMS to identify a selected drug for which there has been a material change to any factor listed in section 1194(e) as a renegotiation-eligible drug and provides CMS with the discretion to determine what constitutes a “material change.”

We propose to consider a change(s) to a section 1194(e) factor for a selected drug to be material if the change(s) to the factor would reasonably be expected to meaningfully alter our consideration of that factor within the context of renegotiation offers and counteroffers, including the initial offer as determined in proposed subpart F, as compared with our consideration of that factor within the context of offers, including the initial offer and, if applicable, counteroffers, during the most recent prior negotiation or renegotiation process for the selected drug. For purposes of determining whether a selected drug is renegotiation-eligible under section 1194(f)(2)(D) of the Act, we would evaluate available information pertaining to section 1194(e) factors (as listed in proposed § 429.505(b) and (d) and section II.F.2.b. of this proposed rule) to determine if there is a material change. We also propose to consider voluntary submissions by a Primary Manufacturer of the information discussed in proposed § 429.615(a) to inform our determination.

This approach complements our review of new indications described in § 429.605(c) and discussed in section II.G.2.c. of this proposed rule as we would consider prescribing information (see section 1194(e)(2)(B) of the Act) as part of this material change evaluation. As part of that inquiry, we would review the FDA-approved labeling for a material change in prescribing information as described in proposed § 429.605(d)(1) and, in doing so, would

also capture the impact of labeling updates within a previously indicated disease or condition during such review (for example, expansion of an existing indication to include an additional age group(s)). That is, labeling updates within a previously indicated disease or condition would not be regarded as a “new indication” for renegotiation eligibility under section 1194(f)(2)(A) of the Act but would be considered as part of the review of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act.

To provide sufficient time to consider the applicable information to determine whether a change in a factor listed in section 1194(e) of the Act is material, we would consider the applicable information that is available on or before September 30 of the calendar year before the selected drug publication date for which the drug would be selected for renegotiation. Our review by September 30 would not be inclusive of information submitted by the Primary Manufacturer through the voluntary submission due November 30. For example, this may include information on any offers or counteroffers made on or before September 30 of the calendar year before the selected drug publication date for which the drug would be selected for renegotiation, including MFPs that were agreed upon for the selected drug or its therapeutic alternatives. Should the Primary Manufacturer choose to submit data through the voluntary submission described in proposed § 429.615(a), then we may update our review of material change(s) with new applicable information.

Table 2 provides a few illustrative examples of this approach to determining a material change(s) to a section 1194(e) factor for the purpose of determining renegotiation eligibility. We reiterate that these are illustrative examples and the potential results may vary in all cases depending on the fact patterns of a given drug.

TABLE 2—ILLUSTRATIVE EXAMPLE SCENARIOS AND POTENTIAL RESULT IN DETERMINATION OF MATERIAL CHANGE

Example scenario	Potential result for changes in section 1194(e) factor
New clinical data is released showing increased clinical value for a greater number or new group of individuals who are prescribed a selected drug.	CMS may determine that in this scenario that this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(C) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.
Unit cost of production and distribution increases from \$1.00 per unit to \$1.50 per unit.	CMS may determine that in this scenario this change would not likely meaningfully impact CMS' consideration of section 1194(e)(1)(B) of the Act in the context of offers and counteroffers. Therefore, this change alone may not be considered a material change.
A therapeutic alternative is now generic, the price for the therapeutic alternative drops significantly, and utilization of the therapeutic alternative increases significantly.	CMS may determine that in this scenario this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(A) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.
New clinical data is released showing increased clinical efficacy of the selected drug for one of its indications; a new black box warning indicates additional safety concerns for the selected drug, limiting its use.	CMS may determine that in this scenario the net impact of these changes would not meaningfully impact CMS' consideration of section 1194(e)(2)(C) of the Act in the context of offers and counteroffers. Therefore, these changes alone may not be considered a material change.

TABLE 2—ILLUSTRATIVE EXAMPLE SCENARIOS AND POTENTIAL RESULT IN DETERMINATION OF MATERIAL CHANGE—Continued

Example scenario	Potential result for changes in section 1194(e) factor
An indication for a selected drug was not covered under Part D or payable under Part B at the time the drug was previously negotiated. The indication is now covered under Part D and/or payable under Part B and there are no alternative treatments available for that indication.	CMS may determine that in this scenario the newly covered indication for which there are no alternative treatments to the selected drug would meaningfully impact CMS' consideration of section 1194(e)(2)(D) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.

3. Selection of Drugs for Renegotiation (§ 429.610)

Section 1194(f)(3) of the Act directs CMS to select drugs for renegotiation from the identified renegotiation-eligible drugs (described in proposed § 429.605). Sections 1194(f)(3)(A) and (B) of the Act require all such drugs eligible for renegotiation due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug, as specified in proposed § 429.610(b), be selected for renegotiation. Section 1194(f)(3)(C) of the Act states that among the remaining renegotiation-eligible drugs (that is, selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), CMS shall select renegotiation-eligible drugs for which CMS expects renegotiation is likely to result in a significant change in the previously agreed-upon MFP. Section 1194(f)(3)(C) of the Act provides CMS with the discretion to make determinations on when a renegotiation is “likely to result in a significant change” in the MFP.

a. Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs due to a Change in Monopoly Status

In accordance with section 1194(f)(3)(A) and (B) of the Act and consistent with the existing policies established in section 130.2 of the Negotiation Program Guidance, we propose at § 429.610(a) to select for renegotiation all drugs that are

determined to be renegotiation-eligible due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug as set forth in proposed § 429.605(b).

b. Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs due to a New Indication or a Material Change in a Section 1194(e) Factor

In accordance with section 1194(f)(3)(C) of the Act and consistent with the existing policies established in section 130.2.1 of the Negotiation Program Guidance, we propose to select remaining renegotiation-eligible drugs (that is, selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), for renegotiation if we expect renegotiation is likely to result in a significant change in the MFP.

To inform our determination of whether renegotiation is likely to result in a significant change in the MFP, we propose to consider two criteria to effectuate this statutory standard, as discussed in greater detail in this section. We propose that the evaluation of these two criteria would be a holistic inquiry based on the totality of the information available and the circumstances of the remaining renegotiation-eligible drug(s). The first criterion that we propose in § 429.610(b)(1)(i) is that we would consider whether a new indication(s) or material change(s) would be likely to result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP upon engaging in renegotiation with the Primary Manufacturer. The second proposed criterion in § 429.610(b)(1)(ii) is to consider whether such a change in the MFP for the remaining renegotiation-eligible drug(s) would have a significant impact on the Medicare Program. We believe these criteria are important to consider holistically to understand the circumstances for each selected drug.

Our evaluation for these two criteria would be a holistic inquiry based on the totality of the information available and the circumstances of the remaining renegotiation-eligible drug(s), including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act, and would support our determination of whether renegotiation is likely to result in a significant change, whether an increase or decrease, to the MFP for the remaining renegotiation-eligible drug(s). The scope of information considered may extend beyond the scope of information evaluated for renegotiation

eligibility to include a CMS-led review of the information sources discussed in proposed § 429.510(b) (described in section II.F.2. of this proposed rule) and the evaluation of such sources as discussed in proposed § 429.510(c), (e), and (f) (described in section II.F.3.d. of this proposed rule) pertaining to section 1194(e)(1) and section 1194(e)(2) factors. We propose to consider these information sources and others to inform whether a renegotiation-eligible drug would be selected for renegotiation because these sources may inform a potential future renegotiation process, including the potential development of the initial offer and subsequent offers, as well as our consideration of potential counteroffers.

We propose that when a remaining renegotiation-eligible drug is subject to this evaluation, we will only select such drug for renegotiation if that renegotiation-eligible drug meets both of these criteria. We believe each of these criteria are of equal importance when considering whether renegotiation is likely to result in a significant change in the MFP otherwise negotiated. We believe that when considering drug selection for renegotiation from among renegotiation-eligible drugs, described previously, the evaluation of the proposed criteria would indicate that renegotiation is both likely to change the MFP and that the change in MFP would be significant, in accordance with the directive under section 1194(f)(3)(C) of the Act to select remaining renegotiation-eligible drugs when CMS “expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.” We interpret section 1194(f)(3)(C) of the Act to require that for a drug that is eligible for renegotiation based on a new indication or material change to a factor listed at section 1194(e) of the Act, we must expect that renegotiation would likely result in a change to the MFP, but also that such change must be considered significant, such that the magnitude of change is meaningful and that such change would be significant for CMS. We believe that evaluating the proposed criteria provides transparency into how we intend to implement section 1194(f)(3)(C) of the Act. As a matter of process and for additional clarity, if a remaining renegotiation-eligible drug(s) were to fail to meet either criterion, we would not proceed to examine the other criterion given that a remaining renegotiation-eligible drug(s) must meet both criteria to be selected for renegotiation.

In establishing the first criterion (the likelihood that the new indication or

material change would result in a renegotiated MFP that would likely represent a 15 percent or greater change relative to the current MFP) we reviewed sections 1194(c)(3)(A) through (C) of the Act, which provide the applicable percentage of non-FAMP used to establish a ceiling during negotiation. The applicable percentages are 75 percent for short-monopoly drugs and vaccines, 65 percent for extended-monopoly drugs, and 40 percent for long-monopoly drugs (as described further in proposed § 429.410). Given that, under sections 1194(c)(3)(A) through (C) of the Act, a change in monopoly status is associated with a percent reduction in the ceiling for negotiation and that such change in monopoly status of a selected drug results in eligibility and selection for renegotiation per sections 1194(f)(2)(B) and (C) of the Act and sections 1194(f)(3)(A) and (B) of the Act, we believe this range of percent change is informative for interpreting what the term “significant change” means in the context of the statute.

We calculated the percent change in the applicable percentage for a drug that had a change in monopoly status from a short-monopoly drug (75 percent) to a long-monopoly drug (40 percent), which is approximately 46.7 percent change; this represents the maximum percent change in the applicable percentage that would correspond with a selected drug becoming renegotiation-eligible and selected for renegotiation. We also calculated the percent change in the applicable percentage for a drug that had a change in monopoly status from a short-monopoly drug (75 percent) to an extended-monopoly drug (65 percent), which is approximately 13.3 percent change; this represents the minimum percent change in the applicable percentage that would correspond with a selected drug becoming renegotiation-eligible and selected for renegotiation. We rounded these percent changes to the nearest 5 percent, resulting in a range of percent change from 15 to 45 percent that we believe represent an informative range for interpreting what a “significant change” means in the context of the statute, as discussed previously. We believe that a potential change in the MFP between 15 and 45 percent would be significant for the Medicare program and Medicare beneficiaries. We propose to use minimum percent change that corresponds with a selected drug becoming renegotiation-eligible and selected for renegotiation, that is 15 percent change, so as to not preclude the benefits that could come from a

change in the MFP that is at least 15 percent. The agency also considered the resources invested in renegotiation. We believe that the resources invested for both CMS and the Primary Manufacturer in a renegotiation process that would likely result in a change to the MFP of 15 percent or greater is an appropriate investment for the potential resulting change.

We also considered the option of evaluating the likelihood that a new indication or material change would result in a 35 percent or greater change to the MFP. In connection with the public comment period for the Negotiation Program Guidance for initial price applicability year 2028 a few commenters noted that the difference between the applicable percentage for short-monopoly drugs and vaccines (75 percent) and long-monopoly drugs (40 percent) is 35 percent and therefore they recommended we adopt an expected change to the MFP of 35 percent as the first criterion indicating a potential change to the MFP is significant. We note that a 35 percent change would fall in the range calculated based on the percent change in the applicable percentages as described previously. However, we believe using the minimum percent change in the applicable percentage that corresponds with a selected drug becoming renegotiation-eligible and selected for renegotiation provides CMS with the best opportunity to both clearly define what constitutes a “significant change to the MFP” and to meet our statutory obligation per section 1194(b)(1) of the Act to establish a process that aims to achieve the lowest MFP for each selected drug. Additionally, we believe using a range based on the *percent change* in the applicable percentage is more aligned with section 1194(f)(3)(C) of the Act that specifies that CMS should select drugs for renegotiation that are likely to have a significant *change* in the MFP [emphasis added]. The suggested approach from commenters represents looking at the arithmetic difference in applicable percentages, rather than the change in applicable percentages. Use of percent change rather than the difference in the applicable percentages has practical importance in that our language more closely aligns with statute, meaning that a renegotiation would result in a change in the MFP. Given the variance in expected percent change in the MFP, a numerical value of 15 percent establishes the minimum amount that may have a meaningful effect for beneficiaries and the Medicare program

and allows CMS to potentially consider more renegotiation-eligible drugs for renegotiation selection, whereas a higher number, like 35 percent, may normalize that any change less than 35 does not have a meaningful effect and may result in the selection of fewer renegotiation-eligible drugs for renegotiation. A 15 percent or greater change is consistent with the range of percent reductions in the ceiling that is statutorily defined for drugs eligible and selected for renegotiation due to monopoly status changes.

We also believe this criterion serves to promote transparency and consistency in the approach to selecting drugs for renegotiation in accordance with section 1194(f)(3)(C) of the Act. Therefore, in an effort to promote transparency and consistency, we propose to include this criterion of considering the likelihood that the new indication(s) and/or material change(s) to a section 1194(e) factor would result in a renegotiated MFP that would represent a 15 percent or greater change relative to the current MFP, which can help provide clarity for interested parties and the public on when we may select remaining renegotiation-eligible drugs in accordance with section 1194(f)(3)(C) of the Act.

We recognize that there may be other circumstances related to the renegotiation-eligible drug that may make selecting the drug for renegotiation less reasonable, for example the impending entry of a generic or biosimilar to market. As such, we propose the complementary criterion of evaluating whether such a change would have a significant impact to the Medicare program. For the second proposed criterion for determining whether renegotiation is likely to result in a significant change in the MFP, we propose at § 429.610(b)(1)(ii) to consider the impact on the Medicare program of such a change in the renegotiated MFP. For example, if we determine there was a likelihood that the new indication(s) or material change(s) could result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP, we would consider the financial impact to the Medicare program and Medicare beneficiaries by reviewing associated changes in expenditures and beneficiary cost-sharing. In doing so, we seek to

incorporate consideration of whether such change in MFP warrants the time and resource investment by the Primary Manufacturers and CMS in the renegotiation process. As an example, consider a scenario where a selected drug becomes renegotiation-eligible and there was a likelihood that the percentage change in the MFP would be greater than 15 percent. However, in this example scenario, patents on the selected drug will have expired before a renegotiated MFP would take effect, and we determine that this patent expiration will likely result in the introduction of robust generic competition. In this example scenario, we believe that: (1) it is likely there will be a substantial price drop in the market price for the selected drug unrelated to a renegotiated MFP; and (2) the drug will no longer be a selected drug on January 1 of the initial price applicability year because such drug has an approved generic drug that is subject to Bona Fide Marketing. As such, we may not select this hypothetical selected drug for renegotiation since the impact to the Medicare program might be minimal and does not warrant the considerable investment of time and resources by the Primary Manufacturer or CMS.

We propose to consider the totality of other available information to determine whether renegotiation is likely to result in a change in MFP of 15 percent or greater and that such a change would have a significant impact on the Medicare program. This would include an initial evaluation of the evidence available for a renegotiation-eligible drug. This holistic consideration of the available information and circumstances for renegotiation drug selection provides for the consideration of drug- and fact-specific circumstances. This approach would also maintain consistency with the process for developing the initial offer, which considers the totality of available evidence as described in proposed §§ 429.510 and 429.620(f).

In making this proposed determination, we do not presume that the result of a renegotiation would reflect these estimations, rather, these criteria would serve to support our selection determination in alignment with the requirements set forth in section 1194(f)(3)(C) of the Act and to help provide clarity for interested parties and the public. We note that no

criteria to select drugs for renegotiation can predict the actual outcome of a renegotiation. A determination by CMS that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation. Any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in MFP, decrease in MFP, or no change in MFP. Further, the magnitude of the change in MFP could be higher or lower than 15 percent. Similarly, we do not presume that the result of a renegotiation will reflect these approximations, for example, with respect to the impact of an agreed upon MFP following the renegotiation process on the Medicare program.

We considered reviewing the remaining renegotiation-eligible drugs solely based on the criterion related to the impact on the Medicare program. We believe this criterion is an important component of defining, as a procedural matter, what constitutes a “significant change to the MFP otherwise negotiated”, that is, we believe it is necessary when paired with some expectation of a change in the actual MFP but not sufficient to define a “significant change”.

We also acknowledge that for renegotiation eligibility and selection of selected drugs that are negotiated or renegotiated for the initial price applicability years 2 years prior and immediately before the initial price applicability year for which eligibility and selection for renegotiation is being conducted, the time between agreeing upon an MFP (through negotiation or renegotiation), and the review for renegotiation eligibility for the applicable initial price applicability year may be relatively short. The relatively short period between the negotiation or renegotiation of an MFP and our subsequent review of such drug for renegotiation may make it less likely that recently negotiated or renegotiated drugs would meet the material change criteria proposed at § 429.610(b) and described in section II.G.3.b. of this proposed rule.

Table 3 provides illustrative examples of how we may consider these criteria to determine whether a renegotiation-eligible drug would be selected for renegotiation.

TABLE 3—ILLUSTRATIVE EXAMPLE SCENARIOS AND POTENTIAL RESULT FOR SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS DUE TO A NEW INDICATION OR CHANGE IN A SECTION 1194(e) FACTOR

Example scenario	Potential result
New comparative clinical effectiveness data has become available that is favorable for the selected drug compared to therapeutic alternatives (for example, studies are published showing the selected drug has a greater positive effect on clinical outcomes relative to therapeutic alternatives), but the ceiling* represents a <15% increase in the MFP.	It is not possible for renegotiation to result in a 15% increase in the MFP (because the ceiling* is less than 15% higher than current MFP), so the selected drug would not be selected for renegotiation.
New comparative clinical effectiveness data has become available that is unfavorable for the selected drug compared to its therapeutic alternatives (for example, studies are published showing the therapeutic alternative has a greater positive effect on clinical outcomes relative to the selected drug) and the MFP is much higher than competitors' prices. If such data were used during renegotiation with the Primary Manufacturer, the renegotiated MFP would likely decrease by 15% or more compared to the original MFP.	The selected drug would be selected for renegotiation if consideration of the other criterion supports the determination that renegotiation is likely to result in a significant change to the MFP.
New comparative clinical effectiveness data has become available that is favorable for the selected drug compared to therapeutic alternatives (for example, studies are published showing the selected drug has a greater positive effect on clinical outcomes relative to the therapeutic alternatives, and the ceiling represents a >15% increase in the MFP.) Upon renegotiating with the Primary Manufacturer, the renegotiated MFP would likely increase by 15% or more compared to the original MFP.	

* See proposed § 429.620(b) for additional detail on the ceiling that would be used for renegotiation.

4. Data Collection To Inform Renegotiation Eligibility, Selection, and Renegotiation of the MFP for a Selected Drug (§ 429.615)

Section 1194(f)(1) of the Act directs CMS to provide for a process to renegotiate the MFP for selected drugs that are determined to be renegotiation-eligible under section 1194(f)(2) of the Act and selected in accordance with section 1194(f)(3) of the Act. With respect to initial price applicability year 2028, we implemented these requirements through guidance, including section 130.3 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 130.3 of Negotiation Program Guidance, we propose two data collections in § 429.615 for purposes of informing renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug. The first data collection as described in § 429.615(a) would inform renegotiation eligibility and selection; the second data collection as described in § 429.615(b) would inform the renegotiation process for drugs selected for renegotiation. We will issue two ICRs, each for a 60-day public comment period, alongside this proposed rule. The ICRs include more details regarding how manufacturers can submit data, including the format for data submission. The associated burdens for these ICRs are also discussed in section IV. of this proposed rule.

a. Voluntary Information Submission From Primary Manufacturers To Inform Renegotiation Eligibility and Selection for Selected Drugs

Sections 1194(f)(2) and 1194(f)(3) of the Act do not identify any specific source for the information used to inform renegotiation eligibility and selection. We believe that the information necessary to determine renegotiation eligibility and selection for drugs with an agreed upon MFP is available without submission by the Primary Manufacturer or other interested parties. The sources of information we intend to use for renegotiation eligibility are listed in proposed § 429.605(c)(2), (d)(2), and (d)(3) and further discussed in sections II.G.2.c. and II.G.2.d. of this proposed rule. The sources of information we intend to use to select drugs for renegotiation from among those that are determined to be renegotiation-eligible are listed in proposed § 429.610(b)(2) and further discussed in section II.G.3.b. of this proposed rule. However, we believe input from the Primary Manufacturer on new indications, including off-label uses, and material changes to any factor listed at section 1194(e) of the Act, if applicable, could provide additional information or further validate our review. To minimize burden on the Primary Manufacturer, we propose to make this data submission voluntary. We do not intend to review information submitted by a Primary Manufacturer if its selected drug is renegotiation-eligible due to a

change in monopoly status as described at proposed § 429.605(b) as sections 1194(f)(3)(A) and (B) of the Act require CMS to select all drugs with a change in monopoly status described at proposed § 429.605(b) regardless of whether the drug has a new indication or a material change to a factor listed at section 1194(e) of the Act; no additional information would be required to make such a determination. We may consider the Primary Manufacturer's past data submissions, including any updates to such information, to inform renegotiation eligibility and selection, and to use such information during renegotiation if a drug is selected for renegotiation.

We also propose at § 429.605(c)(2)(ii)(A) that we would only review off-label uses as a new indication for the purpose of determining renegotiation eligibility if the off-label use meets the definition proposed in § 429.20 and is submitted by the Primary Manufacturer in this voluntary submission. We believe that the review of off-label use is discretionary and not explicitly mandated in section 1194(f)(2)(A) of the Act. Further, there is no single reliable directory or source of information regarding off-label use of FDA-approved drugs. Therefore, consideration of off-label use would be based on the evidence available for a given selected drug. Should a Primary Manufacturer of a selected drug decide to submit information about off-label use of the selected drug through this process, the

Primary Manufacturer should indicate in their submission if the referenced off-label use meets the definition of off-label use as proposed in § 429.20.

Consistent with the policies for implementation provided in section 130.3.1 of the Negotiation Program Guidance, we propose at § 429.615(a) to provide each Primary Manufacturer of a selected drug the opportunity to submit information on new indications, including new off-label use, and new or updated information on the factors listed in section 1194(e) of the Act to inform renegotiation eligibility (as described in proposed § 429.605(c) and (d)) and selection (as described in proposed § 429.610(b)). We intend to collect this information through the Drug Selection ICR (CMS–10844, OMB 0938–1443) which would include revisions to collect such information to inform renegotiation eligibility and selection. We would deem this voluntary submission to be proprietary information from the Primary Manufacturer that is protected from disclosure in accordance with the confidentiality policies described in section II.D.1. of this proposed rule and in proposed § 429.300.

b. Data Collection From Primary Manufacturers and Other Interested Parties for Renegotiation of the MFP

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200(b)) and consistent with the policies for implementation provided in section 130.3.2 of Negotiation Program Guidance, we solicit comment on these proposed policies for data collection in the context of renegotiation of the MFP, including whether it may be preferable to more expressly establish CMS' intent to align with data collection in the context of the original negotiation process by replacing the text in proposed § 429.615(b) with text that parallels that used in § 429.505(a).

Specifically, we propose at § 429.615(b)(1)(i) that the Primary Manufacturer of a drug selected for renegotiation would be required to submit information regarding the section 1194(e)(1) factors for the selected drug to CMS, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, as occurs following selection for negotiation. We also propose at § 429.615(b)(1)(ii) that if the drug selected for renegotiation was originally selected for negotiation for initial price applicability year 2026 or 2027 and has

not previously been selected for renegotiation for initial price applicability year 2028 or thereafter, the Primary Manufacturer would be required to submit, if available, non-FAMP, unit type, and total unit volume for all NDC–11s of the selected drug payable under Part B, not covered under Part D, and for which the Primary Manufacturer did not report such information with the Primary Manufacturer's data submission for the initial price applicability year for which the selected drug was first selected for negotiation, for the same calendar years for which non-FAMP data was reported in the Primary Manufacturer's data submission for the initial price applicability year for which the selected drug was first selected for negotiation. Such data, if applicable, will be used to update the non-FAMP used in the renegotiation ceiling calculation described at proposed § 429.620(b) and further discussed in section II.G.5.a. of this proposed rule. The submission of information described at proposed § 429.615(b)(1) would be due at the same time the submission described at § 429.505(a) is due for drugs selected for negotiation for the same initial price applicability year, that is by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug was selected for negotiation or renegotiation, as applicable. This information would be submitted through the Drug Price Negotiation ICR (CMS–10849, OMB 0938–1452).

We also propose at § 429.615(b)(2) to provide any interested party with the opportunity to submit information related to section 1194(e)(2) factors, as occurs for negotiation. We propose at § 429.615(b) that the submission of section 1194(e)(2) information would be due at the same time such information is due for drugs selected for negotiation for the same initial price applicability year, that is March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug is selected for renegotiation. We intend to collect this information through the Drug Price Negotiation ICR (CMS–10849, OMB 0938–1452) which will include revisions to collect the mandatory and optional information regarding the section 1194(e)(2) factors (set forth in proposed in § 429.505(d)(3)) to inform renegotiation of selected drugs). To minimize burden on Primary Manufacturers, we propose that this information collection be a streamlined version of that used for negotiation.

5. Renegotiation Process (§ 429.620)

In accordance with section 1194(f)(4)(B) of the Act, we intend, to the extent practicable, for the renegotiation process to be consistent with the methodology and process established under section 1194(b) of the Act. We propose to implement policies consistent with the policies for implementation set forth in section 130.4 of the Negotiation Program Guidance, with revisions discussed later in this section based on implementation experience.

a. Determining the Ceiling

Section 1194(f)(4)(B) of the Act requires that the process specified for renegotiation must, to the extent practicable, be consistent with the methodology and process established under section 1194(b) of the Act and in accordance with sections 1194(c), (d), and (e) of the Act. Section 1194(f)(4)(B) of the Act further provides that for purposes of applying sections 1194(c)(1)(A) and 1194(d) of the Act, the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the MFP established pursuant to such renegotiation applies, including for applying section 1194(c)(3)(B) of the Act in the case of renegotiation-eligible drugs described in section 1194(c)(3)(A) of the Act and section 1194(c)(3)(C) of the Act in the case of renegotiation-eligible drugs described in section 1194(c)(3)(B) of the Act.

Consistent with section 1194(b)(2)(F)(i) of the Act, in renegotiating the MFP of a selected drug, we propose at § 429.620(b) that CMS would not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling determined under section 1194(c) of the Act, as adjusted, if applicable, as described in this section II.G.5.a. of this proposed rule. Additionally, consistent with the policies for implementation set forth in section 130.4.1 of the Negotiation Program Guidance, we propose at § 429.620(a) to use the same methodology to calculate the ceiling amounts under section 1194(c) of the Act for renegotiation as is used for negotiation (described in proposed § 429.410) with limited revisions to reflect the updates required by statute.

For the purposes of calculating the ceiling amount under section 1194(c) of the Act, we interpret section 1194(f)(4)(B) of the Act as permitting limited updates to the ceiling applied during negotiation when a drug is first

selected. We interpret section 1194(f)(4)(B) of the Act as directing CMS to update the applicable percents applied to selected drugs determined to be renegotiation-eligible due to a change in monopoly status under sections 1194(f)(3)(A) and 1194(f)(3)(C) of the Act, in accordance with the applicable percent for such monopoly statuses described in sections 1194(c)(3)(B) and 1194(c)(3)(C) of the Act. In contrast, section 1194(f)(4)(B) of the Act does not specify that the agency should otherwise recalculate the ceiling amounts described under sections 1194(c)(1)(B) and 1194(c)(1)(C) of the Act, including any redeterminations of the time periods used to calculate such amounts. We interpret the absence of such language in statute, in the context of the more specific instructions to update the applicable percents applied with respect to certain renegotiation-eligible drugs, to provide that CMS largely may not recalculate the ceiling amounts determined with respect to the negotiation for which the drug was first selected. We believe that a contrary interpretation, under which we recalculate the ceiling amounts described under sections 1194(c)(1)(B) and 1194(c)(1)(C) of the Act using the most recent data available with respect to the initial price applicability year for which a drug is selected for renegotiation, would likely result in a renegotiation ceiling that, over time, exclusively decreases. Such an interpretation would effectively preclude the possibility of renegotiating a higher MFP for the selected drug, and such a limitation is not set forth in the statute, including in the criteria for renegotiation selection described under section 1194(f)(3)(C) of the Act. We do not believe such an interpretation is the best reading of the statutory text set forth in section 1194(f) of the Act.

In accordance with this interpretation, and consistent with the policies for implementation set forth in section 130.4.1 of the Negotiation Program Guidance, we propose to determine the ceiling applicable to renegotiation using the ceiling amounts determined with respect to the negotiation for which a drug is first selected, with limited updates discussed below, including to account for the statutory directive to update the applicable percent for certain renegotiation-eligible drugs.

We propose at § 429.620(b)(1) to update the ceiling amounts under section 1194(c) of the Act to incorporate NDC-11s that are payable under Part B if a drug that was originally selected for initial price applicability year 2026 or 2027 is selected for renegotiation and has such NDC-11s. In accordance with

section 1192(d)(1) of the Act, initial price applicability years 2026 and 2027 were the only years in which CMS was directed to limit drug selection to drugs covered under Part D and as such, the ceiling amount under section 1194(c) of the Act did not include NDC-11s payable under Part B, if any, since such NDCs were not considered negotiation-eligible at that time. This proposal would address the fact that the Negotiation Program is no longer limited to drugs covered under Part D. Because renegotiation under this proposed rule applies to initial price applicability year 2029 and beyond, any NDC-11s of a selected drug that are on the HCPCS-NDC crosswalks would be included in the negotiation process, including for renegotiation, and thus any such NDC-11s should be incorporated into the ceiling used for such renegotiation. Not doing so would mean applying a ceiling amount under section 1194(c) of the Act that is based only on NDC-11s covered under Part D of the selected drug, despite the renegotiation process and the MFP that may result from such renegotiation applying to all NDC-11s covered under Part D and/or payable under Part B.

We propose at § 429.620(b)(2) to update the applicable percent under section 1194(c)(3)(C) of the Act for purposes of calculating the non-FAMP ceiling under section 1194(c)(1)(C) of the Act for drugs selected for renegotiation due to a change in monopoly status. Consistent with § 429.435(a)(4)(vi), the applicable percent would be based on the initial approval date associated with the earliest-approved FDA application belonging to the NDA holder or BLA holder, as described in section II.B.6. of this proposed rule, for the selected drug and the initial price applicability year for which the drug is selected for renegotiation.

Finally, for all drugs selected for renegotiation, we propose at § 429.620(b)(3) to adjust the amounts considered for the ceiling described under section 1194(c) of the Act and proposed at § 429.410 by the percent increase in the CPI-U from July of the calendar year that is 2 years prior to the initial price applicability year of the most recent agreed upon MFP through July of the calendar year prior to the calendar year in which the drug is selected for renegotiation. This approach is consistent with sections 1194(f)(4) and 1195(b)(1)(A) of the Act and proposed § 429.705 under which we would publish an updated MFP increased by the annual percentage increase in the CPI-U. That is, for each year subsequent to the first initial price

applicability year of the price applicability period for the selected drug with an agreed-upon MFP, the annual percentage increase in the CPI-U would be based on the 12-month period ending with the July immediately preceding November 30 of the year that is 2 years prior to such subsequent year. For example, if a drug was selected for negotiation for initial price applicability year 2026, CMS and the Primary Manufacturer agreed upon an MFP, and the drug was selected for renegotiation for initial price applicability year 2029, we would increase the amounts considered for the ceiling that were applicable to the initial price applicability year 2026 negotiation (incorporating any Part B data as applicable) by the increase in CPI-U from July 2024 through July 2027. This increase represents the cumulative inflation adjustment that we would have applied to the initial price applicability year 2026 MFP through the most recent published MFP files at the time that the drug is selected for renegotiation (which would be the files for MFPs effective January 1, 2029, published in November 2026). If we did not similarly increase the amounts considered for the ceiling by the same inflation adjustment that we apply to the MFP under section 1195(b)(1)(A) of the Act, the inflation-adjusted MFP could, over time, approach and eventually exceed the original ceiling amount. This could preclude our ability to select a drug for renegotiation and renegotiate the MFP for such drug that may otherwise be renegotiation-eligible and selected in accordance with sections 1194(f)(2) and 1194(f)(3) of the Act and under the criteria proposed in §§ 429.605 and 429.610, respectively. This potential limitation on CMS' ability to renegotiate increased MFPs would be inconsistent with section 1194(f)(3)(C) of the Act, which does not limit selection for renegotiation to instances exclusively in which renegotiation would likely result in a decrease in the MFP and thus contemplates that renegotiation may be appropriate where we expect renegotiation would be likely to result in an increased MFP.

b. Negotiation Factors

Section 1194(f)(4)(B) of the Act requires that the renegotiation process shall be consistent with the methodology and process for negotiation, to the extent practicable. As such, we propose at § 429.620(c) to consider the negotiation factors listed at sections 1194(e)(1) and (e)(2) of the Act inclusive of information submitted or shared about the factors listed at sections 1194(e)(1) and (e)(2) of the Act

in any prior negotiation or renegotiation(s) as described in proposed § 429.505 and discussed in II.F.2. of this proposed rule consistent with the policies for implementation at section 130.4.2 of Negotiation Program Guidance.

c. Methodology for Developing an Initial Offer

Consistent with policies for implementation as described in section 130.4.2 of Negotiation Program Guidance, we propose at § 429.620(d) that the methodology for developing the initial offer for all drugs selected for renegotiation be the same process and timeline set forth for development of the initial offer for the negotiation process under proposed § 429.510. This would apply the process described in proposed § 429.510 including the review of information related to the section 1194(e)(1) and 1194(e)(2) factors described in proposed § 429.505. By uniformly adopting the initial offer process described in proposed § 429.510 for the purpose of the development of all initial offers in the context of renegotiation this aspect of renegotiation process would be fully aligned with the negotiation process consistent with the requirement at section 1194(f)(4)(B) of the Act. We note that we would apply the ceiling calculated for renegotiation per proposed § 429.615(b) when adopting the process described in proposed § 429.510 where applicable. As part of this proposed policy, we intend to require the Primary Manufacturer to submit the most recent agreed upon MFP as part of the data submission requirement described in proposed § 429.615(b)(1) through the Drug Price Negotiation ICR (OMB 0938–1452) discussed in section II.G.4.b. of this proposed rule. We believe that considering the MFP during the development of the initial offer would better allow us to incorporate the impact of the offer and counteroffer process from the prior negotiation or renegotiation into the initial offer for the current renegotiation.

Submission of the MFP would be a new collection requirement within the existing data submission. All drugs selected for renegotiation will have an agreed upon MFP and adding collection of the MFP as a data point in this submission requirement would be standard for all such selected drugs. We believe the MFP is an important data point to consider as part of our consideration of “market data and revenue and sales volume data for the drug in the United States” (the factor listed at section 1194(e)(1)(E) of the Act)

as it is a Medicare-specific price that, per section 1193(a) of the Act, Primary Manufacturers are required to make available to MFP-eligible individuals (as defined at section 1191(c)(2) of the Act). We also believe that considering the MFP under the factor listed at section 1194(e)(1)(E) of the Act and therefore as a part of the totality of data submitted related to section 1194(e)(1) factors is consistent with the process used to develop the initial offer for negotiation as described at proposed § 429.510, and more specifically the adjustment described at proposed § 429.510(f). By collecting the MFP as part of the data submission requirement described at proposed § 429.615(b)(1), we may then consider the MFP as a component of the factor listed at section 1194(e)(1)(E) of the Act and the adjustment to the preliminary price described at proposed § 429.510(f)(2). We note that while the MFP is a publicly available price updated regularly by CMS, section 1194(e)(1) of the Act requires information related to the section 1194(e)(1) factors to be submitted by the Primary Manufacturer for consideration in offer development and during consideration of counteroffers, if applicable (as discussed in section II.F.2.a. of this proposed rule). Thus, collecting the MFP through the Drug Price Negotiation ICR (OMB 0938–1452) would allow us to consider the MFP within the context of the section 1194(e)(1) adjustment as discussed in proposed § 429.510(f)(2).

As an alternative to the proposal at § 429.620(d), we considered applying the policy set forth in the Negotiation Program Guidance. In this option we would not include the MFP as a component of the factor listed at section 1194(e)(1)(E) of the Act and therefore the MFP would not be considered within the section 1194(e)(1) adjustment described at § 429.510(f). With this alternative, we would also not collect the MFP through the Drug Price Negotiation ICR as the data would not be required for offer development or counteroffer consideration. We did not propose this option as we believe that the MFP is an important data point to consider within the context of renegotiation, as discussed previously.

As another alternative, we considered applying a third and separate adjustment based on the prior agreed upon MFP after the adjustment based on the section 1194(e)(1) factors is applied to the preliminary price as described at proposed § 429.510(f)(2). We believe this alternative would also be consistent with the methodology and process for the negotiation process to the extent practicable, but which would

incorporate additional adjustments for the renegotiation context to afford distinct weight to the prior negotiation. In this approach, the MFP would be collected through the data submission requirement described at proposed § 429.615(b)(1) but considered separately from other information collected related to the section 1194(e)(1) factors. For example, for drugs selected for negotiation for initial price applicability year 2028, the Primary Manufacturer and CMS may have conducted up to three negotiation meetings following CMS’ provision of the initial offer. During those meetings, the Primary Manufacturer may have, for example, presented additional evidence or otherwise raised a point not previously considered that contributes to our determination to accept a counteroffer or provide a subsequent offer that is different than the initial offer. If we were to follow the initial offer development process as described in proposed § 429.510 without considering the information that may have been exchanged over the course of the negotiation (or prior renegotiation, if applicable), then there may be circumstances where the initial offer is similar to the initial offer from the previous negotiation or renegotiation, and does not account for the additional discussions and information that contributed to the agreed upon MFP. By adjusting the amount determined after the section 1194(e)(1) adjustment described at proposed § 429.510(f)(2) by the MFP, we would be able to consider such negotiation meeting discussions and provide an initial offer that is informed by the prior negotiation or renegotiation process. We acknowledge that this approach would consider the MFP separately from the other section 1194(e)(1) factors. However, we believe this alternative approach would be consistent with the negotiation process to the extent practicable per sections 1194(f)(4)(B) and 1194(b)(1) of the Act as the initial offer development process would otherwise remain the same except for the single MFP adjustment.

d. Engagement With Primary Manufacturers and Interested Parties

We propose at § 429.620(e) through (l) that the renegotiation process would conform to the same procedures, structure, and timeline set forth for the negotiation process to the extent practicable. We note that we would apply the ceiling calculated for renegotiation per proposed § 429.615(b) when adopting these processes where applicable. We may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for

negotiation or host separate events specifically for drugs selected for renegotiation, as described in § 429.620(e).

If the Primary Manufacturer is delayed in meeting one or more deadlines in proposed §§ 429.525 through 429.535, such as submitting the renegotiation written counteroffer, we would continue to engage in the renegotiation process and would complete the established process as described in section II.C.6. of this proposed rule and as proposed subpart F. In the circumstance that CMS and the Primary Manufacturer do not agree to an MFP by the deadline set forth in proposed § 429.535, we refer to the discussion and proposal in subpart K, as described in section II.C.7. of this proposed rule. Additionally, if the failure to meet a deadline results in the failure of CMS and the Primary Manufacturer to reach an MFP following renegotiation, this may result in certain sales of the selected drug being subject to a potential excise tax (see 26 U.S.C. 5000D(b)(3)).

e. Publication of the MFP

For a selected drug for which CMS and a Primary Manufacturer agree upon an MFP through the renegotiation process, we propose at § 429.620(k) to publish and update the renegotiated MFP and related information as proposed in § 429.705 and as described in section II.H.2. of this proposed rule.

We do not intend to include redacted information from any voluntary information submitted by a Primary Manufacturer in response to the Drug Selection ICR in the MFP explanation if the selected drug of the Primary Manufacturer is selected for renegotiation and there is an agreement upon a renegotiated MFP. If the selected drug is then selected for renegotiation and the Primary Manufacturer submits the same information the Primary Manufacturer provided in response to the Drug Selection ICR also provided in response to the Drug Price Negotiation ICR, as described in section II.G.4. of this proposed rule and in proposed § 429.615, we may redact and include information provided in response to the Drug Price Negotiation ICR in the MFP explanation of a renegotiated MFP as proposed in section II.H.2. of this proposed rule and § 429.705(b) and in accordance with section II.H.2. of this proposed rule and proposed § 429.705(c) and the confidentiality policy described in section II.D.1. of this proposed rule and in proposed § 429.300.

H. Implementation of the MFP (§§ 429.700 Through 429.710)

1. Application of the MFP Across Dosage Forms and Strengths (§ 429.700)

Section 1196(a)(2) of the Act states an administrative duty in which we must establish procedures to compute and apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 60.5 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We propose at § 429.700 to codify the administrative duty requirement and that once the MFP has been agreed upon for a selected drug, we would compute and apply the MFP across different dosage forms and strengths of a selected drug. We propose at § 429.700 the methodology that we would use to apply the single agreed-upon MFP (which, as proposed at § 429.415 and section II.E.4. of this proposed rule, would be an average price per 30-day equivalent supply for the selected drug across all formulations of the selected drug) across NDC-9s and HCPCS codes, as applicable, and calculate an MFP-per-billing unit price for each billing unit and payment code associated with the selected drug, as applicable, as contemplated under section 1196(a)(2) of the Act and described at § 429.700(b)(4). CMS proposes to use a methodology that scales the MFP per unit and the MFP per billing unit based on price differentials across different dosage forms and strengths of the selected drug to ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to dispensing entities and Part B providers), we would publish the MFP per NCPDP unit (for example, tablet) for each NDC-9 and per billing unit for each HCPCS code, as applicable, associated with the selected drug based on the list of NDCs and HCPCS codes determined as described at § 429.100(c). We advise supply chain entities to use the NDC-9 MFP per unit price when effectuating the MFP for a selected drug with a formulation covered under Part D to ensure accuracy (for example, in the event of partial package dispense).

As proposed at § 429.700(b), we describe the proposed procedures to compute and apply the MFP across dosage forms and strengths of the selected drug using the WAC of the selected drug as reported by Primary Manufacturer in the CMS HPMS (as

described in proposed § 429.20). This proposed process would apply the MFP to any NDCs of the selected drug, to include NDCs of a self-administered drug, assigned to the Primary Manufacturer and/or Secondary Manufacturer(s) where such NDCs do not represent sample packages and where the Primary Manufacturer reported a non-zero WAC for at least one calendar quarter of the calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation. (The proposed process for applying the MFP to NDCs of the selected drug with insufficient data is set forth in proposed § 429.700(c) as described below.) For NDCs of selected drugs covered under Part D, we would use PDE records from the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation where the PDE record is associated with a prescription filled between January 1st of that year and December 31st of that year, and meets the inclusion criteria proposed at § 429.120(a)(2) through (a)(5) (as discussed in section II.B.5.a. of this proposed rule). With respect to NDCs of selected drugs payable under Part B, we would use OM Part B claims data and/or MA encounter data for Part B items and services from the calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation where the claim and/or record is associated with a service date between January 1st of that year and December 31st of that year, and meets the inclusion criteria proposed in proposed at § 429.120(b)(1)(ii) through (b)(1)(vi) (as discussed in section II.B.5.b. of this proposed rule). We propose to use the calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation for purposes of the calculations set forth in § 429.700(b) because it will be the most recent period of data available.

We propose at § 429.700(b)(1)(i), for each NDC-11 and calendar quarter, to calculate the quarterly WAC per unit by dividing the WAC quarterly units by the total WAC annual units (from the manufacturer-submitted data) and multiply this quotient by the quarterly WAC per unit. At § 429.700(b)(1), we propose to use the WAC unit cost for the period beginning on January 1 and ending December 31 for the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for

negotiation. We propose at § 429.700(b)(1)(ii), for each NDC–11, to sum the results determined under § 429.700(b)(1)(i) and to calculate the annual WAC per-unit cost for each of the NDC–11s for the selected drug (including NDC–11s payable under Part B, which are assigned to HCPCS codes in NDC–HCPCS code crosswalk files published by CMS, as well as NDC–11s covered under Part D) from the manufacturer-submitted quarterly WAC per unit and unit volume data to account for potential variation in unit volume across quarters.

We propose at § 429.700(b)(2) to convert the annual WAC per unit for each NDC–11 into an amount for a 30-day equivalent supply (using the methodology described § 423.104(d)(2)(iv)(A)(2) for Part D and at § 429.415(a)(2)(v) for Part B), so that the WAC will be comparable to the negotiated single MFP. We propose in § 429.700(b)(2)(i) to determine total units for the purpose of this calculation as the sum of the total quantity dispensed for NDC–11s present only in PDE data and the NDC–11 NCPDP unit equivalent conversion of the total Part B billing units administered for NDC–11s associated with HCPCS codes present in Part B data.

We propose at § 429.700(b)(3)(i) through (b)(3)(v), to then aggregate the WAC per 30-day equivalent supply for each NDC–11 into a WAC per 30-day supply for each NDC–9 of the selected drug. The WAC per 30-day equivalent supply for each NDC–9 would then be used to calculate a WAC price ratio for each NDC–9 of the selected drug as proposed in § 429.700(b)(3)(vi). The WAC price ratio derived from the WAC per 30-day equivalent supply for each NDC–9 would then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each NDC–9 of the selected drug as proposed in § 429.700(b)(4)(A).

Lastly, we propose at § 429.700(b)(4)(i)(B), we would convert from an MFP for a 30-day equivalent supply to an MFP per NCPDP unit based on the average number of NCPDP units in a 30-day equivalent supply to determine the per NCPDP unit MFP for an NDC–9. We propose at § 429.700(b)(4)(ii), that for selected drugs payable under Part B, we would further convert the MFP per NCPDP unit of each NDC–9 into an MFP per billing unit by converting the per-NCPDP unit amount into an amount per billing unit as necessary to account for any differences in the NDC–9 unit versus the billing unit. This conversion would require us to convert the NDC–9 MFP

per NCPDP unit to an NDC–11 MFP per package (by multiplying the NDC–9 MFP per NCPDP unit by the NDC–11 NCPDP package quantity), and then divide this product by the HCPCS billing units per NDC–11 package to arrive at an NDC–11 MFP per billing unit. We would then take an average of the NDC–11 MFP per billing unit across all NDC–11s associated with a HCPCS code for the selected drug, weighted by the ASP units reported by manufacturers for each NDC–11 under section 1847A of the Act.

We would include the MFP per billing unit, calculated at § 429.700(b)(4)(ii)(E), and the MFP per NCPDP unit price for each NDC–9 of the selected drug, calculated at § 429.700(b)(4)(i)(B) in the publication of MFPs as proposed in § 429.705. We recognize there may be other ways to apply the MFP to dosage forms and strengths and intend to monitor this policy. We propose to codify the approach taken in policies for implementation as described in section 60.5 of Negotiation Program Guidance to list in the public pricing file only the NDC–9 MFP-per-unit price (rounded to six decimals) rather than also including the NDC–11 MFP-per-package price. The NDC–11 MFP-per-package price was removed due to the potential for confusion arising from differences between the NDC–11 MFP-per-package price as published by CMS (calculated without rounding any values in interim steps) and the NDC–11 MFP-per-package price that would result if another entity were to take the product of the published NDC–9 MFP-per-unit price (rounded to six decimals) and the package size. The application of the MFP is not inclusive of NDCs of the selected drug that are not manufactured, marketed, controlled, or sold by the Primary Manufacturer or a Secondary Manufacturer, or NDC–11s to which the MFP would not apply, such as sample packages, inner packages, and discontinued products.

Consistent with policies for implementation as described in section 60.5.1 of Negotiation Program Guidance, we propose at § 429.700(c), the process by which we would apply the MFP to NDCs associated with new NDAs/BLAs, NDCs, or HCPCS codes, including those added during the negotiation period or after agreeing upon an MFP, and to NDCs and HCPCS codes with insufficient PDE, Part B data, or WAC data in calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation to apply the MFP across those dosage forms and strengths. We propose at § 429.700(c)(1),

the process for how we would apply the MFP to NDCs associated with new NDAs or BLAs and we propose at § 429.700(c)(2), the process for how we would apply the MFP to NDCs associated with HCPCS codes of new NDAs or BLAs. We propose at § 429.700(c)(3), the process for how we would apply the MFP to NDCs and HCPCS codes with insufficient data, which would be considered if there was no data available to calculate a sum of the plan-specific enrollment weighted amount in the applicable calendar year, no payment amount under section 1847A(b)(4) of the Act, and no average non-FAMP data (when it has not yet been a full year following the market entry for such drug) are determined to have insufficient data. As proposed at § 429.700(c)(4)(i), we would determine whether there is an existing NDC that is comparable to the new NDC and has sufficient data for the MFP application calculations proposed § 429.700(b). We would base our review of a comparable NDC using the FDA-approved label of the selected drug and other relevant sources. We would evaluate whether an existing NDC is comparable to a new NDC if it shares the same NDC–9, has a different NDC–9 but has the same dosage form and strength, has a different NDC–9 but has a similar dosage form and strength, or has the same active moiety/active ingredient. We propose at § 429.700(c)(3)(i)(A) and (B), respectively, the process that we would use if an existing, comparable NDC exists and the process if a comparable NDC does not exist.

We propose at § 429.700(c)(3)(ii), the process for which we would adjust the MFP application. Specifically for the NDCs and HCPCS codes described in § 429.700(c)(3)(ii), we would monitor total quantity dispensed or administered and 30-day equivalent supply from PDE data and Part B data over time, beginning when these NDCs and/or HCPCS codes are first added to our computation of how we will apply a single MFP across dosage forms and strengths of the selected drug. We would update the total quantity dispensed and 30-day equivalent supply values and recompute the application of the single MFP across dosage forms and strengths for these NDCs and/or HCPCS codes (but only for such NDCs and/or HCPCS codes, not for all NDCs and/or HCPCS codes of the selected drug) based on which of the following situations occurs first: (1) a year has elapsed since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B data; or (2) the NDC or HCPCS

code has accrued the same number of units dispensed/administered as the NDC–11 that had the fewest units dispensed/administered at the time that the WAC ratios were originally calculated. We included a third condition in section 60.5.1 of the Negotiation Program Guidance; CMS determines the variation in average total quantity dispensed and 30-day equivalent supply is stable over time. We propose to remove this condition due to its subjectivity and lack of predictability compared to the other two conditions and codify proposed § 429.700(c). We propose at § 429.700(c)(3)(iii), the process we would apply if a new NDC is assigned to a HCPCS code for which we have already calculated an MFP per billing unit.

We propose at § 429.700(d), that after we recompute the application of the single MFP across dosage forms and strengths for the new NDC–11 as proposed in § 429.700(c)(4)(i)(B)(1), to provide Primary Manufacturers with the calculations described at proposed § 429.700(b) and (c) and if the Primary Manufacturer believes in good faith that we made an error, a Suggestion of Error may be submitted, as set forth in § 429.445(c), in a form and manner as specified by CMS, as set forth in § 429.445(d), as described in section II.E.11. of this proposed rule. We solicit comments on our proposed approaches for the application of the MFP across dosage forms and strengths.

2. Publication of the MFP (§ 429.705)

Section 1195(a)(1) of the Act requires that with respect to an initial price applicability year and a selected drug with respect to such year, not later than November 30 of the year that is 2 years prior to such initial price applicability year, CMS shall publish the MFP for such drug negotiated with the manufacturer of such drug. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we propose at § 429.705(a) that we would publish by November 30 of the year that is 2 years prior to the initial price applicability year, the MFP for each selected drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP. For example, we would publish the MFP for each

selected drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP no earlier than November 1, 2027 and no later than November 30, 2027 for initial price applicability year 2029. Related to this requirement, we propose at § 429.705(a)(1) to publish the following on the CMS website: the selected drug; the initial price applicability year; and the MFP file. The MFP file⁶⁴ would contain the single MFP for a 30-day equivalent supply of the selected drug, NDC–9 MFP-per-unit price and HCPCS code dosage price and would be updated annually to show the inflation-adjusted MFP for the selected drug. We would also update the file as needed if any NDC–9s or HCPCS codes are added or removed for the selected drug, or if the NDC–9 MFP per-unit price or HCPCS code dosage price is updated as a result of additional data.

Further, as proposed at § 429.705(a)(1)(iv), we would publish on the CMS website whether an MFP between a Primary Manufacturer and CMS is not agreed upon. As proposed at § 429.705(a)(1)(v), we would also publish on the CMS website whether a drug is no longer a selected drug and the reason for that change. In accordance with section 1192(c) of the Act, a selected drug with an agreed-upon MFP would cease to be a selected drug and no longer be subject to an MFP in accordance with the timeline described in section II.B.6.d. of this proposed rule and in proposed subpart B if we determine that a generic drug or a biosimilar for the selected drug is approved or licensed by the FDA and—as proposed under subpart B—is subject to Bona Fide Marketing. We further recognize that, in accordance with section 1194(f) of the Act, the MFP for a selected drug may also change due to renegotiation beginning in initial price applicability year 2028 (in the case of a renegotiation-eligible drug selected by the Secretary under section 1194(f)(3) of the Act), as described in section II.G. of this proposed rule and in proposed subpart G.

Section 1195(b)(1)(A) of the Act requires that, for a selected drug for each year subsequent to the first initial price applicability year of the price applicability period with respect to such

drug, with respect to which an agreement for such drug is in effect under section 1193 of the Act, not later than November 30 of the year that is 2 years prior to such subsequent year, CMS shall publish the MFP applicable to such drug and year, which shall be the amount equal to the MFP published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we are proposing in § 429.705(a)(2) that for each selected drug, for each year subsequent to the first initial price applicability year of the price applicability period (unless renegotiation occurs as set forth in section II.G. of this proposed rule and under proposed subpart G), we would publish an updated MFP no later than November 30 of the year that is 2 years prior to such subsequent year. We propose at § 429.705(a)(2)(i) that the updated MFP for each selected drug would be equal to the MFP that was published for such drug for the previous year, increased by the annual percentage increase in the CPI–U for the 12-month period ending with the July immediately preceding such November 30. For example, no later than November 30, 2028, we would publish on the CMS website updated amounts for any MFPs for initial price applicability year 2029 selected drugs for which a manufacturer agreement is in effect. Those updated MFPs would take effect in 2030 and would be equal to the initial price applicability year 2029 MFP for the selected drug increased by the percent increase in CPI–U from July 2027 to July 2028.

Section 1195(b)(2) of the Act requires that, in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the date of publication under section 1195(a) of the Act, CMS shall publish such MFP by not later than 30 days after the date such MFP is so determined. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for

⁶⁴ The Maximum Fair Price Layout file would display the NDC–9 MFP per-unit price to six decimal places. Publishing an NDC–9 MFP per-unit price rounded to the sixth decimal point place aligns with how CMS publishes other prices. Furthermore, publishing an NDC–9 MFP per-unit price rounded to the sixth decimal place would also result in the same agreed-upon MFP per 30-day equivalent when reversing the application of the single MFP across dosage forms and strengths calculations.

example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we propose in § 429.705(a)(3) that in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, such as due to the circumstances described in proposed § 429.710, we would publish the MFP no later than 30 days after the date such MFP is so determined.

Section 1195(a)(2) of the Act requires that with respect to an initial price applicability year and a selected drug with respect to such year, not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1193(c) of the Act, the explanation for the MFP with respect to the factors as applied under section 1194(e) of the Act for such drug. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we propose in § 429.705(b) that we would publish explanations for the MFPs no later than March 1 of the year prior to the initial price applicability year. We propose in § 429.705(b)(1) to develop and publish the explanations for the MFPs for each selected drug, or drug selected for renegotiation, subject to the requirements for treatment of confidential and proprietary information in proposed § 429.300 and described in section II.D.1. of this proposed rule. The explanation for the MFP includes: the narrative explanation of the MFP; redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable; and the redacted information submitted by a Primary Manufacturer in proposed § 429.505(b)(2) or § 429.615(b)(1) (as described in section II.F.2. or section II.G.4. of this proposed rule), as applicable, and the redacted information submitted by interested parties in proposed § 429.505(d)(3) or § 429.615(b)(3), as applicable.

Within the explanation of the MFP, we may also make public, high-level comments about the sections 1194(e)(1) and 1194(e)(2) data submitted to CMS

that are determined to be proprietary, without sharing any PHI/PII or any proprietary information reported to CMS under section 1193(a)(4) of the Act for purposes of the negotiation. Similar to the approach taken for publication of the public MFP explanations for initial price applicability year 2026 and 2027, for each drug, we would make available on the CMS website redacted versions of section 1194(e)(2) data that are determined to be nonproprietary and will not disclose any PHI, PII, or information that is protected from disclosure under other applicable law.

If an agreement for an MFP is reached for a selected drug and CMS makes a determination before the end of the negotiation period (as set forth in proposed § 429.535) that an approved generic drug or licensed biosimilar for the selected drug is subject to Bona Fide Marketing (consistent with proposed § 429.130(a)), we would neither publish an MFP nor publish an MFP explanation because the selected drug ceases to be subject to the negotiation, pursuant to section 1192(c)(2) of the Act and as described in proposed § 429.135(b)(1) (see further discussion in section II.B.6.d. of this proposed rule).

If an agreement for an MFP is not reached for a selected drug, we would neither publish an MFP nor publish an MFP explanation, as proposed at § 429.705(b)(2). Instead, we would indicate on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug.

3. Establishment of MFPs After the Negotiation Deadline (§ 429.710)

Section 1194(b)(2) of the Act contemplates that agreement upon an MFP must be reached prior to November 1 following the selected drug publication date, with respect to the initial price applicability year, to avoid potential imposition of an excise tax. If negotiations have not ended by this date, the Primary Manufacturer may be subject to an excise tax under 26 U.S.C. 5000D. As a general matter, if the Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, we would continue to engage in the negotiation process described in section II.F. of this proposed rule and under proposed subpart F.

Certain actions or delays by the Primary Manufacturer may delay the process such that the MFP may be agreed to after the end of the negotiation period as described in proposed § 429.535(b). Section 1194(b)(1) of the Act requires that the Secretary shall develop and use a consistent

methodology and process, in accordance with section 1194(b)(2) of the Act, for negotiations under section 1194(a) of the Act that aims to achieve the lowest MFP for each selected drug. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, we propose in § 429.710 that, in the event of a delay by the Primary Manufacturer such that the MFP may be agreed to after the end of the negotiation period described in the proposed § 429.535(b), we would follow timelines consistent with the negotiation process established in section II.F. of this proposed rule and under proposed subpart F and take the time to complete the established process so described as appropriate for the selected drug. Certain actions by the Primary Manufacturer may delay the negotiation process to such an extent that a selected drug has a change in status that is material to CMS' statutory obligations under the negotiation process. If this occurs, as proposed at § 429.710(a), when CMS initiates or resumes the negotiation process, we would apply the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including with respect to renegotiation, as applicable, as described in subpart G.

If the manufacturer and CMS complete each step of the negotiation process as described in section II.F. of this proposed rule and under subpart F, including CMS' issuance of a final offer in accordance with § 429.535(a), and then, after the statutory end of the negotiation period, the Primary Manufacturer of a selected drug wishes to agree to an MFP, the Primary Manufacturer must notify CMS in writing that it would like to accept the final offer from CMS, as proposed at § 429.710(b).

In accordance with section 1195(b)(2) of the Act and as proposed at § 429.705(a)(3), in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, we would publish the MFP no later than 30 days after the date such MFP is so determined. For such a drug, in accordance with §§ 429.705(b) and 429.710, we would follow timelines consistent with the established process for publishing the explanation of the

MFP and would not expedite our timeline due to late action from the Primary Manufacturer.

I. Manufacturer Compliance and Oversight (§ 429.900)

Section 1196(b) of the Act requires that CMS monitor compliance by a Primary Manufacturer with the terms of the Negotiation Program Agreement and establish a mechanism through which violations of such terms shall be reported. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 90.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, we are proposing to codify our policies for effectuating the compliance monitoring required by section 1196(b) of the Act, consistent with those policies described in section 90.1 of the Negotiation Program Guidance, in proposed subpart J. Section 429.900 codifies sections 90 through 90.1 of the Negotiation Program Guidance.

1. Monitoring Manufacturer Compliance (§ 429.900)

Proposed § 429.900 establishes CMS' approach to monitoring and assessment of Primary Manufacturer compliance with the terms of the Negotiation Program Agreement as described in § 429.200, the Primary Manufacturer's obligation to cooperate with CMS's compliance monitoring activities, and actions CMS may take to address Primary Manufacturer noncompliance.

In accordance with section 1193(a)(5) of the Act, section 429.900(a) proposes that CMS may monitor and assess Primary Manufacturer compliance with the Negotiation Program Agreement, including compliance with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program. We will closely monitor the Primary Manufacturer's compliance with the terms of the Negotiation Program Agreement, including the requirements for Primary Manufacturers of selected drugs as described in part 429. Following the publication of selected drugs for negotiation and renegotiation for each initial price applicability year, as described in § 429.100, we may provide information about the negotiation or renegotiation process, as applicable, to the Primary Manufacturer of each

selected drug. We anticipate this information would include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information. During the negotiation and renegotiation periods, we would track and monitor progress during all steps of the process. CMS compliance monitoring will continue beyond the negotiation period and extend to all aspects of Primary Manufacturer participation in the Negotiation Program. For example, during the negotiation period and after it has closed, we may require additional information from the Primary Manufacturer to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. This may include requiring recurring reporting (for example, providing evidence that the MFP is being made available), or making specific ad hoc requests to the Primary Manufacturer for information related to targeted monitoring, auditing, or investigation efforts. Methods CMS may use to monitor and assess compliance, during the negotiation and renegotiation periods or otherwise, include but are not limited to: evaluation of complaints made by individuals and entities to CMS; CMS' engagement in direct communications with the Primary Manufacturer; and CMS audits and comprehensive reviews.

As described in proposed § 429.900(b), Primary Manufacturers must cooperate with CMS compliance monitoring activities. This includes providing complete, accurate, and relevant responses to CMS requests for clarifications, corrections, and additional information and complying fully with requests for corrective action during the compliance monitoring process and when noncompliance is identified. For example, we propose that Primary Manufacturers must submit complete, accurate, and relevant responses, in the form and manner and on the timeline specified by CMS, in response to written requests CMS provides to the Primary Manufacturer in the course of our compliance monitoring activities when we deem appropriate. We are committed to providing Primary Manufacturers with reasonable timeframes to accommodate these information requests; Primary Manufacturers have the burden of establishing why an extension of any deadline to submit information should be considered by CMS. If a Primary Manufacturer articulates a reasonable basis for seeking an extension for a reasonable duration of time, and the request is submitted at a reasonable

point in time before the deadline (for example, 3 calendar days prior to the initial deadline), then CMS may grant an extension of a limited duration to the extent consistent with statutory timelines and other operational considerations.

Likewise, we propose that a Primary Manufacturer must comply fully with corrective action requests that we provide to the Primary Manufacturer when we deem it appropriate; for example, including but not limited to, in the event that a Primary Manufacturer fails to submit data as described in proposed §§ 429.100 and 429.505 of this proposed rule. We recognize the substantial role that manufacturer-submitted information will play in the negotiation and renegotiation processes and the need for complete and accurate information. Should CMS determine that a submission is incomplete or contains inaccurate information, CMS may provide a written request to the Primary Manufacturer to clarify the submission, correct the inaccuracy, or provide the necessary information, with a deadline by which the Primary Manufacturer must respond. The written corrective action request would outline the needed action and establish a deadline for the Primary Manufacturer to correct the submission and/or provide additional information to validate the accuracy and completeness of the original submission. We intend to be available to engage with the Primary Manufacturer about the specifics of a corrective action request and to answer questions and provide clarification.

The information required in this proposed part is information required by CMS to administer and monitor the Negotiation Program in accordance with section 1193(a)(5) of the Act. As such, as proposed at § 429.900(b), failure to provide complete and accurate information, initially or in response to CMS' initial questions or corrective action requests, may result in the Primary Manufacturer being subject to a civil monetary penalty as authorized under section 1197(c) of the Act and as described in proposed § 429.1005.

In proposed § 429.900(c), we would establish the actions CMS may take if we conclude that a Primary Manufacturer is noncompliant with one or more requirements of the Negotiation Program Agreement, including all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program. Upon identifying a

violation, CMS may take one or more of the following actions: (1) CMS may provide a written notice to the Primary Manufacturer of the violation; (2) CMS may request the Primary Manufacturer to take specific corrective action to address the noncompliance; or (3) CMS may impose a civil monetary penalty on the Primary Manufacturer as set forth in subpart K. In instances in which CMS provides a written notice to the Primary Manufacturer of the violation and/or requests specific corrective action, the agency may offer the Primary Manufacturer the opportunity, by a specified deadline, to provide information regarding the circumstances of violation, evidence seeking to refute the finding of violation, proof of mitigation of noncompliance, and other factors for CMS' consideration. CMS proposes to consider such information if timely submitted when determining whether to pursue further enforcement action such as imposition of civil monetary penalties.

J. Civil Monetary Penalties (§§ 429.1005 Through 429.1020)

1. Civil Monetary Penalties

Section 1197 of the Act provides for the imposition of civil monetary penalties on manufacturers for: (1) failure to provide access to a price that is less than or equal to the maximum fair price for a drug; (2) failure to pay the rebate amount for a biological product inclusion of which on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act; (3) violation of certain terms of the Negotiation Program Agreement; and (4) the provision of false information as described in section 1197(d) of the Act.

With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 100 of the Negotiation

Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, with the exception of our authority pursuant to section 1197(a) of the Act as described later in this section, we are proposing to codify our policies for implementation of our CMP authorities as set forth in section 1197 of the Act, consistent with those policies described in section 100 of the Negotiation Program Guidance, in proposed subpart K.

In future rulemaking, we will codify our policies for implementation of section 1197(a) of the Act, under which manufacturers may be subject to a civil monetary penalty for failure to provide access to a price less than or equal to the MFP, for 2029 and subsequent years. Consistent with the statutory directive to use program instruction or other forms of program guidance to implement sections 1191 through 1198 of the Act for 2026, 2027, and 2028, a Primary Manufacturer's compliance obligations with respect to its obligation to provide access to a price less than or equal to the MFP for 2026, 2027, and 2028 are established in the applicable program guidance, and we are reserving codifying the civil monetary penalty associated with violation of this obligation, including the process, calculation, and substantive compliance obligations, for 2029 and subsequent years, for future rulemaking.

In proposed § 429.1005, we address potential imposition of civil monetary penalties for a Primary Manufacturer's violation of a requirement determined by CMS to be necessary for the purposes of administering and monitoring compliance with the Negotiation Program, including without limitation, the requirement to submit information pursuant to section 1193(a)(4) of the Act, in accordance with section 1197(c) of the Act. In proposed § 429.1010, we address potential imposition of civil

monetary penalties for provision of false information for use in applying the eligibility rules at sections 1192(d)(2)(B) and (f)(1)(C) of the Act, in accordance with section 1197(d) of the Act. In proposed § 429.1015, we address potential imposition of civil monetary penalties for failure to pay a rebate as required by section 1192(f)(4) of the Act, in accordance with section 1197(b) of the Act. In proposed § 429.1020, we address details about the process for imposition of civil monetary penalties. Separate from CMS imposition of CMPs, per 26 U.S.C. 5000D, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program may result in potential excise tax liability.

Our primary goal is to successfully administer all aspects of the Negotiation Program; we intend to exercise the authority to impose civil monetary penalties in instances of noncompliance that substantively obstruct Negotiation Program processes. Such instances may include, but are not limited to, the examples shown in Table 4, such as failure to provide timely, complete, and accurate information that is necessary to execute the negotiation process or other administrative or monitoring functions of the Negotiation Program; repeated violations of the Negotiation Program Agreement or other Negotiation Program requirements determined by CMS to be necessary for the purposes of administering and monitoring compliance with the Negotiation Program; or egregious or knowing violations of Negotiation Program requirements. Note that these examples are not an exhaustive list of violations that could warrant civil monetary penalties. We reserve the authority to issue civil monetary penalties for other violations as required to effectively administer and monitor the Negotiation Program.

TABLE 4—EXAMPLES OF SUBSTANTIVE VIOLATIONS ⁶⁵

Category	Example
Violations of the Negotiation Program Agreement.	• Failure to submit data required under proposed §§ 429.100(d), 429.405(a), and 429.505(b)(2) including failure to engage in requested corrective action to mitigate such failures. • Omission or inaccuracy of manufacturer-submitted information described in proposed §§ 429.100(d), 429.405(a) and 429.505(b)(2) (for example, non-FAMP data from the Primary Manufacturer, including non-FAMP data for a selected drug manufactured, marketed, controlled, or sold by any Secondary Manufacturer(s), required for ceiling calculation) or other violations that impede CMS efforts to administer or monitor the Negotiation Program (for example, failure to report new NDC-11s, failure to provide information requested during an audit) as well as failure to engage in requested corrective action to mitigate such omissions, inaccuracies or other violations. • Submission of false information that interferes with the negotiation process (for example, submission of false data on unit costs of production or research and development costs).

⁶⁵ This table does not address violations related to a Primary Manufacturer's failure to make MFP available.

TABLE 4—EXAMPLES OF SUBSTANTIVE VIOLATIONS⁶⁵—Continued

Category	Example
Other Violations	• Failure to provide information requested by CMS in accordance with CMS' oversight responsibilities under section 1196(b) of the Act and described in subpart J. • Knowing provision of false information to CMS for use in applying the aggregation rule described at § 429.110(b)(1)(iv)(A). • Knowing provision of false information to CMS for use in applying the test to determine if a selected drug or drug selected for renegotiation is eligible for the Temporary Floor for Small Biotech Drugs as described in proposed § 429.440(b)(2). • Failure to pay a biosimilar delay rebate by the deadline established in proposed § 429.110(h).

Broadly, we propose to establish a structure for enforcement actions that: (1) is within CMS' statutory authority; (2) is not punitive in response to immaterial noncompliance, or other instances of noncompliance that are not substantive; (3) can be applied consistently across applicable instances of Primary Manufacturer noncompliance; and (4) facilitates the ability to successfully engage in all components of the negotiation process within the established timeframes.

2. Violations of the Negotiation Program Agreement (§ 429.1005)

In accordance with section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Negotiation Program Agreement with CMS as set forth in proposed § 429.200 that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including failure to provide information required under section 1193(a)(4) of the Act, including information required to be submitted under proposed §§ 429.405(a) and 429.505(b)(2), may be subject to statutorily-specified civil monetary penalties for each day of such violation. The statutorily specified amount of \$1,000,000 a day is updated yearly per the Federal Civil Penalties Inflation Adjustments Improvements Act of 2015. In applying civil monetary penalties for Primary Manufacturer violations of the Negotiation Program Agreement, we intend to use discretion such that civil monetary penalties are reserved for instances of substantive noncompliance.

Effective oversight of the Negotiation Program requires that CMS receive complete and accurate data from Primary Manufacturers. We view the authority to impose civil monetary penalties as established in section 1197(c) of the Act as a tool to ensure that a Primary Manufacturer is participating in the Negotiation Program consistent with its signed Negotiation Program Agreement, including, but not

limited to, providing complete and accurate information CMS deems necessary for administering and monitoring compliance with the Negotiation Program and promptly responding to any communications from CMS regarding the Negotiation Program, including requests for clarification, correction, additional information, or specific corrective actions.

In this proposed rule, we propose to consolidate and clarify our approach to monitoring and enforcement in the context of data reporting. Specifically, we are not proposing to codify the policies previously stated in section 40.2.3 of the Negotiation Program Guidance but rather are pursuing a consolidated approach to monitoring and enforcement that is consistent with the policies regarding data reporting obligations previously stated in sections 90 and 100 of the Negotiation Program Guidance. For example, we may impose a civil monetary penalty for violation of a requirement of the Negotiation Program Agreement if a Primary Manufacturer fails to provide data required under the Drug Price Negotiation ICR Forms, such as information on non-FAMP for each applicable quarter, as described in proposed § 429.405 of this proposed rule, for each NDC-11 of the selected drug for the applicable period, by the deadline established at proposed § 429.505(b)(1). In this scenario, upon identifying the missing data, we may take a variety of actions. For one, in accordance with proposed § 429.900(c), we may send the Primary Manufacturer a request for corrective action to address the noncompliance, such as a request that the Primary Manufacturer provide a complete and accurate production of the outstanding non-FAMP data by a specified date. If the Primary Manufacturer complies with the request for corrective action by timely providing complete and accurate non-FAMP data, we may exercise discretion and determine not to impose a civil monetary penalty for the Primary Manufacturer's initial failure to provide complete and accurate non-FAMP data

by the specified deadline. Or, depending on the circumstances, in accordance with enforcement priorities, we may determine that, even if a Primary Manufacturer complies with a request for corrective action, it remains appropriate to issue a violation notice and impose a CMP for the initial violation. Alternatively, in accordance with proposed § 429.900(c), we may not issue a request for corrective action and instead send a notice of violation to the Primary Manufacturer and impose a CMP in accordance with subpart K. Finally, if we send the Primary Manufacturer a request for corrective action and the Primary Manufacturer does not comply with such request, in accordance with proposed § 429.900(c), we may issue a violation notice and impose a CMP for the failure to comply with CMS' corrective action request, which would be separate from any violation notice and CMP imposition addressing the violation that arose from the Primary Manufacturer's initial failure to provide complete and accurate non-FAMP data by the specified deadline.

In a case where a civil monetary penalty is pursued, we intend to send a written civil monetary penalty notification, as described in proposed § 429.1005(d), that reflects the start date of the penalty accrual, the end date of the penalty accrual, and the total amount of the penalty assessed, as described in proposed § 429.1020(a). As described at proposed § 429.1005(c), the state date of the penalty accrual is the first day of the violation as set forth in proposed § 429.1005(a). In the earlier example, the start date of the penalty accrual would be the day after the applicable submission deadline. As described at proposed § 429.1005(c), the civil monetary penalty shall accrue until the Primary Manufacturer has provided the necessary information or otherwise taken any corrective action determined by CMS to be necessary to address the violation, including, as applicable, providing documentation to evidence that the Primary Manufacturer has provided all past due information, or

the Negotiation Program Agreement is terminated. In the earlier example, in the event the Primary Manufacturer never provides the required information, the daily civil monetary penalty would continue to accrue until the Negotiation Program Agreement was terminated as described in proposed § 429.205. We plan to adopt the same approach to enforcement in a circumstance where a Primary Manufacturer failed to provide data for a drug selected for renegotiation, with a violation accruing each day after the deadline established for provision of the data in proposed § 429.615 until the Primary Manufacturer provided the data. In the event the Primary Manufacturer never provides the required data, the civil monetary penalty will continue to accrue until the Negotiation Program Agreement is terminated as described in proposed § 429.205. The imposition of a civil monetary penalty related to failure to provide required data for the renegotiation process does not negate the Primary Manufacturer's ongoing obligation to provide access to the previously negotiated MFP. Primary Manufacturers continue to have the obligation to make the previously negotiated MFP available.

Another example of when CMS may impose a civil monetary penalty for violation of the Negotiation Program Agreement is if the Primary Manufacturer submits information that is required under the Negotiation Program Agreement and CMS determines the information is false. In this example, the Primary Manufacturer would be determined to be noncompliant with the requirement to submit information and may be subject to a civil monetary penalty. In instances of a Primary Manufacturer submitting false information that is required under the Negotiation Program Agreement, in accordance with proposed § 429.1005, a civil monetary penalty would begin to accrue on the day after the established deadline for submission of information under the Negotiation Program Agreement and would continue to accrue until the Primary Manufacturer provides a complete and accurate submission of the required information to CMS or the Negotiation Program Agreement is terminated as described in § 429.205. The start and end date of civil monetary penalty accrual as well as the total amount accrued will be noted on the civil monetary penalty notification sent by CMS, following the process established in proposed § 429.1020.

3. Provision of False Information Related to the Biosimilar Delay and Temporary Floor for Small Biotech Drugs (§ 429.1010)

In accordance with section 1197(d) of the Act, we are proposing at § 429.1010 two circumstances where CMS may impose a CMP due to provision of false information: (1) CMS may impose a statutorily specified civil monetary penalty on a Biosimilar Manufacturer for each item of false information the Biosimilar Manufacturer knowingly provides to CMS for use in applying the aggregation rule described at proposed § 429.110(b)(1)(iv)(A); and (2) CMS may impose a statutorily specified civil monetary penalty on a Primary Manufacturer for each item of false information the Primary Manufacturer knowingly provides to CMS for use in applying the test to determine if a selected drug or drug selected for renegotiation is eligible for the Temporary Floor for Small Biotech Drugs described at proposed § 429.440(b)(2). Section 1197(d) of the Act provides for imposition of a civil monetary penalty in the amount of \$100,000,000 per item of false information. This amount will be updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.

CMS adopts a standard for "knowingly" that has the meaning set forth in 42 CFR 1003.110. Knowingly means that a manufacturer: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. Upon identifying instances of knowing submission of false information under this provision, CMS intends to provide the Biosimilar Manufacturer or Primary Manufacturer, as applicable, with a civil monetary penalty notification following the process established in proposed § 429.1020.

4. Failure To Pay a Biosimilar Delay Rebate (§ 429.1015)

In accordance with section 1197(b) of the Act, where a Reference Manufacturer fails to comply with the rebate requirements under section 1192(f)(4) of the Act as described at proposed § 429.110(i) and section II.B.3. of this proposed rule, CMS is proposing at § 429.1015 that the Reference Manufacturer may be subject to a civil monetary penalty equal to 10 times the amount of the rebate the Reference Manufacturer failed to pay. When CMS makes a determination to assess a civil

monetary penalty under section 1197(b) of the Act, CMS intends to follow the procedures established in proposed § 429.1020.

5. Notice and Appeal Procedures (§ 429.1020)

Under section 1197(e) of the Act, civil monetary penalties imposed in accordance with sections 1197(a) through (d) of the Act are subject to the provisions of section 1128A of the Act (other than subsections (a) and (b)). Accordingly, when CMS makes a determination to assess a civil monetary penalty, we intend to provide a written civil monetary penalty notification that the manufacturer has engaged in one or more violations as described at proposed §§ 429.1005 through 429.1015 and is subject to a civil monetary penalty. We are proposing at § 429.1020(a) that the civil monetary penalty notification would include the following:

- A description of the basis for the determination.
- The basis for the penalty,
- The start date of the penalty (if applicable).
- The end date of the penalty (if applicable).
- The total amount of the penalty assessed.
- The date the penalty is due.
- The manufacturer's right to a hearing.
- Information about where to file the request for a hearing.

In the case of violations associated with civil monetary penalties with daily accruals as described in proposed § 429.1005, we intend to send the civil monetary penalty notification after the accrual has ended to reflect both the start date, end date, and total amount of penalty assessed within the notice. We have considered an alternative policy in which civil monetary penalty notification letters would be issued during the period that the daily penalty amounts are still actively accruing. Such an approach would result in assessment of interim civil monetary penalties on Primary Manufacturers, each for the dollar amount that had accrued as of the date we issue each applicable interim CMP notice. We would issue such interim notices at set time intervals (for example, every 14 days) throughout the period in which the penalty continues to accrue as described in proposed § 429.1005. CMS is soliciting comment on this alternative option.

Per section 1128A of the Act, civil monetary penalties are due 60 calendar days after the receipt of the civil monetary penalty notification, unless the manufacturer chooses to initiate an

appeal. At the conclusion of any appeal process initiated by the manufacturer, where there is still a civil monetary penalty amount owed, the civil monetary penalty is due within 60 calendar days of the appeal decision.

To operationalize the civil monetary penalty appeal process in the Negotiation Program, we propose adopting the existing procedures as codified in 42 CFR part 423 subpart T: Appeal Procedures for Civil Money Penalties (see 42 CFR 423.1000 through 423.1094) that currently apply to Part D sponsors and to manufacturers under the Manufacturer Discount Program. In accordance with this appeals process, the manufacturer would have 60 calendar days after receipt of the civil monetary penalty notification to request a hearing (42 CFR 423.1020). If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by 42 CFR part 423, subpart T would apply. As set forth in section 1128A(f) of the Act, if the manufacturer does not pay the civil monetary penalty timely, the civil monetary penalty amount may be deducted from any sum then or later owing by the United States. Civil monetary penalty funds would be deposited in accordance with section 1128A(f) of the Act.

As described in proposed § 429.1020(e), in the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code and fails to pay either the full rebate amount of a Biosimilar Delay rebate owed or the total sum of civil monetary penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or civil monetary penalties owed by the manufacturer. Filing a proof of claim does not waive any other rights of the United States to recover such amounts or to assert priority status as permitted under applicable law. CMS may exercise its offset authority under section 1128A(f) of the Act independently of, and in addition to, other available collection remedies permitted under Federal law.

K. Application of Medicare Part B and Part D Drug Inflation Rebate Programs to Selected Drugs

Section 1847A(i) of the Act requires that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Section 1860D–14B of the Act requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare

for certain Part D rebatable drugs based on specific requirements and formulas.

As described in section 120 of the Negotiation Program Guidance, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Medicare Part B and Part D Drug Inflation Rebate Program. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated. As such, in the calendar year (CY) 2025 Physician Fee Schedule (PFS) final rule (89 FR 98582 through 98583), at § 427.303(c)(5) and (e)(5), we codified the identification of the payment amount benchmark quarter and the identification of the benchmark period CPI–U, respectively, in the case when a Part B rebatable drug is no longer considered to be a selected drug. Additionally, in the CY 2025 PFS final rule (89 FR 98591 through 98592), at § 428.202(c)(5) and (e)(5), we codified the identification of the payment amount benchmark period and the identification of the benchmark period CPI–U, respectively, in the case when a Part D rebatable drug is no longer considered to be a selected drug.

III. Proposed Implementation of Inflation Reduction Act Provisions for the Medicare Prescription Drug Benefit Program

A. Part D Formulary Inclusion of Selected Drugs

1. Background

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) created Part E under Title XI of the Act (sections 1191 through 1198) which established the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products.

Section 11001(b) of the IRA added section 1860D–4(b)(3)(I)(i) of Act, which requires that, starting in 2026 and for each subsequent year, Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year. Section 11001(b) of the IRA also added section 1860D–4(b)(3)(I)(ii) of the Act, which clarifies that nothing in clause (i) shall be construed as prohibiting Part D plan sponsors from removing from their formularies such a selected drug if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation.

Section 11001(c) of the IRA directed the Secretary to implement the provisions in section 11001 of the IRA, including amendments made by such section, for 2026, 2027, and 2028, by program instruction or other forms of program guidance. In accordance with the law, CMS has issued several guidance documents for implementing the Negotiation Program, including the requirement that Part D plan sponsors include on their formularies selected drugs for which an MFP is in effect, starting in 2026.

CMS issued revised or final guidance on June 30, 2023, October 2, 2024, and September 30, 2025 for implementation of the Negotiation Program for initial price applicability years 2026, 2027, and 2028, respectively.⁶⁶ In these guidance documents, CMS described the requirement for Part D plan sponsors to include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year as well as the exception that allows Part D plan sponsors to remove a selected drug from their formulary if such removal meets the requirements specified in § 423.120(b)(5)(iv) or any successor regulation. As discussed in section I.A.2, in this proposed rule, unless otherwise specified, references hereinafter to “the Negotiation Program Guidance” are to the most recent program guidance published by CMS, which is the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 that was published on September 30, 2025.

On April 7, 2025, CMS issued the Final CY 2026 Part D Redesign Program Instructions which described certain changes under the IRA to the Part D benefit for CY 2026.⁶⁷ In section 90 of these program instructions, CMS identified § 423.120(e)(2)(i), and the corresponding notice requirements at § 423.120(f)(2), (3), and (4), as the successor regulation for purposes of implementing section 1860D–4(b)(3)(I)(ii) of the Act, as added by

⁶⁶ <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>; <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>; <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

⁶⁷ <https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf>.

section 11001(b) of the IRA. In section 110.1 of the Negotiation Program Guidance, CMS incorporated section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extended the policies therein to 2027 and 2028.

In this proposed rule, we are proposing new § 423.120(b)(2)(vii) and (viii) to codify the requirement that Part D plan sponsors include each Part D drug that is a selected drug with an MFP in effect on their formularies and the exception that permits Part D plan sponsors to remove such a selected drug if the removal would be permitted under the successor regulation at § 423.120(e)(2)(i), (f)(2), (3), and (4) that we are proposing to codify. In alignment with these changes, we are also proposing to codify a conforming change to the definition of corresponding drug at § 423.100.

2. Part D Formulary Inclusion of Selected Drugs (§ 423.120)

Section 11001(b) of the IRA added section 1860D–4(b)(3)(I)(i) of the Act to require that for 2026 and each subsequent year, Part D plans include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies if an MFP is in effect for that drug with respect to that year. For 2026, 2027, and 2028, we have implemented this requirement through guidance.⁶⁸ With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we now propose to codify this requirement at new § 423.120(b)(2)(vii) with respect to selected drugs for which an MFP is in effect in 2029 and subsequent years.

While section 1860D–4(b)(3)(I)(i) of the Act specifies that Part D plans must include on their Part D formularies covered Part D drugs that are selected drugs for which an MFP is in effect with respect to the year, it does not otherwise specify formulary requirements for tier placement or utilization management. CMS received comments⁶⁹ expressing concerns that plans may hinder beneficiary access to selected drugs (for

example, by applying utilization management requirements that are not based on medical appropriateness or placing selected drugs on less favorable tiers compared to non-selected drugs). In response to these comments, we stated⁷⁰ that CMS agrees on the importance of ensuring meaningful beneficiary access to selected drugs and their MFPs and ensuring that plans do not engage in behavior that hinders access to selected drugs or non-selected drugs when medically appropriate. However, CMS also understands that not all selected drugs and drug classes will present Part D plan sponsors and their Pharmacy and Therapeutics Committees with the same formulary considerations, and the same formulary placement might not be warranted in all situations. In order to ensure meaningful beneficiary access to selected drugs and their MFPs, CMS would continue to use its comprehensive formulary review process to assess any practices that may undermine beneficiary access to selected drugs and ensure that Part D plan sponsors comply with existing statutory and regulatory restrictions on formulary design.

Sections 1860D–2(b)(2)(B) and 1860D–4(c)(1)(A) of the Act permit Part D plan sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and require them to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate. Under section 1860D–11(e)(2)(D)(i) of the Act, CMS may approve a prescription drug plan only if the agency does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan. In addition, § 423.272(b)(2)(i) requires that CMS not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. Further, § 423.120(b)(2)(iii) requires each Part D plan formulary to “include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment

guidelines”. Finally, § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must “base clinical decisions on the strength of scientific evidence and standards of practice”. CMS maintains a robust clinical formulary review process to ensure that all Medicare Part D plans meet these and other applicable requirements. CMS reviews all formularies annually to ensure that each formulary meets the agency’s clinical review criteria, which include comprehensive evaluation of tier placement and all utilization management restrictions and criteria.

Consistent with section 110 of the Negotiation Program Guidance, given CMS’ statutory obligation to monitor Medicare Part D plans’ compliance with all applicable formulary requirements, we would continue to use our formulary review process to assess: (1) any instances where Part D plan sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) any instances where Part D plan sponsors require utilization of an alternative non-selected brand drug prior to a selected drug (that is, step therapy); or (4) any instances where Part D plan sponsors impose more restrictive utilization management (for example, step therapy and prior authorization) for a selected drug compared to a non-selected brand drug in the same class.

For this review, we would consider, consistent with section 110 of the Negotiation Program Guidance, class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action. Specifically, CMS would expect Part D plan sponsors to provide a reasonable justification to support their submitted plan benefit design and formulary design that includes any of the practices noted previously during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design’s compliance with applicable statutory and regulatory requirements (for example, the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS would evaluate these justifications for compliance with applicable statutory and regulatory requirements and would approve a Part D plan bid submitted by a Part D plan sponsor only if the plan

⁶⁸ Section 110, Negotiation Program Guidance. <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>; <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>; <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

⁶⁹ <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>; <https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>; <https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf>.

⁷⁰ <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>; <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>; <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

benefit design and formulary design complies with those requirements.

As discussed in the Negotiation Program Guidance, CMS also is aware that there are concerns that Part D plan sponsors could broadly shift access with respect to a drug selected for negotiation after the drug has been announced as a selected drug, that is, in the contract year prior to the selected drug's MFP taking effect. To address these concerns, CMS would continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year. We believe this approach would continue to provide Part D plan sponsors with the flexibility to continue to manage costs through utilization management in a clinically appropriate manner, while allowing us to monitor practices that may undermine beneficiary access to selected drugs and potentially inform new requirements for future contract years.

Finally, because a selected drug includes all dosage forms and strengths to which the MFP applies, section 1860D-4(b)(3)(I)(i) of the Act requires that formularies include all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. Thus, consistent with section 110 of the Negotiation Program Guidance, we are proposing that Part D plan sponsors would continue to be required to include all such dosage forms and strengths of the selected drug that constitute a Part D drug and for which the MFP is in effect on their formularies.

In summary, in alignment with section 1860D-4(b)(3)(I)(i) of the Act, as added by section 11001(b) of the IRA, we are proposing to codify at new § 423.120(b)(2)(vii) the requirement that, for 2026 and each subsequent year, Part D plan sponsors include each Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year.

3. Successor Regulation Exception Permitting Formulary Substitutions of Selected Drugs

Section 11001(b) of the IRA added section 1860D-4(b)(3)(I)(ii) of the Act, which states that nothing in section 1860D-4(b)(3)(I)(i) of the Act shall be construed as prohibiting a Part D plan sponsor from removing a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation.

At the time the IRA was enacted, then-current § 423.120(b)(5)(iv) permitted a plan to immediately

substitute on the formulary a newly available generic drug for its brand name drug if certain notice and timing requirements were met. However, due to changes made to the regulations in the Contract Year 2025 Parts C/D Final Rule (89 FR 30448), there is no longer a § 423.120(b)(5)(iv) in the current Part D regulations. Under the current Part D regulations, the approval requirements for immediate substitutions, which were revised to provide for the substitution of additional types of products, are now codified at § 423.120(e)(2)(i), and the corresponding notice requirements for such formulary changes are now codified at § 423.120(f)(2), (3), and (4).

Because there was no longer a § 423.120(b)(5)(iv) in the Part D regulations, CMS had to identify the successor regulation to § 423.120(b)(5)(iv) for the purposes of the exception to the formulary inclusion requirement for selected drugs in section 1860D-4(b)(3)(I)(ii) of the Act. Because section 11001(c) of the IRA directed the Secretary to implement the provisions in section 11001 of the IRA, including amendments made by such section, for 2026, 2027, and 2028, by program instruction or other forms of program guidance, CMS identified the successor regulation for such years by guidance. For 2026, CMS identified the successor regulation in section 90 of the Final CY 2026 Part D Redesign Program Instructions. For 2027 and 2028, in section 110.1 of the Negotiation Program Guidance, CMS incorporated section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extended the policies therein to 2027 and 2028.

With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we now propose to codify, consistent with our previously issued guidance in the Final CY 2026 Part D Redesign Program Instructions and the Negotiation Program Guidance, the section 1860D-4(b)(3)(I)(ii) of the Act exception to the formulary inclusion requirement for selected drugs at new § 423.120(b)(2)(viii). We are also proposing, consistent with the Final CY 2026 Part D Redesign Program Instructions and the Negotiation Program Guidance, to codify our identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the “successor regulation” for the purposes of implementing section 1860D-4(b)(3)(I)(ii) of the Act, and proposed § 423.120(b)(2)(viii). In alignment with these changes, we are also proposing to codify a conforming change to the definition of corresponding drug at § 423.100.

a. Exception Permitting Formulary Substitutions of Selected Drugs

As discussed in the previous section, we are proposing to codify our identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for purposes of implementing section 1860D-4(b)(3)(I)(ii) of the Act. Under § 423.120(e)(2)(i), a Part D plan sponsor is permitted to—

[M]ake negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval . . . because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of [section 423.120].

Under § 423.120(f)(2), (3), and (4), a Part D plan sponsor making an immediate substitution under § 423.120(e)(2)(i) is required to provide advance general notice and retrospective notice to enrollees, among others, and to ensure that written notices include specified content. Specifically, the advance general notice must be provided to all current and prospective enrollees and other specified entities, must be in the Part D plan sponsor's formulary and other applicable beneficiary communication materials, and must advise that the Part D plan sponsor may make immediate negative formulary changes, consistent with the regulation, at any time. The required retrospective notice must be provided to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The content of these notices is specified in § 423.120(f)(4).

Under this successor regulation, nothing in section 1860D-4(b)(3)(I)(i) of the Act, and proposed § 423.120(b)(2)(vii), would be construed as prohibiting a Part D plan sponsor from removing a selected drug from its formulary if, in accordance with § 423.120(e)(2)(i) and the notice requirements of § 423.120(f)(2), (3), and (4), the Part D plan sponsor adds to its formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements a newly available corresponding drug, as defined at § 423.100, with respect to such selected drug.

By proposing to codify the current identification of § 423.120(e)(2)(i) as part of the successor regulation, we are also proposing to codify that, in addition to continuing to permit Part D plan sponsors to remove a selected drug that is a brand name drug and replace it with a generic drug as an immediate substitution, we would also continue to permit Part D plan sponsors to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution.⁷¹

As discussed in section 90 of the Final CY 2026 Part D Redesign Program Instructions, allowing removal of selected drugs that are reference products and replacement with interchangeable biological products as immediate substitutions under the successor regulation that was first identified for 2026 was similar in kind to and consistent with the original regulation that was identified in the statute for the exception. Our proposed codification of the successor regulation in this rule would continue to apply the same rules to interchangeable biological products as are applied to generic drugs. As we explained when we first identified the successor regulation for 2026, this promotes consistency across selected drugs because, regardless of whether a selected drug is a drug or biological product, the Part D plan sponsor is able to remove a selected drug that is a brand name drug or reference product as an immediate substitution.

CMS would continue to permit, consistent with the agency's longstanding practice, including under § 423.120(b)(5)(iv) at the time of enactment of the IRA and under the identified successor regulation for 2026, 2027, and 2028, Part D plan sponsors to immediately substitute a selected drug for which there is a generic drug or interchangeable biological product available in the same dosage form, route of administration, and strength. The exception to the selected drug formulary inclusion requirement in section

1860D–4(b)(3)(I)(ii) of the Act allows for a selected drug to be removed as permitted under § 423.120(b)(5)(iv) (or any successor regulation). Accordingly, it is consistent with the exception established under section 1860D–4(b)(3)(I)(ii) of the Act to continue to apply this longstanding policy under the Part D program to the removal of selected drugs under the proposed codification of the current successor regulation pursuant to section 1860D–4(b)(3)(I)(ii) of the Act, and proposed § 423.120(b)(2)(viii).

Consistent with § 423.120(e)(2)(i), Part D plan sponsors that implement an immediate substitution for any brand name drug or reference product that is a selected drug on their formulary in accordance with section 1860D–4(b)(3)(I)(ii) of the Act, and proposed § 423.120(b)(2)(viii), would not be required to exempt enrollees who were already taking the selected drug. An enrollee may avail themselves of the formulary exception process, in accordance with § 423.578(b), if it is medically necessary for them to remain on a selected drug that has been removed from the formulary.

As discussed in the comment responses of the Final CY 2026 Part D Redesign Program Instructions, we also note that Part D plan sponsors would not need to remove selected drugs from their formularies to add a new generic drug, interchangeable biological product, or biosimilar biological product other than an interchangeable biological product to their formularies. A Part D plan sponsor can make such an addition at any time during the plan year, while keeping the brand name drug or reference product on the formulary. In addition, we remind Part D plan sponsors that they may also make maintenance changes with respect to selected drugs other than removing them from the formulary, in accordance with § 423.120(e) and the notice requirements of § 423.120(f).

In the Draft CY 2026 Part D Redesign Program Instructions,⁷² CMS solicited comments on alternative approaches to identifying the successor regulation. These proposed alternative approaches included identifying additional regulations to expand the successor regulation exception to encompass maintenance changes, in addition to immediate substitutions. While we maintain that section 1860D–4(b)(3)(I)(ii) of the Act gives CMS the authority to identify such maintenance changes as part of the successor regulation for purposes of section

1860D–4(b)(3)(I)(ii) of the Act, CMS continues to decline to do so at this time and is proposing to maintain § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation. However, in the future, CMS may identify new regulations that constitute the successor regulation (for example, as the biosimilar market matures or as additional changes are made to the underlying regulations).

In summary, consistent with the Negotiation Program Guidance and the Final CY 2026 Part D Redesign Program Instructions, CMS is proposing to codify the identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act and add a new paragraph at § 423.120(b)(2)(viii) that specifies that nothing shall prohibit a Part D plan sponsor from removing a selected drug from their formulary if such removal meets the requirements specified in § 423.120(e)(2)(i) and the notice requirements specified in paragraphs (f)(2), (3), and (4) of this section.

b. Corresponding Drugs Do Not Include Selected Drugs

Consistent with CMS' proposed codification of the current identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act, a Part D plan sponsor may remove a selected drug from its formulary if, in accordance with § 423.120(e)(2)(i) and the notice requirements of § 423.120(f)(2), (3), and (4), the Part D plan sponsor adds to its formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements a newly available corresponding drug with respect to such selected drug.

Section 423.100 currently defines “corresponding drug” as “respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.” As discussed in section 90 of the Final CY 2026 Part D Redesign Program Instructions, when read in isolation, the current definition might incorrectly appear to suggest that a Part D plan sponsor could remove a selected drug under section 1860D–4(b)(3)(I)(ii) of the Act, if the Part D plan sponsor adds an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product.

⁷¹ As noted in section 90 of the Final CY 2026 Part D Redesign Program Instructions, the section 1860D–4(b)(3)(I)(ii) exception to the IRA's formulary inclusion requirement for selected drugs addresses when a Part D plan sponsor can remove a selected drug from a formulary. Accordingly, this section of the proposed rule applies specifically to negative formulary changes that result in the removal of a selected drug from a formulary. This section does not affect Part D plan sponsors' ability to implement negative formulary changes other than removal where a Part D plan sponsor would continue to include a selected drug on its formulary as required by section 1860D–4(b)(3)(I)(i) of the Act (for example, moving the selected drug to a higher cost-sharing tier or adding utilization management practices) if all applicable requirements are met.

⁷² <https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf>.

However, such a removal would be inconsistent with the Part D plan sponsor's obligation under section 1860D–4(b)(3)(I)(i) of the Act, and proposed § 423.120(b)(2)(vii), to include on its formulary each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP is in effect with respect to the year.

As stated in section 1192(e)(2)(A) of the Act (as added by section 11001 of the IRA), and as discussed in section II.B.6 of this proposed rule, an authorized generic drug and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug and, thus, the same selected drug. For the purposes of the Negotiation Program, an “authorized generic drug” is defined in section 1192(e)(2)(B) of the Act and in proposed § 429.20 as:

(1) in the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act); and

(2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

As discussed in section II.B.6.a of this proposed rule, authorized generics of a brand name drug that is a selected drug and unbranded biological products marketed under the same license as a brand name biological product that is a selected drug are treated as the same selected drug as the respective listed drug or reference product.

For example, section II.B.6.a of this proposed rule states that, for drug products, CMS is proposing at § 429.125(b)(1) to identify a potential qualifying single source drug using all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed under different NDAs. The potential qualifying single source drug also includes all dosage forms and strengths of the drug with the same active moiety and marketed under the same NDA(s) that are authorized generic drugs (defined in section 1192(e)(2)(B)(i) of the Act and at proposed § 429.20) that are marketed under such NDA(s). Likewise, section II.B.6.a of the proposed rule states that, for biological products, CMS is proposing at § 429.125(b)(2) to identify a potential

qualifying single source drug using all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed under different BLAs. The potential qualifying single source drug also includes all dosage forms and strengths of the biological product with the same active ingredient and marketed under the same BLA(s) that are authorized generic drugs, the definition of which at section 1192(e)(2)(B)(ii) of the Act and proposed § 429.20 includes unbranded biological products that are marketed under such BLA(s).

Because an authorized generic of a brand name drug that is a selected drug or an unbranded biological product marketed under the same BLA as a brand name biological product that is a selected drug also qualifies as the selected drug, section 1860D–4(b)(3)(I)(i) of the Act, and proposed § 423.120(b)(2)(vii), requires the Part D plan sponsor to include each such authorized generic or unbranded biological product that is a covered Part D drug for which an MFP is in effect on its formulary.

Consequently, the statute does not permit a Part D plan sponsor to remove a selected drug that is a brand name drug or brand name biological product on the basis of adding an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product.

In situations where a selected drug includes both a brand name biological product and an unbranded biological product marketed under the same BLA as the brand name biological product, a Part D plan sponsor may remove both the brand name biological product and the unbranded biological product from its formulary when making an immediate substitution under § 423.120(e)(2)(i) by adding a single interchangeable biological product to its formulary. The interchangeable biological product that is the corresponding drug for the selected drug may replace both the reference product and the unbranded biological product provided that the requirements specified in the proposed successor regulation at § 423.120(e)(2)(i), (f)(2), (3), and (4) are met.

To ensure consistency with the IRA's formulary inclusion requirement, which we are proposing to codify at § 423.120(b)(2)(vii), and avoid any potential confusion related to the identification of § 423.120(e)(2)(i) as part of the successor regulation to § 423.120(b)(5)(iv) for the purposes of

section 1860D–4(b)(3)(I)(ii) of the Act, we amended the definition of “corresponding drug” in section 90 of the Final CY 2026 Part D Redesign Program Instructions, consistent with the statutory directive to implement section 11001 of the IRA, including amendments made by such section, by program instruction or other forms of program guidance. Specifically, section 90 of such program instructions defined “corresponding drug” for 2026 to “mean[, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product. A corresponding drug does not include a selected drug as defined in section 1192(c) of the Act.” Section 110.1 of the Negotiation Program Guidance incorporated section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extended the policies therein, including the revised definition of “corresponding drug,” to 2027 and 2028.

With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, CMS is proposing to codify for 2029 and subsequent years the current definition set forth in guidance at § 423.100. Specifically, the definition at § 423.100 would include language stating that a corresponding drug does not include a selected drug, as defined in section 1192(c) of the Act.

c. Timing of Immediate Substitutions

Section 423.120(e)(2)(i), (f)(2), (3), and (4), which we are proposing to codify as the successor regulation consistent with current guidance, permit a Part D plan sponsor, provided it has met the notice requirements, to remove a selected drug that is a brand name drug or reference product from its formulary and replace it with a generic of the brand name drug or an interchangeable biological product of the reference product “so long as the Part D sponsor previously could not have included such corresponding drug on its formulary *when it submitted its initial formulary* for CMS approval consistent with paragraph (b)(2) of this section because such drug was *not yet available on the market*” [emphasis added]. As such, under these regulations, for Part D plan sponsors that have a selected drug for initial price applicability year 2029 on their 2028 formulary, if a generic drug or interchangeable biological product of a selected drug becomes available on the market in 2028 after the Part D plan

sponsor submitted its initial 2029 formulary for CMS approval, consistent with our longstanding policy on immediate substitutions, a Part D plan sponsor could add such generic drug or interchangeable biological product and remove the selected drug from its formulary as an immediate substitution for 2028, as well as for 2029. In other words, where the Part D plan sponsor could not have included the generic drug or interchangeable biological product on either its 2028 initial formulary submission or its 2029 initial formulary submission, and such Part D plan sponsor removes the selected drug as an immediate substitution, the Part D plan sponsor can apply the removal to both the current year formulary as well as the already-submitted formulary for the following year.

A Part D plan sponsor that does not have the selected drug on its 2028 formulary, but has submitted a formulary for 2029 that includes the selected drug, in accordance with section 1860D–4(b)(3)(I)(i) of the Act, could remove the selected drug as part of an immediate substitution only with respect to its 2029 formulary. That is, if a generic drug of a brand name drug that is a selected drug or an interchangeable biological product of a reference product that is a selected drug was first available on the market after the initial submission of the 2029 formulary, the Part D plan sponsor could, in the latter part of 2028, remove that selected drug from its 2029 formulary.

This application of the immediate substitutions policy to both the 2028 and 2029 formularies with respect to a generic drug or interchangeable biological product that becomes available on the market after the Part D plan sponsor has already submitted its initial formulary to CMS is consistent with section 1860D–4(b)(3)(I) of the Act. As discussed previously, the formulary inclusion requirement in section 1860D–4(b)(3)(I) of the Act applies with respect to selected drugs starting in initial price applicability year 2026 and the only permitted exception to the requirement is the “removal” of “such selected drug.” The plain text of the statute contemplates that a selected drug will need to be included on the plan’s formulary for the first initial price applicability year in which the MFP for the selected drug is in effect, regardless of whether the plan ever previously included the drug. Moreover, the only statutory exception to the formulary inclusion obligation is the “removal” of “such a selected drug” in accordance with § 423.120(b)(5)(iv) or its successor regulation, which we are proposing to codify as § 423.120(e)(2)(i), (f)(2), (3),

and (4). The references to “removal” and “such selected drug” indicate that the selected drug must first be included on the formulary for the initial price applicability year under section 1860D–4(b)(3)(I)(i) of the Act and only then can be removed under section 1860D–4(b)(3)(I)(ii) of the Act.

Accordingly, as discussed previously, a Part D plan sponsor that includes a selected drug with an initial price applicability year of 2029 on its initial formulary submission for 2029 could remove the selected drug as part of an immediate substitution prior to the start of 2029 if a generic drug or interchangeable biological product of the selected drug becomes available on the market in 2028 after the initial formulary submission. In such cases, the Part D plan sponsor will have included the selected drug on the formulary with respect to the initial price applicability year in which the MFP is in effect (that is, 2029), as required by section 1860D–4(b)(3)(I)(i) of the Act, and subsequently removed the selected drug, as permitted by section 1860D–4(b)(3)(I)(ii) of the Act.

Further, we note that there may be scenarios in which a generic drug or interchangeable biological product of, for example, a selected drug with an initial price applicability year of 2029 becomes available on the market in 2028 (after the Part D plan sponsor has submitted its initial 2028 formulary in 2027) but before the Part D plan sponsor submits its 2029 initial formulary for CMS approval in 2028. Under such a scenario, a Part D plan sponsor would be permitted, assuming all requirements are met, to remove the selected drug with an initial price applicability year of 2029 (prior to its MFP taking effect) from its 2028 formulary under § 423.120(e)(2)(i), but would be required under section 1860D–4(b)(3)(I)(i) of the Act to include the selected drug with an initial price applicability year of 2029 on its 2029 formulary when the MFP takes effect.

Consistent with section 90 of the Final CY 2026 Part D Redesign Program Instructions, if there is a generic drug or interchangeable biological product for a selected drug with an initial price applicability year of 2029 and such generic drug or interchangeable biological product is available on the market before a Part D plan sponsor’s 2029 initial formulary submission, such Part D plan sponsor would still need to include the selected drug on its 2029 formulary submission, regardless of whether the Part D plan sponsor had removed such selected drug from its 2028 formulary via an immediate substitution in 2028, to comply with the

formulary inclusion requirement in section 1860D–4(b)(3)(I)(i) of the Act. Moreover, the Part D plan sponsor would not be permitted to remove the selected drug from the formulary for 2029 as an immediate substitution and replace it with the generic drug or interchangeable biological product that became available on the market prior to the initial formulary submission for 2029 because section 1860D–4(b)(3)(I)(ii) of the Act permits removal only in accordance with § 423.120(b)(5)(iv) or its successor regulation. As discussed previously, the successor regulation, which we propose to codify for 2029 and subsequent years, includes § 423.120(e)(2)(i), which, like § 423.120(b)(5)(iv) at the time of enactment, permits an immediate substitution only if the Part D plan sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval. In this scenario, because the Part D plan sponsor could have included the generic drug or interchangeable biological product in its initial formulary submission for 2029, an immediate substitution would not be available.

Further, consistent with section 90 of the Final CY 2026 Part D Redesign Program Instructions, the regulatory language at § 423.120(e)(2)(i), that a Part D plan sponsor previously could not have included the corresponding drug on its formulary when it submitted its initial formulary for CMS approval, would continue to mean, in practice, that the corresponding drug is not included on the final formulary reference file (FRF) update that CMS releases before the bid submission deadline. Consistent with our longstanding practice, the determination of whether a new generic drug or interchangeable biological product is included on the final FRF update that CMS releases before the bid submission deadline will be based on the presence of a RxNorm Concept Unique Identifier (RxCUI) on that FRF update that represents the generic drug or interchangeable biological product.

Finally, consistent with section 110.1 of the Negotiation Program Guidance, we are proposing that removals under the statutory formulary inclusion exception, which we are proposing to codify at new § 423.120(b)(2)(viii), cannot be carried over to subsequent years within the price applicability period simply because a selected drug was removed in a preceding year during the price applicability period. Instead, any removal must independently meet the immediate substitution requirements for each plan year

because, consistent with CMS' longstanding policy, CMS considers each plan year's formulary to be separate and distinct from the prior year. Therefore, a removal could only apply to multiple plan years in a price applicability period if it independently meets the immediate substitution requirements for each applicable plan year.

B. Negotiated Price for Selected Drugs

Section 1860D–2(d)(1) of the Act requires Part D sponsors to provide beneficiaries with access to negotiated prices for covered Part D drugs. Section 1860D–2(d)(1)(A) of the Act requires Part D sponsors to “provide enrollees with access to negotiated prices used for payment for covered Part D drugs.” Subparagraph (B) further clarifies that negotiated prices, subject to subparagraph (D), “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include any dispensing fees for such drugs.”

The negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee and reported to CMS at the point of sale by the Part D sponsor. This point of sale price is used to calculate beneficiary cost sharing. The negotiated price also serves as the primary basis for adjudicating the Part D benefit because it is used to determine plan, beneficiary, manufacturer, and government liability during the payment year, subject to final reconciliation after the coverage year ends.

In our final rule, “Medicare Program; Medicare Prescription Drug Benefit,” which appeared in the January 28, 2005 **Federal Register** (70 FR 4194) (hereinafter referred to as the January 2005 final rule), we first codified the definition of negotiated prices described at section 1860D–2(d)(1) of the Act at § 423.100. We explained that the Act required “negotiated prices . . . to take into account negotiated price concessions for covered Part D drugs such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and would include any applicable dispensing fees.”⁷³ Accordingly, we defined negotiated prices at § 423.100 to mean prices for covered Part D drugs that—

- Are available to beneficiaries at the point of sale at network pharmacies;
- Are reduced by those discounts, direct or indirect subsidies, rebates,

other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

- Includes any dispensing fees.

After issuing the January 2005 final rule, we revised the definition of negotiated prices at § 423.100 several times. Most significantly, in the final rule “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” which appeared in the May 23, 2014 **Federal Register** (79 FR 29844) we amended the definition of “negotiated prices” at § 423.100 to require Part D sponsors to include all pharmacy price concessions and incentive payments to pharmacies in the negotiated price at the point of sale. The rule also established an exception that allowed sponsors to exclude contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the reasonably determined exception).

In the May 9, 2022 **Federal Register**, we further amended § 423.100 by revising the term “negotiated prices” (plural) to “negotiated price” (singular) to clarify that a negotiated price may be set for each covered Part D drug. Based on feedback from stakeholders and information submitted by plan sponsors in their annual direct and indirect remuneration (DIR) reports indicating that sponsors had applied the reasonably determined exception more broadly than initially envisioned, we defined “negotiated price” as the lowest possible reimbursement a network pharmacy receives, in total, for a particular drug, taking into account pharmacy price concessions, and thus eliminated the reasonably determined exception. As a result, the definition of “negotiated price” at § 423.100 currently means the price for a covered Part D drug that—

- The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;
 - Meets all of the following:
 - ++ Includes all price concessions (as defined in this section) from network pharmacies or other network providers.
 - ++ Includes any dispensing fees.
 - ++ Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and
 - Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor

passes through to Part D enrollees at the point of sale.

Section 11001(b) of the IRA amended section 1860D–2(d)(1) of the Act by adding subparagraph (D). That provision requires that, in the case of a covered Part D drug that is a selected drug, with respect to a price applicability period, the negotiated price “used for payment (as described in this subsection) shall be no greater than the [maximum fair price] for such drug . . . plus any dispensing fees for such drug.” Section 11001(b) of the IRA also added “subject to subparagraph (D)” to section 1860D–2(d)(1)(B) of the Act.

Section 11001(c) of the IRA directed CMS to implement section 11001 of the IRA, including the amendments made by such section, by program instruction or other forms of program guidance for initial price applicability years 2026 through 2028. Accordingly, we did not revise the regulatory definition of negotiated price to reflect the statutory amendment to section 1860D–2(d)(1) of the Act for purposes of 2026, 2027, and 2028. Instead, we applied the statutory negotiated price requirements for selected drugs through the applicable Negotiation Program guidance.

Most recently, in section 40.4 of the Negotiation Program Guidance, we stated that under section 1860D–2(d)(1)(D), the negotiated price for selected drugs “must not exceed the applicable [maximum fair price (MFP)] plus any dispensing fees for such drug.”⁷⁴ CMS also stated that the statute requires manufacturers to provide access to the MFP for selected drugs to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drugs.

With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we are proposing to codify the statutory amendments to the definition of negotiated price for selected drugs in the definition of “negotiated price” at § 423.100. The proposed revisions to § 423.100 would take effect with respect to 2029 and subsequent years.

Specifically, we propose to revise paragraph (2) of the definition to state that the required elements of the negotiated price are subject to a new paragraph (4) and add a new paragraph (4) to the definition to require that, for a covered Part D drug that is a selected

⁷⁴ Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, Section 40.4. <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

⁷³ 70 FR 4244.

drug, and for each year of a price applicability period with respect to such selected drug, the negotiated price used for payment, as described in paragraphs (1) through (3) of the negotiated price definition, must not exceed the MFP for such drug, plus any applicable dispensing fees.

In addition, we propose a revision to the regulatory definition of negotiated prices to codify longstanding requirements in guidance. Specifically, we have historically interpreted the definition of “negotiated price” under section 1860D–2(d)(1) of the Act to include sales tax. CMS currently requires Part D plan sponsors to report sales tax as part of the negotiated price on Prescription Drug Event (PDE) records.⁷⁵ CMS has also historically interpreted and required the negotiated price to include vaccine administration fees, because beneficiaries do not purchase vaccines without the expectation that the vaccine will be administered.⁷⁶

To better align the definition of “negotiated price” at § 423.100 with this historical interpretation, we propose to revise the required elements of the negotiated price in subparagraph (2) of the definition. Specifically, the word “and:” would be deleted from the end of paragraph (2)(ii), current paragraph (2)(iii) would be redesignated as paragraph (2)(v), a new paragraph (2)(iii) would be added to require the inclusion of sales tax, and a new paragraph (2)(iv)

would be added to require the inclusion of vaccine administration fees. These changes would have the effect of adding sales tax and applicable administrative fees to the definition of “negotiated price” without altering any existing elements of that definition.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide notice in the **Federal Register** and solicit public comment before a “collection of information” requirement (as defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations) is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comments (see section II. of this proposed rule) on

each of the aforementioned issues for the following sections of this document that contain information collection requirements (ICRs). Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ (BLS) May 2025 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry, when available, to derive average labor costs for all salary estimates.⁷⁷ When industry-specific wage estimates were not available, the BLS’ May 2025 Occupational Employment and Wage Statistics data was used (<https://www.bls.gov/oes/tables.htm>). In this regard, Table 5 presents BLS’ hourly median wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly median wage to estimate total cost is a reasonably accurate estimation method.

TABLE 5—BLS’ OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Hourly median wage (\$/hr)	Fringe benefits and other indirect costs (\$/hr)	Adjusted hourly wage (\$/hr)
All occupations ⁷⁸	00–0000	24.51	24.51	49.02
Business Operations Specialists	13–1000	47.53	47.53	95.06
Chief Executive	11–1011	177.65	177.65	355.30
Cost Estimator	13–1051	41.41	41.41	82.82
Economist ⁷⁹	19–3011	59.96	59.96	119.92
Financial Manager	11–3031	87.99	87.99	175.98
General and Operations Managers	11–1021	82.99	82.99	165.98
General Internal Medicine Physicians ⁸⁰	29–1216	123.35	123.35	246.70
Lawyer	23–1011	142.57	142.57	285.14
Pharmacist	29–1051	66.73	66.73	133.46
Registered Nurse	29–1141	35.57	35.57	71.14

⁷⁵ Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE), Section 2. <https://www.cms.gov/medicare/prescription-drug-coverage/drugcoverageclaimsdata/downloads/pdeguidance.pdf>.

⁷⁶ Medicare Prescription Drug Benefit Manual, Chapter 6, Section 10.14. www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.

⁷⁷ See May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400—Pharmaceutical and Medicine Manufacturing. Available at: <https://www.bls.gov/oes/tables.htm>.

⁷⁸ Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000—Cross-industry. Available at: <https://www.bls.gov/oes/tables.htm>.

⁷⁹ Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000—Cross-industry. Available at: <https://www.bls.gov/oes/tables.htm>.

⁸⁰ Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000—Cross-industry. Available at: <https://www.bls.gov/oes/tables.htm>.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Drug Price Negotiation Program Under Sections 11001 and 11002 of the Inflation Reduction Act (CMS–10844, OMB 0938–1443 and CMS–10849, OMB 1948–1452) (§§ 429.110, 429.200, 429.300, 429.405, 429.445, 429.505, and 429.600 through 429.615)

a. Negotiation Program Drug Selection for Initial Price Applicability Year 20XX (§§ 429.110, 429.600 through 429.615)

The following was submitted to OMB for review under control number 0938–1443 (CMS–10844).

(1) Biosimilar Delay

This ICR addresses information for CMS to determine the applicability of section 1192(f)(1)(B) of the Act (which is proposed at § 429.110 of this proposed rule). Using information provided through this information collection in its determination, CMS

may delay the inclusion of a negotiation-eligible drug that includes the reference product for a biosimilar biological product on the selected drug list for a given initial price applicability year if certain statutory requirements are met regarding the biosimilar's status of licensure and marketing (the “Biosimilar Delay”) in accordance with section 1192(f) of the Act.

CMS estimates collecting a total of 10 requests for an Initial Delay Request (defined in proposed § 429.20 and discussed in proposed § 429.110(b)) per year. We believe that collection of these data will be a one-time cost for each Biosimilar Manufacturer (defined in proposed § 429.20) for each negotiation-eligible drug for which it is seeking the Initial Delay Request for each initial price applicability year.

Using the wage rates in Table 5 of this proposed rule, we expect, for a Biosimilar Manufacturer, a lawyer 20.5 hours to gather and review the relevant ICR provisions, identify any controlled group members, identify and review any

agreements between the Reference Manufacturer (defined in proposed § 429.20) and the Biosimilar Manufacturer, identify and review FDA licensure documentation and manufacturing schedule, trade agreements, and Securities and Exchange disclosures related to the Biosimilar Drug for each submission, and request technical assistance from CMS, a general and operations manager 4.5 hours to examine the gathered information, submit the form to CMS, and request technical assistance from CMS, and a chief executive 1.0 hour to review the information prior to submission and log into CMS' existing information technology system to certify the submission.

In aggregate, we estimated an annual burden of 260 hours (10 Biosimilar Manufacturers × 26.0 hr/response × 1 response/year) at a cost of \$69,475.80 (10 responses × [(20.5 hr × \$285.14/hr + (4.5 hr × \$165.98/hr) + (1.0 hr × \$355.30/hr)] (see Table 6).

TABLE 6—SUMMARY OF TOTAL ANNUAL BURDEN FOR BIOSIMILAR MANUFACTURERS TO COMPLETE AN INITIAL DELAY REQUEST ICR FORM

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Biosimilar Delay	10 Biosimilar Manufacturers.	10 Biosimilar Manufacturers.	26.0	260	Varies	69,475.80

(2) Identification and Selection of Renegotiation-Eligible Drugs

This ICR also offers Primary Manufacturers the voluntary option to submit information to CMS to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug, in accordance with section 1194(f)(2) of the Act, and as proposed at § 429.605 of this proposed rule, and may be selected for renegotiation in accordance with section 1194(f)(3) of the Act, and as proposed at § 429.610 of this proposed rule. Specifically, section 1194(f)(2)(D) of the Act provides that a selected drug is eligible for renegotiation if a new indication has been added to the selected drug or if CMS determines that there has been a material change to any of the factors listed in section 1194(e) of the Act and proposed at § 429.610(b) of this proposed rule.

CMS estimates collecting up to 36 responses for the burden estimate base year of initial price applicability year 2029 in response to the Identification and Selection of Renegotiation-Eligible

Drugs ICR Form. This estimate of potential burden incorporates assumptions that a negotiated MFP will be agreed to for all selected drugs for initial price applicability year 2028 and that, at the time of this information collection, certain previously selected drugs will no longer be considered a selected drug by CMS consistent with section 1193(c) of the Act. This would include responses from all Primary Manufacturers of selected drugs with agreed-upon MFPs for prior initial price applicability years unless the selected drug has a change in monopoly status or a previously selected drug is no longer considered a selected drug by CMS consistent with section 1193(c) of the Act. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug.

Using the wage rates in Table 5 of this proposed rule, we expect, for a Primary Manufacturer, a business operations

specialist or team of business operations specialists 25.00 hours to gather cost data and compile required information, as specified in the data elements instructions, an economist or team of economists 75.00 hours to perform necessary economic analyses of data elements specified in the data element instructions, a financial manager 6.25 hours to review the results of all the analyses and cost estimates prior to submission to CMS, a lawyer 0.50 hours to review the compiled data submission, a cost estimator 17.75 hours to compile and report the required data to CMS, per the data element form instructions, and a chief executive 0.50 hours to review the data submission and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 4,500 hours (36 Primary Manufacturers × 125.00 hr/response × 1 response/year) at a cost of \$513,383.40 (36 responses × [(25.00 hr × \$95.06/hr + (75.00 hr × \$119.92/hr) + (6.25 hr × \$175.98/hr) + (0.50 hr × \$285.14/hr) + (17.75 hr × \$82.82/hr) + (0.50 hr × \$355.30/hr)]).

TABLE 7—SUMMARY OF TOTAL ANNUAL BURDEN FOR IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS ICR FORM

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Identification and Selection of Renegotiation-Eligible Drugs.	36 Primary Manufacturers.	36 Primary Manufacturers.	125.00	4,500	Varies	513,383.40

TABLE 8—SUMMARY OF TOTAL ANNUAL BURDEN FOR NEGOTIATION PROGRAM DRUG SELECTION ICR

Section(s) under title 42 of the CFR	OMB control number (CMS ID No.)	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act (with base year of initial price applicability year 2029).	0938–1443 (CMS–10844).	46	46	Varies	4,760	Varies	582,859.20

b. Drug Price Negotiation for Initial Price Applicability Year 20XX (§§ 429.300, 429.405, 429.445, 429.505, 429.600, and 429.615)

The following was submitted to OMB for review under control number 0938–1452 (CMS–10849).

(1) Negotiation Data Elements for Selected Drugs for Negotiation From Primary Manufacturers

In accordance with section 1193(a)(4) and section 1194(b)(2)(A) of the Act and as proposed at § 429.200(b)(5) of this proposed rule, the Primary Manufacturer of a selected drug must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price (“non-FAMP”) as defined in 38 U.S.C. 8126(h)(5) for the selected drug and information that CMS requires to carry out the negotiation process, including the factors outlined in section 1194(e)(1) of the Act, which, in conjunction with the available evidence on the factors outlined in section 1194(e)(2), will serve as the basis for determining the initial offer, any offer(s) associated with negotiation meeting(s), and the final offer, if applicable. In addition, manufacturers and the public may

submit information on the factors outlined in section 1194(e)(2) of the Act, which describes evidence about the selected drug and its therapeutic alternative(s). This ICR serves as a way for a Primary Manufacturer of a selected drug to submit the required 1194(e)(1) data as well as serving as one of multiple ways that CMS will collect data described in section 1194(e)(2) of the Act. Although information submission for factors outlined in section 1194(e)(2) of the Act are voluntary and open to all interested parties, this burden estimate assumes that all Primary Manufacturers would choose to submit this type of data.

CMS estimates collecting up to 20 responses for burden estimate base year initial price applicability year 2029 from Primary Manufacturers. For purposes of this collection of information, this represents one response for each selected drug, and up to 20 drugs selected for negotiation, which represents the statutory maximum. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect,

aggregate, analyze, and report the data for a selected drug.

Using the wage rates in Table 5 of this proposed rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists 200 hours to gather cost data and compile required information, as specified in the data elements instructions, an economist or team of economists 600 hours to perform necessary economic analyses of data elements specified in the data element instructions, a financial manager 50 hours to review the results of all the analyses and cost estimates prior to submission to CMS, a lawyer 4 hours to review the compiled data submission, a cost estimator 142 hours to compile and report the required data to CMS, per the data element form instructions, and a chief executive 4 hours to review the data submission and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 20,000 hours (20 Primary Manufacturers × 1,000 hr/response × 1 response/year) at a cost of \$2,281,704.00 (20 responses × [(200 hr × \$95.06/hr + (600 hr × \$119.92/hr) + (50 hr × \$175.98/hr) + (4 hr × \$285.14/hr) + (142 hr × \$82.82/hr) + (4 hr × \$355.30/hr)]).

TABLE 9—SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF NEGOTIATION DATA ELEMENTS ICR FORM FOR SELECTED DRUGS FOR NEGOTIATION BY PRIMARY MANUFACTURERS

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Negotiation Data Elements for Selected Drugs for Negotiation from Primary Manufacturers.	20	20	1,000	20,000	Varies	2,281,704.00

(2) Negotiation Data Elements for Selected Drugs for Renegotiation From Primary Manufacturers

In accordance with section 1194(f)(4)(B) of the Act and as proposed at § 429.615(b) of this proposed rule, along with definitions proposed in § 429.20, CMS will apply a similar approach regarding data collection once a drug is selected for renegotiation of the MFP, if any drugs are selected for renegotiation. Although information submission for factors outlined in section 1194(e)(2) of the Act are voluntary and open to all interested parties, this burden estimate assumes that all Primary Manufacturers will choose to submit this type of data. CMS assumes a lower burden for data submissions for drugs selected for renegotiation relative to the original submission of data for negotiation because Primary Manufacturers will

need to report only new data for a short period of time.

CMS estimates collecting up to 36 responses from Primary Manufacturers of selected drugs for burden estimate base year initial price applicability year 2029 for renegotiation. CMS anticipates that fewer than 36 drugs will be selected for renegotiation, but CMS cannot provide definitive assumptions about how many drugs may be selected for renegotiation. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug.

Using the wage rates in Table 5 of this proposed rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists 150 hours to gather cost data and compile required information, as specified in the data elements

instructions, an economist or team of economists 450 hours to perform necessary economic analyses of data elements specified in the data element instructions, a financial manager 37.5 hours to review the results of all the analyses and cost estimates prior to submission to CMS, a lawyer 3 hours to review the compiled data submission, a cost estimator 106.5 hours to compile and report the required data to CMS, per the data element form instructions, and a chief executive 3 hours to review the data submission and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 27,000 hours (36 Primary Manufacturers × 750 hr/response × 1 response/year) at a cost of \$3,080,300.40 (36 responses × [(150.0 hr × \$95.06/hr + (450.0 hr × \$119.92/hr) + (37.5 hr × \$175.98/hr) + (3.0 hr × \$285.14/hr) + (106.5 hr × \$82.82/hr) + (3.0 hr × \$355.30/hr)]).

TABLE 10—SUMMARY OF TOTAL ANNUAL BURDEN COMPLETION OF NEGOTIATION DATA ELEMENTS ICR FORM FOR SELECTED DRUGS FOR RENEGOTIATION BY PRIMARY MANUFACTURERS

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Selected Drugs for Renegotiation from Primary Manufacturers.	36	36	750.0	27,000	Varies	3,080,300.40

(3) Negotiation Data Elements for Selected Drugs for Negotiation and Renegotiation from the General Public

To generate burden estimates for the section 1194(e)(2) data collection for burden estimate base year initial price applicability year 2029, CMS reviewed the public feedback that was received for the initial price applicability year 2028 negotiation period and adjusted accordingly due to the inclusion of selected drugs for renegotiation and the year-over-year greater awareness around

the public input process for the Drug Price Negotiation Program.

CMS estimates collecting a total of 325 requests from the general public for initial price applicability year 2029. We believe that approximately 150 individual respondents and 175 organizations will respond because the proportion of individuals and organizations remained generally consistent across the first two initial price applicability years for which data has been collected thus far.

Using the wage rates in Table 5 of this proposed rule, we expect, for an

individual respondent to spend 3 hours to review literature and submit information to CMS for a selected drug and for an organization to spend 30 hours to review literature and submit information to CMS for a selected drug.

In aggregate, we estimated an annual burden of 5,700 hours [(150 individuals × 3 hr/response × 1 response/year) + (175 organizations × 30 hr/response × 1 response/year)] at a cost of \$279,414.00 [(150 responses × 3 hr × \$49.02/hr) + (175 responses × 30 hr × \$49.02/hr)].

TABLE 11—SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF NEGOTIATION DATA ELEMENTS ICR FORM FOR SELECTED DRUGS FOR NEGOTIATION AND RENEGOTIATION BY THE GENERAL PUBLIC

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Selected Drugs for Negotiation and Renegotiation from the General Public.	325	325	Varies	5,700	49.02	279,414.00

(4) Temporary Floor for Small Biotech Drugs

This ICR also collects information necessary for CMS to determine eligibility of a selected drug, for negotiation or renegotiation in initial price applicability years 2029 or 2030,

for the temporary floor of the maximum fair price provided to selected drugs determined by CMS to be small biotech drugs consistent with section 1194(d) of the Act and as proposed at § 429.445 (the “Temporary Floor for Small Biotech Drugs”) of this proposed rule. Because eligibility for the Temporary Floor for

Small Biotech Drugs relies on the same eligibility criteria specified in section 1192(d)(2) of the Act to determine if an otherwise negotiation-eligible drug was excluded from selection for initial price applicability years 2026, 2027, or 2028 because the drug met the qualifications for the exception for small biotech drugs

(the “small biotech exception” or “SBE”), CMS is repurposing the SBE ICR form (CMS–10844) to now collect the applicable information for the Temporary Floor for Small Biotech Drugs in this ICR (CMS–10849) for initial price applicability years 2029 and 2030.

CMS estimates up to 10 respondents will need to submit data to determine applicability of the Temporary Floor for Small Biotech Drugs per year. We believe that the collection of these data will be a one-time cost for a Primary Manufacturer for each selected drug that

may be eligible for the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 or 2030.

Using the wage rates in Table 5 of this proposed rule, we expect, for a Primary Manufacturer, a lawyer 6.50 hours to gather and review the relevant ICR provisions, identify any controlled group members, and request technical assistance from CMS, a general and operations manager 3.00 hours to examine the gathered information and submit the ICR Form for eligibility for the Temporary Floor for Small Biotech Drugs to CMS and request technical

assistance from CMS, and a chief executive 0.25 hour to review the information prior to submission and to log into CMS’ existing information technology system to certify the submission.

In aggregate, we estimated an annual burden of 97.5 hours (10 Primary Manufacturers × 9.75 hr/response × 1 response/year) at a cost of \$24,401.75 (10 responses × [(6.50 hr × \$285.14/hr + (3.00 hr × 165.98/hr) + (0.25 hr × \$355.30/hr)]).

TABLE 12—SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS ICR FORM

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Temporary Floor for Small Biotech Drugs	10	10	9.75	97.5	Varies	24,401.75

(5) Counteroffer

A Primary Manufacturer must complete and submit the information requested on the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, if it both chooses not to accept CMS’ initial offer and chooses to submit a Counteroffer for a selected drug. The Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form are collectively referred to as the “Counteroffer ICR Form” due to CMS approximating the estimates for each form to be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

CMS estimates collecting up to 56 responses from Primary Manufacturers for burden estimate base year initial price applicability year 2029. CMS chose this number because by statute only up to 20 drugs payable under Medicare Part B and/or covered under Medicare Part D can be selected for negotiation for 2029 and a maximum of 36 drugs can be selected for renegotiation for initial price applicability year 2029, and for each selected drug CMS will undergo negotiation or renegotiation with only

one Primary Manufacturer, so it is not possible that there would be more than 57 respondents for initial price applicability year 2029.

Using the wage rates in Table 5 of this proposed rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists 27.00 hours to review CMS’ initial offer and justification and compare it to current prices, revenue, and other market and clinical data for the selected drug and compare CMS’ justification with the data the Primary Manufacturer submitted as part of the section 1194(e)(1) and 1194(e)(2) factors and the section 1194(e)(2) data from other interested parties shared by CMS with the Primary Manufacturer, if feasible, and put together recommendations on how the initial offer compares to what was submitted and develop Counteroffer options and justifications, a team of healthcare professionals (a pharmacist 15.00 hours, a registered nurse 5.00 hours, and a general internal medicine physician 5.00 hours) 25.00 hours to compare CMS’ initial offer and justification to the section 1194(e)(2) factors around the selected drug and therapeutic alternatives and develop Counteroffer options and justifications, an economist or team of economists 64.00 hours to

consider team recommendations of the business operations specialist(s) and healthcare professionals, model counteroffer options, and recommend Counteroffer options, a general and operations manager or team of general and operation managers 14.25 hours to review Counteroffer options and justifications and develop a Counteroffer proposal for the MFP and to examine the gathered information, populate the Counteroffer ICR Form, and submit the Counteroffer ICR Form to CMS, a lawyer or team of lawyers 64.00 hours to review counteroffer options and draft a justification for the selected Counteroffer proposal for the MFP, and a chief executive 10.00 hours to review the Counteroffer proposal for the MFP, make a decision on the Counteroffer proposal for the MFP, review the Counteroffer information prior to submission, and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 11,438 hours (56 Primary Manufacturers × 204.25 hr/response × 1 response/year) at a cost of \$2,127,987.40 (56 responses × [(27.00 hr × \$95.06/hr + (15.00 hr × \$133.46/hr) + (5.00 hr × \$71.14/hr) + (5.00 hr × \$246.70/hr) + (64.00 hr × \$119.92/hr) + (14.25 hr × \$165.98/hr) + (64.00 hr × \$285.14/hr) + (10.00 hr × \$355.30/hr)]).

TABLE 13—SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF COUNTEROFFER ICR FORM

Requirement	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Counteroffer	56	56	204.25	11,438	Varies	2,127,987.40

TABLE 14—SUMMARY OF TOTAL ANNUAL BURDEN FOR DRUG PRICE NEGOTIATION ICR

Section(s) under Title 42 of the CFR	OMB control number (CMS ID No.)	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act (using base year initial price applicability year 2029).	0938–1452 (CMS–10849).	447	447	Varies	64,235.50	Varies	7,793,807.55

C. Summary of Annual Burden Estimates

Table 15 sets out the burden for this rulemaking's finalized provisions that

are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of the provisions.

TABLE 15—ANNUAL REQUIREMENTS AND BURDEN ESTIMATES
[With Base Year Initial Price Applicability Year 2029]

Section(s) under Title 42 of the CFR	OMB control number (CMS ID No.)	Number of respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost (\$/hr)	Total cost (\$)
§§ 429.110, 429.610, and 429.615 Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act.	0938–1443 (CMS–10844).	46	46	Varies	4,760	Varies	582,859.20
§§ 429.110, 429.610 and 429.615 Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act.	0938–1452 (CMS–10849).	447	447	Varies	64,235.50	Varies	7,793,807.55
Total		493	493	Varies	68,995.50	Varies	8,376,666.75

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule proposes to codify, with limited modification, policies related to the implementation of certain provisions of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), which were established in the final guidance for the Medicare Drug Price Negotiation Program (hereinafter the “Negotiation Program”). The primary driver for this rulemaking is the statutory mandate to codify changes made by the IRA. Without regulatory implementation of the Negotiation Program, the Medicare program cannot comply with Federal law or reduce prescription drug costs for beneficiaries or achieve cost savings provided under statute.

This rulemaking proposes to codify policies for the Negotiation Program at part 429 consistent with sections 1191 through 1198 of the Social Security Act (hereinafter “the Act”) and to codify policies for the Medicare Prescription Drug Benefit Program at part 423 consistent with section 11001(b) of the IRA, which made certain amendments to the Act, including with respect to Medicare Part D. Our policies in this rulemaking specifically address: general provisions; identification of selected drugs; Negotiation Program Agreement;

program administration; establishment of a single maximum fair price (MFP) and determination of the ceiling; negotiation process; renegotiation of an MFP; implementation of the MFP; manufacturer compliance and oversight; civil monetary penalties; and requirements related to qualified prescription drug coverage. In addition, we are proposing new policies for the Negotiation Program as follows: a narrow modification to the general fixed combination drug policy to clarify our treatment for certain fixed combination drugs that are new formulations; clarification related to how CMS would identify the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the orphan drug exclusion; revisions regarding the process and schedule of CMS review of information in making determinations with respect to Bona Fide Marketing; additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity; calculation of the 30-day equivalent supply for a selected drug that is typically administered one time; how CMS would implement the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of off-

label use in consideration for renegotiation eligibility and selection. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for lower prices for Medicare through negotiation or price competition by lowering drug prices and making Medicare prescription drugs more affordable for beneficiaries.

The absence of regulatory action would result in statutory non-compliance regarding IRA implementation and missed opportunities for program improvement and innovation. Therefore, this rulemaking is necessary to ensure the Negotiation Program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13132, “Federalism”; Executive Order 13563, “Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96 354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts.). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OIRA has determined that this rulemaking is “significant” under section 3(f)(1) of E.O. 12866.

We have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

The CMS Office of the Actuary estimated the impacts of the drug provisions of the IRA using the 2024 President’s Budget as a baseline early in calendar year 2023. These estimates were made prior to many policy decisions to implement the law, and independently from other components of CMS. Since the majority of these provisions have already been implemented through program instruction, including Medicare Drug Price Negotiation Program guidance with respect to initial price applicability years 2026, 2027, and 2028 (as discussed in further detail in section I.A.2. of this proposed rule), this estimate should be taken only in its historical context, not as a reflection on the experience since its effectuation. We will highlight certain components of this estimate where recent experience has diverged from our initial assumptions. The IRA has a range of Medicare provisions, including restraining price growth and negotiating drug prices for certain drugs payable under Part B and covered under Part D, as well as redesigning the Part D benefit structure to decrease beneficiary out-of-pocket costs. The provisions of the IRA take effect over several years, resulting in very different effects by year. Much of the Part D benefit redesign became effective in 2025, for example, before

the Negotiation Program provisions can have any offsetting effects.

To model the negotiation provisions of the IRA, we first determined which drugs would be selected for negotiation in accordance with sections 11001 and 11002 of the IRA. Using 2022 experience for Part B and Part D claims, we ranked drugs by Part B and Part D expenditures and then applied the eligibility criteria specified in the IRA—verifying, in particular, that the ranked drugs had been on the market long enough to qualify for negotiation. From this list, we generated the potential list of drugs to be negotiated in each year for Part B and Part D.

To estimate the impact of negotiation and to measure the differences between the current prices and the ceiling price and other pricing parameters laid out in the IRA, we used 2021 data from a variety of sources, including PDE records, Medicaid AMP data, and Part B ASP data. We assumed, after comparing the Medicare prices to the ceiling prices in each projection year, that Medicare would be able to negotiate slightly below the ceiling price in Part D. We then adjusted for generic and biosimilar launches that, should they happen after the selection process, would potentially limit the impact of the maximum fair price. Lastly, we adjusted for changes in the percentage of spending that the selected drugs would represent over time. The discounts relative to total 2021 Part D allowed cost, prior to manufacturer rebates and total Part B allowed cost, are shown in Table 16.

TABLE 16—CUMULATIVE NEGOTIATION DISCOUNT FROM ALLOWED COSTS

	2026 %	2027 %	2028 %	2029 %	2030 %	2031 %
<i>Part B</i>	0	–1	–5	–6	–9	–12
<i>Part D</i>	–9	–16	–20	–23	–24	–25

For Part D, the benefit is considerably enriched under the IRA, and the most impactful changes took effect in 2025. To estimate these effects inclusive of the Negotiation Program impacts, we incorporated the negotiated price at the drug level into a beneficiary- and claim-

level detailed model. Then, we recalculated the new benefit on the negotiated prices to determine the combined result under the defined standard benefit design by year. To protect beneficiaries from large premium increases, the IRA limits the

premium change in years 2024 through 2029 before ultimately readjusting the base beneficiary premium percentage to a minimum of 20 percent in 2030 and later years. The major benefit changes and beneficiary premium protections by year are shown in Table 17.

TABLE 17—IRA PART D BENEFIT AND PREMIUM CHANGES

	2023	2024	2025–2029	2030
<i>Benefits</i>	Reduced cost sharing for insulins and Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines.	No cost sharing in catastrophic phase.	Removal of coverage gap, \$2,000 out-of-pocket max (indexed), new manufacturer discount.	No benefit changes.
<i>Premium</i>	Funded by retrospective government subsidy.	Base beneficiary premium (BBP) limited to 6% increase from prior year.	BBP limited to 6% increase from prior year.	BBP equal to lesser of prior year’s BBP increased by 6% or the BBP calculated under section 1860D–13(a)(2) of the Act, with BBP not less than 20% of bid and reinsurance costs.

To complete the modeling of the Negotiation Program, prescription drug inflation rebates, and benefit provisions, we applied the results from the Part D claim-level detailed simulation to our total Part D benefit model. This model also incorporated changes to the per capita cost trends to reflect: (i) the impact of most existing brand-name drugs moving to a CPI-level increase; (ii) the expected growth in new drug costs; and (iii) the expected induced utilization due to the enriched benefit. We assumed that drugs with a significant amount of spending in Part D would temper their price increases rather than pay the inflation rebates required by the IRA. Additionally, we reduced our estimate of manufacturer rebates to compensate for the lower negotiated prices and lower price growth on existing drugs.

For drugs payable under Part B, we applied the negotiated price discounts to the OM spending for separately payable Part B drugs. We further adjusted these results to account for the impact to private health plan expenditures to obtain a total impact. While there are also inflation rebates required for certain drugs payable under Part B under the IRA, price increases on existing drugs payable under Part B historically have been close to the CPI in aggregate, and therefore we did not project an effect for this provision in the

drugs payable under Part B. We also incorporated other, less significant changes from the IRA, such as the lower cost sharing for insulins furnished under durable medical equipment and the temporary payment increase for qualifying biosimilar products.

Our assumptions on the impacts of the IRA differed from those used in other public estimates in a few critical ways. Most importantly, we assumed that the inflation rebates required by the IRA would result in manufacturers owing relatively small inflation rebate amounts for drugs covered under Part D and nothing for drugs payable under Part B. We assumed that manufacturers would prefer to have lower price trends that would incentivize greater use than pay publicly reported fees for price increases that exceed inflation. Under this assumption, the effects of the inflation rebate provisions of the IRA are changed because the difference in price is shared across the benefit rather than accruing directly to the government. In other words, lower list price trends will reduce prices paid at the pharmacy relative to the baseline, which results in lower beneficiary cost-sharing and lower state clawback payments, thereby increasing the Federal cost for the Part D benefit. To compensate for the loss of price increases, we expected manufacturers to reduce rebates offered to plan sponsors.

Additionally, we expected that the initial pool of drugs covered under Part D selected for negotiation would have a large proportion of heavily rebated drugs. In these cases, we expected that the price net of rebate will be substantially lower than the other ceiling prices described in the IRA. We further estimated that the effect of negotiation in the early years would be similar to the impact of shifting rebates to the point of sale. This shift reduces beneficiary cost sharing as the price at the point of sale is lower but increases bid amounts and increases Federal expenditures.

In summary, the total effects were to reduce government expenditures for Part B, to increase expenditures for Part D through 2030, and to decrease Part D expenditures beginning in 2031. Part B savings were primarily due to: (i) the substantial lowering of payments, relative to current payment, as a result of maximum fair prices; and (ii) small impacts from other provisions. Part D ultimately generated cost savings at the end of the budget window, but many of the gains from maximum fair prices and lower trends were initially spent on increased benefits and the loss of manufacturer rebates. The impact on benefits and premiums and the impact in total are shown in Table 18 using the 2024 President's Budget as a basis.

TABLE 18—PART B AND PART D IRA IMPACTS
[In billions]

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Part B:										
Total benefits	\$0.1	\$0.1	\$0.1	–\$0.2	–\$0.3	–\$5.8	–\$8.4	–\$14.7	–\$21.4	–\$28.4
Premium	0.0	0.0	0.0	–0.1	–0.1	–1.5	–2.1	–3.7	–5.3	–7.1
Total Federal impact	0.1	0.1	0.1	–0.2	–0.2	–4.4	–6.3	–11.0	–16.1	–21.3
Part D:										
Total benefits	0.9	6.5	9.5	11.3	7.5	3.0	0.4	–4.5	–10.4	–12.5
Premium	0.0	–0.3	–0.6	–0.3	0.2	0.7	1.3	0.7	–0.1	–0.3
Inflation rebates	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.3	0.3
State transfer impact	0.0	–0.1	–0.4	–0.6	–1.7	–3.5	–5.1	–6.4	–7.6	–8.6
Total Federal impact ¹	0.4	6.6	10.2	11.9	8.8	5.6	3.9	1.0	–3.0	–3.9

The Federal impact is calculated as the benefit impact less: (i) the premium impact; (ii) the inflation rebate impact; and (iii) the State transfer impact.

Note: Totals do not necessarily equal the sums of rounded components.

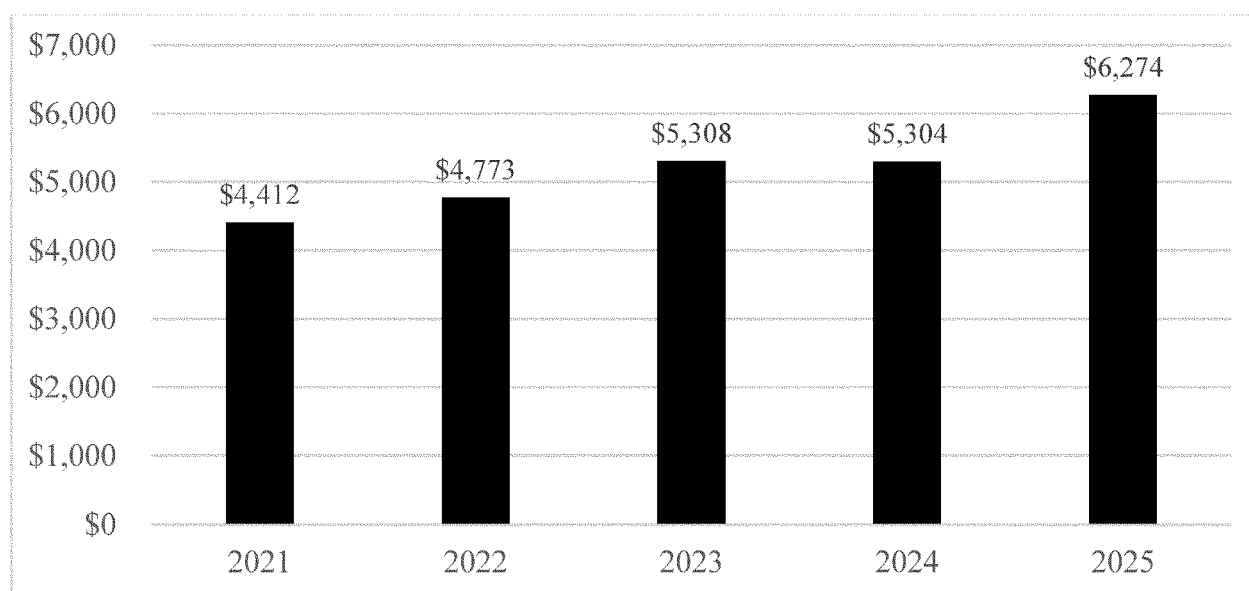
Since we produced these estimates, both the Part B and Part D programs have had large increases in drug expenditures. Part D trends have accelerated dramatically, with the per capita gross drug cost increasing more than 18 percent in 2025 over 2024, driven by higher glucagon-like peptide-1 (GLP-1) and specialty drug usage. Meanwhile Part B drug trends have also increased, although the primary driver was skin substitutes that were payable as biologicals for the purposes of Medicare payment. There are a variety of other causes contributing to observed

changes in expenditures for both programs.

The Part D trends in per capita gross costs are shown in Figure 3. Much of the IRA Part D benefit redesign took effect in 2025, including limiting annual out-of-pocket expenditures to \$2,000 per enrollee for 2025 (to be annually increased by the annual percentage increase, as described in section 1860D–2(b)(6) of the Act). While this new feature could have induced spending beyond the assumption we included in our initial estimate, it is worth noting that the 2024 benefit structure under the

IRA also eliminated cost-sharing in the catastrophic phase of the benefit, effectively implementing an out-of-pocket maximum without a pronounced increase in costs. Additionally, some of the increase may be attributable to manufacturers reducing spending on patient assistance programs, which would cause more claims to run through the Part D program. Expanded indications for cancer drugs also contributed to the increase.

Figure 3: Part D per Capita Gross Drug Costs



The observed discounts from MFPs for selected drugs also differed from what we initially assumed. For initial price applicability year 2026, the projected negotiated discount impact on allowed costs—ingredient cost, dispensing fee, and sales tax—using 2025 experience data is 11.3 percent, while the projected impact for initial price applicability year 2027 is 18.2 percent. Compared with the original estimated effects shown in Figure 3, the actual negotiated discounts are more than 2 percent greater than the original modeling results. These differences reflect the deviation in price levels, updated information about generic and biosimilar launches, and the percentage of expense the negotiated drugs represent for each year. Part B MFPs for initial price applicability year 2028 are not currently available, so we do not quantify the change from our original assumptions. We also had assumed that MFPs for initial price applicability years 2026 and 2027 would also apply to Part B utilization. Final policies for those years contained the MFPs to the Part D benefit. This change from our assumption did not meaningfully affect overall estimates, due to multiple factors including limited observed utilization of most initial price applicability years 2026 and 2027 drugs in Part B and the timing of certain generic or biosimilar entrants. Until the entirety of 2026 Part D data is available, including Part D Direct and Indirect Remuneration data, we are unable to determine the ultimate impact of initial price applicability year 2026 MFPs. Even after such data is available, there will not be an accurate way to attribute elements of the experience to particular

provisions. For example, the 2026 claims experience will undoubtedly be impacted by the benefit redesign changes implemented in 2025, but determining what portion of 2026 results are due to those benefit changes compared with the implementation of MFPs is unclear.

Part D drug inflation rebates were higher than originally assumed. Converting the published inflation rebates owed from the applicable period to a calendar year basis, 2023 inflation rebates were over \$500 million dollars. This is higher than the \$400 million dollar estimate shown in Table 18. This implies that drug prices increased slightly faster than originally assumed, generating higher inflation rebates. As a percentage of gross drug costs, the original estimate represents 0.01 percent, while the actuals amount to 0.02 percent.

For Part B, our original estimates assumed that the drug inflation rebates would be negligible. Actual drug inflation rebates due for calendar years 2023 and 2024 were \$14 million and \$121 million, respectively. These amounts represent approximately 0.01 percent and 0.04 percent of the incurred charges for OM in 2023 and 2024. Since drug inflation rebates are not incurred on MA utilization at this time, this is the most appropriate comparison.

Other, more nuanced elements of the IRA changes also differed from our original expectations. For example, the IRA Manufacturer Discount Program is likely larger than we initially assumed, but the PDE reporting is not yet complete for the discount's first year. Similarly, the impacts of the IRA on Part D DIR are unknown, as Part D plan sponsors have not yet submitted the

2025 DIR reports. These elements may have larger effects on overall Part D expense than the other assumption deviations previously described.

Additionally, this rule implements provisions of the “Working Families Tax Cuts Act” (“WFTC Act”) (Pub. L. 119–21) of 2025. This legislation expanded the IRA’s orphan drug exclusion, allowing drugs that are designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act and approved by FDA only for indications within such designated rare disease(s) or condition(s) to be excluded from the Negotiation Program effective with respect to initial price applicability year 2028. Additionally, and also effective with respect to initial price applicability year 2028, the WFTC Act amended how CMS identifies the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the orphan drug exclusion. These amendments lead to changes in projections of which drugs will be eligible for negotiation and corresponding changes to the overall effects of negotiation.

We analyzed these effects using baseline estimates from the 2026 Mid-Session Review budget exercise. Following the general procedures described previously for estimating the effects of the IRA negotiation provisions, we adjusted the projected drugs to be negotiated by year to account for the WFTC Act amendments. Orphan drug exclusions were determined using data from the FDA on orphan drug designations. We did not forecast the likelihood of these drugs losing their orphan status, as we assume

the relative value of orphan and non-orphan drugs remains stable over time. While it is possible that some drugs will avoid non-orphan indication approvals to take advantage of this exclusion,

these situations will vary widely from drug to drug, and we do not have a basis to assume the future effects of such behavior.

Table 19 shows the impacts to Medicare Part B and Part D benefits and premiums. These impacts are reflected in accounting Table 19.

TABLE 19—PART B AND PART D WFTC ACT IMPACTS

[in billions]

	2028	2029	2030	2031	2032	2033	2034
Part B:							
Total benefits	\$2.8	\$2.7	\$0.2	\$0.5	\$0.4	\$1.3	\$1.6
Premium	0.7	0.7	0.1	0.1	0.1	0.3	0.4
Total Federal impact	2.1	2.0	0.2	0.3	0.3	0.9	1.2
Part D:							
Total benefits	−0.2	0.0	0.1	0.0	0.4	0.8	1.0
Premium	0.0	0.0	0.0	0.0	0.1	0.1	0.2
Inflation rebates	0.0	0.0	0.0	0.0	0.0	0.0	0.0
State transfer impact	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Federal impact ¹	−0.2	0.0	0.1	0.1	0.4	0.6	0.9

1. Analysis of New Policies

In addition, we are proposing new policies for the Negotiation Program as follows: a narrow modification to the general fixed combination drug policy to clarify our treatment of certain new formulations; clarification related to how CMS would identify the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the orphan drug exclusion; revisions regarding process and schedule of CMS review of information in making determinations for Bona Fide Marketing; additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity; calculation of the 30-day equivalent supply for a selected drug that is typically administered one time; how CMS would implement the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of off-label use in consideration for renegotiation eligibility and selection. Of these proposals, only the proposed narrow modification to the general fixed combination drug policy would potentially have an impact as the other provisions are technical changes that would not result in additional costs or savings to the Negotiation Program.

The fixed combination drug proposal involves costs and savings that extend outside the budget window for this regulatory impact analysis. For purposes of this discussion, we refer to a potential qualifying single source drug containing active moiety/active ingredient/antigen component X as Product A, and a new formulation of such potential qualifying single source drug containing active moiety/active ingredient/antigen

component X plus active moiety/active ingredient/antigen component Y, which meets the criteria proposed at § 429.125(b)(4)(i), as Product B. While a narrow modification to the fixed combination drug policy that aggregates Product A and Product B into the same qualifying single source drug would, if such qualifying single source drug were selected, result in Product B being part of the selected drug and thus having any agreed upon MFP applied earlier, this narrowly modified fixed combination policy would also expand the number of products aggregated under a selected drug that would become deselected once a generic or biosimilar is subject to Bona Fide Marketing for any dosage form or strength of the selected drug, resulting in Product B potentially having the agreed-upon MFP applied for a shorter period of time than if it had been identified as a separate qualifying single source drug that was selected and negotiated separately. Therefore, potential savings generated by aggregating more products into a qualifying single source drug to which, if selected, the agreed-upon MFP would apply could be limited due to corresponding potential savings lost by the larger number of products that would be deselected once a generic or biosimilar is subject to Bona Fide Marketing, though changes in price after the drug is deselected may be contained (and thus savings preserved) by the Inflation Rebate Program for drugs payable under Part B.⁸¹ In addition, a

narrow modification to the fixed combination drug policy that would aggregate Product A and Product B into the same potential qualifying single source drug could result in a scenario where Product A has a generic or biosimilar that is subject to Bona Fide Marketing before that drug's eligibility for selection, which could result in both Product A and Product B being ineligible for selection for negotiation, meaning that an MFP could not be negotiated for either product.

As an illustrative example, if a drug selected for negotiation for initial price applicability year 2029 has a new formulation that is a fixed combination drug containing hyaluronidase, the proposed policy would include the new formulation containing hyaluronidase in the selected drug if the criteria in proposed § 429.125(b)(4)(i) were met. In this case, the MFP, if one is agreed to by CMS and the Primary Manufacturer, would apply to all dosage forms and strengths of the qualifying single source drug, including the new formulation containing hyaluronidase, in initial price applicability year 2029 and each subsequent year unless and until CMS makes a determination in accordance with § 429.135(a) that such drug ceases to be a selected drug because a manufacturer for a biosimilar for the non-hyaluronidase product engages in Bona Fide Marketing. Alternatively, if we do not finalize the proposal, the new formulation containing hyaluronidase might be separately selected for negotiation in 2039 (an illustrative year to represent the earliest date when the 11-year timing criterion set forth in proposed § 429.125(c)(2) for a biological product has been reached). These effects would be outside the budget window, and we do not have a credible, drug-

⁸¹ As clarified in the CY 2026 Physician Fee Schedule Final Rule, the average sales price (ASP) reported by a manufacturer must include the MFP, and the ASP is typically the basis for calculating the Part B inflation rebate. (In contrast, the average manufacturer price [AMP] that is the basis for calculating the Part D inflation rebate excludes the MFP per section 1927(k)(1)(B)(i)(VI) of the Act.)

level forecast for that time period. Such a forecast would be required to estimate this provision, as the impacted set of drugs is small and the effects will depend on the level of utilization of this subset of drugs far in the future. Additionally, we are unable to accurately estimate the impact of finalizing the narrow modification to the general fixed combination drug policy within the budget window since the budgetary effects of the counterfactual (that is, not finalizing such proposal) are outside the budget window, and we do not have baseline estimates for that time horizon. We welcome comments on methodologies to estimate these effects.

D. Alternatives Considered

In this section, CMS includes discussions of alternatives considered.

1. Fixed Combination Products (§ 429.105(b)(4))

The first alternative we considered would further narrow the proposed modification to the application of the Negotiation Program’s general fixed combination drug policy to biological products only. As compared to the

policy proposed at § 429.125(b)(4), this alternative may not meaningfully impact which products would be aggregated under a qualifying single source drug.

The second alternative we considered would modify the general fixed combination drug policy for fixed combination drugs for which one of the active ingredients or active moieties contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference. As compared to the policy proposed at § 429.125(b)(4), this alternative may not meaningfully impact which products would be aggregated under a qualifying single source drug.

The third alternative we considered would maintain the policy established for initial price applicability years 2026 through 2028, wherein, for a fixed combination drug with two or more active moieties or active ingredients, we would treat the distinct combination of active moieties or active ingredients as one active moiety or active ingredient. As compared to the policy proposed at § 429.125(b)(4), this alternative may reduce the number of products that

would be aggregated under a qualifying single source drug. If we maintained the policy established for initial price applicability years 2026 through 2028, selection and negotiation for a new formulation of a qualifying single source drug could be delayed, which might reduce total savings under the Negotiation Program.

Because these alternatives considered involve financial impacts outside the 10-year budget window and we do not have credible drug-level forecast that far out, quantifying longer-term effects would be speculative, and only considering impacts within the window would not adequately explain the full results of these alternatives.

Further discussion of this proposal is included in section II.B.6. of this proposed rule.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at <https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf>), we have prepared an accounting statement in Table 20 showing the classification of the impact associated with the provisions of this rule.

TABLE 20—ACCOUNTING STATEMENT
[\$ millions]

Category	3% Discount rate	7% Discount rate	Notes
Transfers: From Federal Government and Medicare Enrollees to pharmaceutical manufacturers ..	9,976	8,695	Orphan drug provision.

F. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the proposed rule effects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

HHS considers a significant impact on a substantial number of small entities to be one with a 3 percent revenue effect

on 5 percent of small entities.⁸² CMS would consider a “significant impact” to be 3 percent or more of the affected entities’ costs or revenues, and a “substantial number” to mean 5 percent or more of affected small entities within the total number of the small businesses in that North American Industry Classification System (NAICS) industry description. As discussed in section II of this proposed rule, the Medicare Drug Price Negotiation Program requires the Secretary to negotiate and renegotiate, for applicable periods, Medicare prices for certain high expenditure, single source drugs and biological products. Our analysis shows that the proposed rule may directly impact one category of small entities, Primary Manufacturers. Given the uncertainty on negotiation

⁸² Department of Health and Human Services. Guidance on Proper Consideration of Small Entities in Rulemaking of the U.S. Department of Health and Human Services, 2003. Available at: <https://aspe.hhs.gov/reports/proper-consideration-small-entities-rulemakings-us-dhhs>.

outcomes and available data, CMS concludes that this proposed rule, if finalized as proposed, may have an economic impact on small entities. This analysis as well as other sections in this proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required by the RFA.

1. Description and Number of Affected Small Entities

We use the NAICS to identify the industry potentially affected by the proposed rule. We also use the Small Business Administration (SBA) size standards in “number of employees” and “millions of dollars” to identify small entities.⁸³ The SBA considers any “Pharmaceutical Preparation Manufacturing” firm (NAICS code 325412) with fewer than 1,300 employees as a small business. The most recent data on private sector

⁸³ Small Business Administration. Table of Size Standards, Available at: <https://www.sba.gov/document/support-table-size-standards>.

entities with an NAICS code 325412 at the time this proposed rule was drafted are from the 2022 Statistics of U.S. Businesses (SUSB),⁸⁴ which reports 1,179 private firms and 1,444 private establishments with paid employees. Of these, 1,049 firms and 1,100

establishments have fewer than 500 employees, while 130 firms and 344 establishments have more than 500 employees as shown in Table 21. The SUSB data does not provide an enterprise range that presents the number of firms or establishments with

fewer than 1,300 employees, however the numbers presented show that 82 percent of the combined firms and establishments have less than 500 employees while 18 percent have 500 or more employees.

TABLE 21—SUSB FIRMS, ESTABLISHMENTS, EMPLOYMENT SIZE, AND RECEIPTS DATA

Enterprise size	Firms	Establishments	Employment	Receipts (\$1,000)
<5 employees	388	388	678	782,552
5–9 employees	143	145	972	425,072
10–19 employees	126	127	1,638	983,091
<20 employees	657	660	3,288	2,190,715
20–99 employees	219	225	9,633	4,276,317
100–499 employees	173	215	31,673	14,503,603
<500 employees	1,049	1,100	44,594	20,970,635
500 + employees	130	344	120,494	128,313,895
Total	1,179	1,444	165,088	149,284,530

As defined in section 1192(e)(3)(B)(i) of the Act, a selected drug must have total expenditures of \$200 million or more during the defined measurement period, between June 1, 2022 and May 31, 2023, for initial price applicability year 2026, adjusted by inflation in subsequent years (hereinafter the “low-spend Medicare drug exclusion”).

For purposes of this proposed analysis, we are unable to determine the

actual employee size or revenue of all manufacturers that may ever have a selected drug in the Negotiation Program. Assuming the low-spend Medicare drug exclusion described previously, we estimate that no Primary Manufacturer would be considered to be a small entity because we expect that the resources needed to produce and distribute a drug with Medicare

expenditures that meet this threshold would require a workforce larger than the small entity threshold of 1,300 employees. As Table 22 demonstrates, none of the drugs that were selected for negotiation, as set forth in § 429.105 of this proposed rule, were manufactured by small entities during the first 3 years of the Negotiation Program.

TABLE 22—PERCENT OF SMALL ENTITY PRIMARY MANUFACTURERS WITH SELECTED DRUGS DURING INITIAL PRICE APPLICABILITY YEARS 2026–2028⁸⁵

Initial price applicability year	Company size	Total number of employees in the U.S.	Percent of unique companies (%)
2026	Small	1,300 or fewer	0
	Large	1,300+	100
2027	Small	1,300 or fewer	0
	Large	1,300+	100
2028	Small	1,300 or fewer	0
	Large	1,300+	100

2. Description of the Potential Impacts on Small Entities

With the expiration of the Small Biotech Exception, which applies to initial price applicability years 2026, 2027, and 2028, and the implementation of the Temporary Floor for Small Biotech Drugs, which becomes effective for initial price applicability years 2029 and 2030, manufacturers of small biotech drugs could have a selected drug for initial price applicability year 2029 or a future year. It is possible that a manufacturer of a small biotech drug could have 1,300 or fewer employees,

but CMS does not have credible information to forecast if or when such manufacturers would have a selected drug.

CMS notes that the estimates of manufacturer size and impact of this rule are based on available data which could change in the future and as such, the estimated impacts could vary. Specifically, the estimates are based on the current status of drug negotiations, employment and revenue information using 2024 or other available data as of the publication of this proposed rule. Despite this uncertainty, CMS certifies

that the proposed rule, if finalized as proposed, would not have a significant impact on a substantial number of small entity Primary Manufacturers because the resources needed to produce and distribute a drug with expenditures that meet the low-spend Medicare drug exclusion is expected to require a workforce larger than the small entity threshold, therefore, we expect that no Primary Manufacturer would qualify as a small entity. A timeline of potential impacts to small entities in the Negotiation Program are showed in Table 23. CMS welcomes comments on

⁸⁴ https://www2.census.gov/programs-surveys/susb/tables/2022/us_state_6digitnaics_2022.xlsx.

⁸⁵ Data based on number of employees listed within the most recently publicly available Annual or Fourth Quarter Report for each Primary

Manufacturer during the associated Initial Price Applicability Year at the time this NPRM was drafted.

our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE 23—POTENTIAL IMPACTS TO SMALL ENTITIES IN THE NEGOTIATION PROGRAM

	2026	2027	2028	2029	2030
Primary Manufacturers ..	No changes	No changes	No changes	Small Biotech Exception no longer applies; previously ex- cepted small biotech drugs now eligible for Negotiation Program.	Small Biotech Exception no longer applies; previously ex- cepted small biotech drugs now eligible for Negotiation Pro- gram.

3. Alternatives To Minimize the Impact on Small Entities

The vast majority of the policies discussed in this proposed rule, including timing for reporting and publications and effective dates of rates, are required by sections 1191 through 1198 of the Act. Due to the IRA establishing the requirements for the selection and identification of negotiation-eligible drugs and the requirements for the negotiation or renegotiation process rather than this proposed rule, CMS is unable to propose alternatives that will accomplish the purpose of the Negotiation Program in a manner consistent with law. In addition, to the extent practicable, processes were standardized and clarified to improve efficiency for Primary Manufacturers to comply with program requirements.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$193 million. This proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of \$193 million or more. The analysis of impacts on this proposed rule does not report an estimate of any unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector that exceeds the \$193 million threshold. However, this proposed rule, if finalized as proposed, would result in additional impacts associated with changes in behavior; these are not quantified. Therefore, the Secretary has concluded that the requirements of section 202 of the UMRA have been met for this proposed rule. We request comments, including on the potential magnitude of this impact.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

I. Executive Order 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.”

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 26, 2026.

List of Subjects

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 429

Administrative practice and procedure, Biologics, Medicare, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 2. Section 423.100 is amended by revising the definition of “Corresponding drug” and revising and republishing the definition of “Negotiated price” to read as follows:

§ 423.100 Definitions.

* * * * *

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product. A corresponding drug does not include a selected drug.

* * * * *

Negotiated price means the price for a covered Part D drug that meets all of the following:

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(2) Subject to paragraph (4) of this definition, meets all of the following:

- (i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers.
- (ii) Includes any dispensing fees.
- (iii) Includes any applicable sales tax.
- (iv) Includes any applicable vaccine administration fee.
- (v) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices.

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

(4) For a covered Part D drug that is a selected drug and for each year of a price applicability period with respect to such selected drug, the negotiated price used for payment, as defined in paragraphs (1) through (3) of this definition, must not exceed the maximum fair price, as defined at section 1191(c)(3) of the Act, for such drug, plus any applicable dispensing fees.

* * * * *

- 3. Section 423.120 is amended by—
- a. Revising the section heading; and
- b. Adding paragraphs (b)(2)(vii) and (viii).

The revisions and additions to read as follows:

§ 423.120 Requirements related to qualified prescription drug coverage.

* * * * *

(b) * * *

(2) * * *

(vii) Except as specified in paragraph (viii) of this section, for 2026 and each subsequent year, include each Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year.

(viii) Nothing in paragraph (b)(2)(vii) of this section may be construed as prohibiting a Part D plan sponsor from removing such a selected drug from its formulary if such removal meets the requirements specified in paragraph (e)(2)(i) of this section and the notice requirements specified in paragraphs (f)(2), (3), and (4) of this section.

* * * * *

- 4. Part 429 is added to read as follows:

PART 429—MEDICARE DRUG PRICE NEGOTIATION PROGRAM

Subpart A—General Provisions

- 429.10 Basis and scope.
- 429.20 Definitions.
- 429.30 Limitation on review.

Subpart B—Identification of Selected Drugs

- 429.100 Publication of the selected drug list.
- 429.105 Selection of drugs for negotiation.
- 429.110 Request for a biosimilar delay.
- 429.115 Identification of negotiation-eligible drugs.
- 429.120 Calculation of total expenditures.
- 429.125 Identification of qualifying single source drugs.
- 429.130 Bona Fide Marketing.
- 429.135 Deselection of a selected drug.

Subpart C—Negotiation Program Agreement

- 429.200 Entrance into an agreement with CMS.
- 429.205 Termination.
- 429.210 Other provisions of the Negotiation Program Agreement.

Subpart D—Program Administration

- 429.300 Confidentiality policy and data use.

Subpart E—Establishment of a Single MFP and Determination of the Ceiling

- 429.400 Establishment of a single MFP for negotiation and renegotiation purposes.
- 429.405 Collection of non-FAMP.
- 429.410 Determination of the ceiling.
- 429.415 Calculation of the 30-day equivalent supply.
- 429.420 Determination of the sum of the plan-specific enrollment weighted amounts.
- 429.425 Determination of the payment amount under section 1847A(b)(4) of the Act.
- 429.430 Determination of the combined Part B and Part D amount.
- 429.435 Determination of the applicable average non-FAMP amounts and applicable percent of the average non-FAMP.
- 429.440 Temporary floor for Small Biotech Drugs.
- 429.445 Calculation information and suggestion of error.

Subpart F—Negotiation Process

- 429.500 General rule.
- 429.505 Negotiation factors.
- 429.510 Methodology for developing the initial offer.
- 429.515 Engagement with Primary Manufacturers and interested parties.
- 429.520 Provision of CMS' written initial offer and concise justification.
- 429.525 Statutory written counteroffers.
- 429.530 Additional price exchange opportunities.
- 429.535 Notification of final offer and conclusion of negotiations.

Subpart G—Renegotiation of an MFP

- 429.600 General rule.
- 429.605 Eligibility of drugs for renegotiation.
- 429.610 Selection of drugs for renegotiation.
- 429.615 Data collection to inform renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug.
- 429.620 Renegotiation process.

Subpart H—Implementation of the MFP

- 429.700 Application of the MFP across dosage forms and strengths.
- 429.705 Publication of the MFP.
- 429.710 Establishment of MFPs after the negotiation deadline.

Subpart I—Access to the MFP

Subpart J—Manufacturer Compliance and Oversight

- 429.900 Monitoring manufacturer compliance.

Subpart K—Civil Monetary Penalties

- 429.1005 Violations of the Negotiation Program Agreement.
- 429.1010 Provision of false information related to the biosimilar delay and Temporary Floor for Small Biotech Drugs.
- 429.1015 Failure to pay a biosimilar delay rebate.
- 429.1020 Notice and appeal procedures.

Authority: 42 U.S.C. 1302, 1320f, 1320f–1 through f–7, and 1395hh.

Subpart A—General Provisions

§ 429.10 Basis and scope.

(a) *Basis.*

(1) This part is based on the indicated provision of the following sections of the Act:

- 1191. Establishment of the Program.
- 1192. Selection of Negotiation-Eligible Drugs as Selected Drugs.
- 1193. Manufacturer Agreements.
- 1194. Negotiation and Renegotiation Process.

1195. Publication of Maximum Fair Prices.

1196. Administrative Duties and Compliance Monitoring.

1197. Civil Monetary Penalties.

1198. Limitation on Administrative and Judicial Review.

(2) The following specific sections of the Inflation Reduction Act also address the Medicare Drug Price Negotiation Program:

11001. Providing for Lower Prices for Certain High-Priced Single Source Drugs.

11002. Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry.

(b) *Scope.* This part sets forth the requirements of the Medicare Drug Price Negotiation Program, which requires the Secretary to negotiate and renegotiate, for applicable periods, Medicare prices for certain high expenditure, single source drugs and biological products.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provision would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of

this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 429.20 Definitions.

As used in this part, unless otherwise specified, the following definitions apply:

Additional delay request means a request to delay the inclusion on the selected drug list of a reference drug for which an initial delay request has been granted for a second initial price applicability year consistent with § 429.110 and section 1192(f)(1)(B)(i)(II) of the Act.

Applicable program agreement means an agreement under the Manufacturer Discount Program as specified in section 1860D–14C of the Act or a rebate agreement described in section 1927(b) of the Act.

Authorized generic drug means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic (FD&C) Act and a biological product that has been licensed under section 351(a) of the Public Health Service (PHS) Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

Authorized representative means an individual that has the authority or capacity to legally bind the Primary Manufacturer to the terms and conditions of the Negotiation Program Agreement and meets one of the following criteria:

- (1) Chief Executive Officer of the Primary Manufacturer.
- (2) Chief Financial Officer of the Primary Manufacturer.
- (3) An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Primary Manufacturer.
- (4) An individual that has been granted delegation of signature authority on behalf of one of the individuals specified in paragraphs (1) through (3) of this definition.

Average manufacturer price (AMP) has the meaning set forth in section 1927(k)(1) of the Act.

Average non-Federal average manufacturer price (non-FAMP) has the meaning set forth in section 1194(c)(6) of the Act.

Average sales price (ASP) means the manufacturer's price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11)

determined under 42 CFR 414.804 of this chapter and as reported in section 1927(b)(3) of the Act.

Billing unit means the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a Healthcare Common Procedure Coding System code), as established by CMS.

Biologics License Application (BLA) means an application submitted under section 351 of the PHS Act.

Biosimilar biological product or biosimilar has the meaning set forth in section 1847A(c)(6) of the Act.

Biosimilar Delay Request means an Initial Delay Request or an Additional Delay Request.

Biosimilar Manufacturer means one of the following:

- (1) The BLA holder for the Biosimilar;
- (2) If a BLA has been submitted to the FDA for review but the Biosimilar has not been licensed, the sponsor of the BLA submitted for review by the FDA; or
- (3) If the Biosimilar has not been licensed and the BLA has not been submitted to the FDA, the organization planning to be the sponsor when the BLA is submitted for review by the FDA.

BLA holder means the entity that is the holder of the license(s) permitting marketing of a biological product in accordance with section 351 of the PHS Act.

Bona Fide Marketing means that an approved generic drug or licensed biosimilar is marketed as determined by CMS based on the information considered in § 429.130(a).

Combined Part B and Part D amount means an amount equal to the weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount as determined by CMS under § 429.410(c).

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

Direct and Indirect Remuneration (DIR) has the meaning set forth in § 423.308 of this chapter.

Drug covered under Part D means a covered Part D drug as defined in section 1860D–2(e) of the Act.

Drug payable under Part B means a drug or biological product for which payment may be made under part B of Title XVIII of the Act.

Estimated remuneration at point-of-sale amounts (ERPOSA) means the estimated amount of rebates or other price concessions that the Part D plan sponsor is required to apply, or has

elected to apply, to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale.

Extended-monopoly drug has the meaning set forth in section 1194(c)(4) of the Act.

FDA-approved indication means the information included in drug labeling per 21 CFR 201.57(c)(2) or FDA regulations as applicable.

Fixed combination drug has the meaning set forth in 21 CFR 300.50.

Generic drug means a drug approved in an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act.

Healthcare Common Procedure Coding System (HCPCS) code means a billing and payment code, as established by CMS for payment under Part B, used to describe a drug or biological and for which CMS may publish a payment amount.

High Likelihood Deadline means the date that is 2 years after the statutorily defined selected drug publication date for the initial price applicability year for which a reference drug would be included on the selected drug list absent a successful Initial Delay Request.

Initial Delay Period means the time period between the selected drug publication date—

- (1) For the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request, as proposed in § 429.110(g); and
- (2) With respect to the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request as set forth in section 1192(f)(2) of the Act.

Initial Delay Request means a request to delay the inclusion of a reference drug on the selected drug list by one initial price applicability year consistent with § 429.110(c) of this part and section 1192(f)(1)(B)(i)(I) of the Act.

Initial price applicability year has the meaning set forth in section 1191(b)(1) of the Act.

Knowingly has the meaning set forth in 42 CFR 1003.110.

Long-monopoly drug has the meaning set forth in section 1194(c)(5) of the Act.

Manufacturer has the meaning set forth in section 1191(c)(1) of the Act.

Manufacturer Discount Program means the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

Maximum fair price (MFP) has the meaning set forth in section 1191(c)(3) of the Act.

Medicare Drug Price Negotiation Program (or Negotiation Program) means the program created by sections 11001 and 11002 of the Inflation Reduction Act and codified in sections 1191 through 1198 of the Act and as amended.

Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement) means the agreement between a Primary Manufacturer and CMS as set forth in § 429.200 and section 1193(a) of the Act.

NDA holder means the entity that is the holder of the approval(s) to market a drug product in accordance with section 505(c) of the FD&C Act.

Negotiation-eligible drug has the meaning set forth in section 1192(d) of the Act and is identified in accordance with § 429.115.

Negotiation period has the meaning set forth in section 1191(b)(4) of the Act.

Net Part D Plan Payment and Beneficiary Liability means, for purposes of the Medicare Drug Price Negotiation Program, the total gross covered prescription drug cost for a selected drug covered under Part D net of direct and indirect remuneration (DIR) and Manufacturer Discount Program payments and excluding prescription drug event (PDE) records for which a compound code indicates the PDE record is for a compounded drug.

New Drug Application (NDA) means an application submitted under section 505(b) of the FD&C Act.

Off-label use means use for a condition for a selected drug or a therapeutic alternative that is not an FDA-approved indication but is included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof.

Orphan drug designation has the meaning set forth in 21 CFR 316.3(b)(11).

Outcomes means the impact of an intervention, which may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life.

Part B data means Original Medicare (OM) Part B claims data and Medicare Advantage (MA) encounter data for Part B items or services.

Partnership has the meaning set forth in section 1192(f)(1)(C)(ii) of the Act.

Personally identifiable information (PII) has the meaning set forth at 2 CFR 200.1.

Plasma-derived product has the meaning set forth in section 1192(e)(3)(C) of the Act.

Preliminary price means the numerical dollar amount used by CMS in developing an initial offer in accordance with § 429.510(e) by adjusting the starting point of a selected drug based on section 1194(e)(2) factors.

Price applicability period has the meaning set forth in section 1191(b)(2) of the Act.

Primary Manufacturer means the manufacturer identified by CMS as the NDA holder or the BLA holder for the selected drug.

Private label distributor has the meaning set forth in 21 CFR 207.1.

Protected health information (PHI) has the meaning set forth at 45 CFR 160.103.

Qualifying single source drug has the meaning set forth in section 1192(e) of the Act and is identified in accordance with § 429.125.

Rare disease or condition has the meaning set forth in section 526(a)(2) of the FD&C Act.

Reference Drug means a negotiation-eligible drug that includes the reference product for a Biosimilar that is named in a Biosimilar Delay Request.

Reference Manufacturer means the Primary Manufacturer of the Reference Drug that is named in a Biosimilar Delay Request.

Reference Product has the meaning set forth in section 1191(c)(4) of the Act.

Relabeler has the meaning set forth in 21 CFR 207.1.

Renegotiation-eligible drug has the meaning set forth in section 1194(f)(2) of the Act.

Repackager has the meaning given the term "repacker" set forth in 21 CFR 207.1.

Request to Terminate means a written request submitted by a Primary Manufacturer to CMS, that CMS determines meets the conditions described in § 429.205(b)(1), to request termination of its applicable program agreements in the context of a Primary Manufacturer's decision not to enter into or to terminate a Negotiation Program Agreement.

Secondary Manufacturer means a manufacturer of a drug product included in the selected drug, that is not the Primary Manufacturer for the selected drug, and that either—

- (1) Is listed as a manufacturer in an NDA or BLA for the selected drug; or
- (2) Markets the selected drug in accordance with an agreement with the Primary Manufacturer but is not listed on an NDA or BLA of the selected drug.

A Secondary Manufacturer includes any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meets either of these criteria.

Second Delay Period means the time period between the publication date of the selected drug list for initial price applicability year that is—

- (1) One year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request; and

- (2) Two years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request.

Section 1194(e)(1) factors mean the factors described in section 1194(e)(1) of the Act.

Section 1194(e)(2) factors mean the factors described in section 1194(e)(2) of the Act.

Selected drug has the meaning set forth in section 1192(c) of the Act and is identified in accordance with § 429.105.

Selected drug publication date has the meaning set forth in section 1191(b)(3) of the Act.

Self-administered drug means a drug or biological identified as self-administered by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in accordance with section 1847A(g)(1) of the Act.

Sequestration payment adjustment means, when applicable, the amount that is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, merit-based incentive payment adjustments, and any applicable Medicare Secondary Payment adjustments.

Small Biotech Drug means a drug that is determined by CMS under § 429.440(b)(2), in accordance with section 1192(d)(2) of the Act, as eligible for the Temporary Floor for Small Biotech Drugs.

Specified Manufacturer has the meaning set forth in section 1860D–14C(g)(4)(B)(ii) of the Act, as determined by CMS for the purposes of the Manufacturer Discount Program in accordance with 42 CFR 423.2716, 423.2720, and 423.2724.

Starting point means the numerical dollar amount used by CMS in developing an initial offer in accordance with § 429.510(d) that is then adjusted by CMS based on section 1194(e)(2) factors to determine the preliminary price, per the process described in § 429.510(e).

Temporary Floor for Small Biotech Drugs has the meaning set forth in § 429.440(b)(3).

Therapeutic advance means a demonstrated improvement in one or more outcomes or other clinical considerations for an identified condition of a selected drug as compared to its therapeutic alternative(s), if any. For the purpose of developing the initial offer CMS considers therapeutic advance as of the date specified in § 429.505(d)(2). For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS will consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration.

Therapeutic alternative means a pharmaceutical product or group of pharmaceutical products other than the selected drug that may be used to treat the same condition or disease state as the selected drug.

Total allowed charges means the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service paid for under part B of Title XVIII of the Act, without a sequestration payment adjustment applied.

Total expenditures has the meaning set forth in section 1191(c)(5) of the Act, as determined under § 429.120.

Total expenditures measurement period means the 12-month period ending on October 31 of the year prior to the year of the selected drug publication date with respect to an initial price applicability year.

Total gross covered prescription drug costs has the meaning given the term “gross covered prescription drug costs” set forth in 42 CFR 423.308 of this chapter.

Unit has the meaning set forth in section 1191(c)(6) of the Act.

Unmet medical need means a circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration.

Wholesale Acquisition Cost (WAC) unit price means the manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt

pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC–11 level.

§ 429.30 Limitation on review.

(a) There is no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, under section 1191(c)(6) of the Act.

(2) The selection of drugs under section 1192(b) of the Act, the determination of negotiation-eligible drugs under section 1192(d) of the Act, the determination of qualifying single source drugs under section 1192(e) of the Act, and the application of section 1192(f) of the Act.

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1194 of the Act.

(4) The determination of renegotiation-eligible drugs under section 1194(f)(2) of the Act and the selection of renegotiation-eligible drugs under section 1194(f)(3) of the Act.

Subpart B—Identification of Selected Drugs

§ 429.100 Publication of the selected drug list.

(a) *General.* Each drug included on the selected drug list for an initial price applicability year is a selected drug with respect to such initial price applicability year and each subsequent year unless and until CMS makes a determination in accordance with § 429.135(a).

(b) With respect to each initial price applicability year beginning with initial price applicability year 2029, CMS publishes a list with the following information no later than the selected drug publication date as defined in § 429.20 with respect to such initial price applicability year:

(1) The selected drug list, which includes the 20 (or all, if such number is less than 20) selected drugs with respect to such initial price applicability year, determined in accordance with § 429.105(c).

(2) The drugs selected for renegotiation, if any, determined in accordance with § 429.610.

(3) For each selected drug included on the selected drug list published in accordance with paragraph (b)(1) of this section, CMS adds the following information to the MFP file:

(i) The active moiety/active ingredient/antigen component (or the

distinct combination thereof), identified in accordance with § 429.125(b).

(ii) The NDC–11s identified in accordance with paragraph (c)(1) of this section, and the corresponding NDC–9s and HCPCS codes (as applicable).

(4) For each drug selected for renegotiation published in accordance with paragraph (b)(2) of this section, if any, CMS adds the following information to the MFP file:

(i) The active moiety/active ingredient/antigen component (or the distinct combination thereof) previously identified for the initial price applicability year for which the drug was originally selected for negotiation.

(ii) The NDC–11s identified in accordance with paragraph (c)(1) of this section as updated to reflect information previously submitted by the Primary Manufacturer, including submissions in accordance with this section, and the corresponding NDC–9s and HCPCS codes (as applicable).

(c) *Identification of the list of NDC–11s of the selected drug.* CMS identifies a list of the NDCs of each selected drug, including for a drug selected for renegotiation, that is developed and maintained using the following process:

(1) CMS identifies a baseline list of NDC–11s associated with the NDA(s)/BLA(s) of the selected drug.

(2) CMS transmits the NDC–11s identified in paragraph (c)(1) of this section to the Primary Manufacturer.

(3) CMS revises its list of NDC–11s of each selected drug, as appropriate, including without limitation using information submitted by the Primary Manufacturer in accordance with this section.

(d) *Primary Manufacturer submission of information for CMS' list of NDC–11s.*

In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, including to ensure CMS' list of NDC–11s of the selected drug developed in accordance with § 429.100(c) is complete and accurate, the Primary Manufacturer must submit all of the following information to CMS in a form and manner specified by CMS by 11:59 p.m. PST on March 1 of the calendar year of the selected drug publication date for the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer:

(1) Any NDC–11s associated with the NDA(s)/BLA(s) of the selected drug that do not appear on CMS' list of NDC–11s of the selected drug, including any missing NDC–11s of a Secondary Manufacturer.

(2) Any NDC–11s on CMS' list of NDC–11s of the selected drug that are

distributed by or under the name of a private label distributor.

(3) Any NDC–11s on CMS' list of NDC–11s of the selected drug that are not manufactured, marketed, controlled or sold by the Primary Manufacturer or a Secondary Manufacturer.

(4) Any NDC–11s on CMS' list of NDC–11s of the selected drug that represent a sample package.

(5) Any NDC–11s on CMS' list of NDC–11s of the selected drug that represent an inner package or an outer package.

(6) Any NDC–11s on CMS' list of NDC–11s of the selected drug that have been discontinued and the discontinuation date for each.

(e) *Primary Manufacturer requirement to timely report changes.* In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, including to ensure CMS' list of NDC–11s of the selected drug developed in accordance with § 429.100(c) remains complete and accurate, the Primary Manufacturer must update the information provided to CMS under paragraph (d) of this section, in a form and manner specified by CMS, at least 30 calendar days prior to the change taking effect.

(f) CMS' list of NDC–11s of the selected drug identified in accordance with paragraph (c) of this section is used in the administration of the Negotiation Program, including all of the following:

(1) To identify the NDC–11s of the selected drug that are subject to the negotiation process set forth in subpart F of this part and the renegotiation process set forth in subpart G of this part, as applicable.

(2) To identify the NDC–11s of the selected drug to which the MFP applies for the price applicability period.

(3) To calculate the ceiling set forth in § 429.410(b) for drugs selected for negotiation.

(4) To calculate the ceiling set forth in § 429.620(b) for drugs selected for renegotiation.

(5) To calculate how to apply the MFP across dosage forms and strengths as set forth in § 429.700 for selected drugs and in § 429.600(b)(2) for drugs selected for renegotiation.

§ 429.105 Selection of drugs for negotiation.

(a) With respect to each initial price applicability year beginning with initial price applicability year 2029, CMS—

(1) Ranks the list of negotiation-eligible drugs identified in § 429.115 by combined total expenditures under both Part B and Part D, calculated using the methodology set forth at § 429.120; and

(2) Lists the ranked drugs in descending order, with the negotiation-

eligible drug with the highest combined total expenditures under Part B and Part D listed first and the negotiation-eligible drug with the lowest combined total expenditures under Part B and Part D listed last.

(b) CMS removes from the ranked list of negotiation-eligible drugs determined in accordance with paragraph (a) of this section any biological products that qualify for delayed selection as determined in accordance with the biosimilar delay process set forth in § 429.110.

(c) With respect to each initial price applicability year beginning with initial price applicability year 2029, CMS selects for negotiation the 20 highest ranked (or all, if the number is less than 20) negotiation-eligible drugs remaining on the ranked list of negotiation-eligible drugs determined in accordance with paragraph (a) of this section and subject to paragraph (b) of this section. If two or more negotiation-eligible drugs have the same combined total expenditures under Parts B and D to the cent, and such combined total expenditures are the 20th highest (or the highest, if the number is less than 20) among negotiation-eligible drugs, CMS ranks those negotiation-eligible drugs based on which drug has the earlier approval or licensure date (as applicable) identified at § 429.125(c), and selects from among the drugs with the same combined total expenditures based on earliest approval or licensure date until there are 20 selected drugs (or until all drugs are selected, if the number of negotiation-eligible drugs is less than 20).

§ 429.110 Request for a biosimilar delay.

(a) For purposes of this section, all references to “marketed” or “marketing” mean Bona Fide Marketing as defined in § 429.20 and set forth at § 429.130(a).

(b) General. A Biosimilar Manufacturer may submit a request, prior to the selected drug publication date, to delay the inclusion of a Reference Drug from the selected drug list for either of the following:

(1) One initial price applicability year based on the criteria specified in paragraph (c) of this section.

(2) A second initial price applicability year after such first initial price applicability year based on the criteria specified in paragraph (e) of this section.

(c) *First 1-year delay (Initial Delay Request).* To delay the inclusion of a Reference Drug for one initial price applicability year, CMS must determine the following:

(1) The Initial Delay Request meets all of the following criteria:

(i) The Reference Drug would be an extended-monopoly drug included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay.

(ii) The Reference Drug includes the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has either been—

(A) Approved by the FDA; or

(B) Accepted for review by the FDA.

(iii) If the Biosimilar has been licensed by FDA, no more than 1 year has elapsed since the licensure of the Biosimilar under section 351(k) of the PHS Act and marketing for the Biosimilar has not commenced.

(iv) The Biosimilar Manufacturer and the Reference Manufacturer—

(A) Are not the same manufacturer and must not be treated as the same manufacturer, where all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC, or in a Partnership, must be treated as one manufacturer; and

(B) Have not entered into any agreement that—

(1) Requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request; or

(2) Directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States on or after the selected drug publication date of the applicable initial price applicability year.

(2) If the requirements in paragraph (c)(1) of this section are met, that there is a high likelihood, as specified in paragraph (d) of this section, that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.

(d) *High likelihood.* There is a high likelihood the Biosimilar will be licensed and marketed before the High Likelihood Deadline if each of the following criteria are met:

(1) By no later than a date to be specified by CMS, which will be in January in the calendar year of the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests the delay, an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been either—

(i) Approved by the FDA; or

(ii) Accepted for review by FDA.

(2) CMS has identified clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline through the following circumstances:

(i) Patents related to the Reference Drug are unlikely to prevent the

Biosimilar from being marketed before the High Likelihood Deadline, as CMS identifies within the documentation specified in paragraph (f)(1) of this section, meaning one or more of the following:

(A) There will be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar.

(B) One or more court decisions or decisions by the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patents relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar.

(C) Neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer's patent assertion(s) pertaining to an unexpired patent or patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar and the Biosimilar Manufacturer has publicly announced a precise launch date for the Biosimilar that is a calendar date before the High Likelihood Deadline.

(D) The Biosimilar Manufacturer has a signed agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without imposing improper constraints, that may include, but are not limited to, the circumstances listed in paragraphs (c)(1)(iv)(A), (B)(1), and (2) of this section (which prohibits the Biosimilar Manufacturer and the Reference Manufacturer being the same or being treated as the same, requiring or incentivizing the submission of a Biosimilar Delay Request, or directly or indirectly restricting the quantity of the Biosimilar sold in the United States on or after the selected drug publication date of the applicable initial price applicability year), on the Biosimilar Manufacturer.

(ii) The Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, as CMS identifies within the documentation specified in paragraph (f)(1) of this section, meaning the Biosimilar Manufacturer is taking the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of the Biosimilar.

(e) *Second 1-year delay (Additional Delay Request).* To delay the inclusion of a Reference Drug for a second initial price applicability year, CMS must determine the following:

(1) The Additional Delay Request meets all of the following criteria:

(i) The Biosimilar listed in the Additional Delay Request was identified in a successfully granted Initial Delay Request (consistent with paragraph (c) of this section).

(ii) During the time between the publication date of the selected drug list for the initial price applicability year for which the Initial Delay Request was granted and the date that is 1 year following that publication date, under section 351(k) of the PHS Act, the Biosimilar has not been both—

(A) Licensed; and

(B) Marketed.

(iii) The Additional Delay Request meets the requirements set forth in paragraphs (c)(1)(ii) through (iv) of this section.

(iv) The Reference Drug would not be a long-monopoly drug (as set forth in § 429.20) for the initial price applicability year for which the Biosimilar Manufacturer is submitting the Additional Delay Request.

(2) If the requirements in paragraph (e)(1) of this section are met, CMS must reevaluate and determine that there is a high likelihood, as specified in paragraph (d) of this section, that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.

(3) If the requirements in paragraph (e)(2) of this section are met, CMS must determine based on a holistic review of the Additional Delay Request, including within the documentation specified in paragraph (f) of this section, there is clear and convincing evidence that the Biosimilar Manufacturer has made a significant amount of progress towards licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request.

(f) *Biosimilar delay request submission.* A Biosimilar Manufacturer may submit a Biosimilar Delay Request to CMS in a form and manner specified by CMS, by no later than a date to be specified by CMS, which will be no later than the end of December of the calendar year prior to the selected drug publication date for such initial price applicability year for which the Biosimilar Manufacturer may submit a Biosimilar Delay Request, and must provide the information specified in paragraphs (1) through (3) of this paragraph (f), as applicable:

(1) With the Biosimilar Manufacturer's Initial Delay Request or Additional Delay Request to support the determinations specified in paragraphs (c) and (e) of this section, as applicable:

(i) All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General under section 1112(a) and (c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

(ii) To the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during the review of the licensure application under section 351(k) of the PHS Act.

(iii) To the extent available, disclosures that pertain to the marketing of the Biosimilar (for example, in filings by the Biosimilar Manufacturer of the Biosimilar with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation that is distributed to shareholders of privately held companies) about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before the marketing of a Biosimilar;

(2) Upon request from CMS after review of a Biosimilar Delay Request, including the information provided consistent with paragraph (f)(1) of this section, additional information and documents from the Biosimilar Manufacturer to be submitted in a form and manner specified by CMS as necessary for CMS to make a determination for an Initial Delay Request or an Additional Delay Request, as applicable.

(3) At the Biosimilar Manufacturer's option, after the deadline for submitting a Biosimilar Delay Request specified in paragraph (f) of this section but prior to the selected drug publication date for such initial price applicability year for which the Biosimilar Manufacturer may submit a Biosimilar Delay Request, updates on the status of the Biosimilar's application for licensure in a form and manner specified by CMS by no later than a date to be specified by CMS.

(g) *Notice of determinations.*

(1) After review of a Biosimilar Delay Request, CMS provides in writing:

(i) A notice of determination, on or after the selected drug publication date for the applicable initial price applicability year, at a time specified by CMS, to:

(A) The Biosimilar Manufacturer that submitted a request, which includes:

(1) Whether the Biosimilar Delay Request was successful or unsuccessful; and

(2) If unsuccessful, the reason CMS determined the request was unsuccessful.

(B) If a Biosimilar Delay Request is successful, the Reference Manufacturer of the reference product named in a successful Biosimilar Delay Request.

(2) CMS publishes the number of Reference Drugs that would have been selected drugs for the applicable initial price applicability year absent the successful Biosimilar Delay Requests as part of publishing the selected drug list (as set forth in § 429.100).

(3) After review for licensure and marketing consistent with paragraph (h) of this section, CMS provides in writing by a date to be specified by CMS, which will be no later than the end of October in the calendar year of the selected drug publication date for the initial price applicability year for which CMS determined the Biosimilar Manufacturer's Biosimilar Delay Request successful, a notice of determination to the Biosimilar Manufacturer of CMS' determination as to whether the Biosimilar is or is not licensed and marketed during the Initial Delay Period or the Second Delay Period, as applicable.

(h) *Review for failure of the biosimilar to be licensed and marketed—*

(1) CMS determines whether a Biosimilar named in a successful Initial Delay Request has been licensed and marketed during the Initial Delay Period.

(i) If CMS determines that the Biosimilar has not been licensed and marketed during the Initial Delay Period, the Biosimilar Manufacturer may submit an Additional Delay Request consistent with paragraph (e) of this section.

(ii) Subject to the circumstance in paragraph (h)(3) of this section, CMS includes the Reference Drug on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request if either of the following occurs:

(A) The Biosimilar Manufacturer does not submit an Additional Delay Request for the Biosimilar included in the successful Initial Delay Request.

(B) CMS determines that the Additional Delay Request submitted by the Biosimilar Manufacturer for the Biosimilar named in the successful Initial Delay Request does not meet the requirements in paragraph (e) of this section.

(2) CMS determines whether a Biosimilar named in a successful Additional Delay Request has been licensed and marketed during the Second Delay Period.

(i) If CMS determines that the Biosimilar has not been licensed and marketed, subject to the circumstance in paragraph (h)(3) of this section, CMS includes the Reference Drug on the selected drug list for the initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request.

(3) If one or more different biosimilars of the Reference Drug for the Biosimilar named in a successful Initial Delay Request (for purposes of paragraph (h)(1) of this section) or a successful Additional Delay Request (for purposes of paragraph (h)(2) of this section) are licensed and marketed, the Reference Drug is not included on the applicable selected drug list.

(i) *Rebate owed for failure of a biosimilar to be licensed and marketed.*

(1) The Reference Manufacturer is required to pay the rebate specified in paragraph (i)(4) of this section for the 1 or 2 years that the Reference Manufacturer would have provided access to the MFP for the Reference Drug but for the Biosimilar Delay, if—

(i) CMS delayed the selection and negotiation of a Reference Drug for 1 year due to a successful Initial Delay Request or 2 years due to a successful Additional Delay Request;

(ii) CMS determined that the Biosimilar was not licensed and marketed, as described in paragraph (h) of this section; and

(iii) The Reference Manufacturer agrees to an MFP.

(2) The Reference Manufacturer must pay any rebates owed under paragraph (i) of this section in a time and manner to be specified by CMS.

(3) The rebates paid are deposited in either of the following:

(i) The Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act, for drugs payable under Part B.

(ii) The Medicare Prescription Drug Account established under section 1860D–16 of the Act, within the Federal Supplementary Medical Insurance Trust Fund, for drugs covered under Part D.

(4) Except if the drug meets the circumstances in paragraph (i)(5) of this section, the rebate amount is calculated as follows:

(i) CMS applies the calculation under paragraphs (i)(4)(ii) through (iv) of this section, as applicable for all the previous initial price applicability years where the Reference Drug would have been on the selected drug list if not for the delay, but for the initial price applicability year for which an

Additional Delay Request was granted, CMS adjusts the MFP by the annual percentage increase in the CPI–U for the 12-month period ending with July of the calendar year that is 2 years before the initial price applicability year for which the Additional Delay Request was granted.

(ii) In the case of a Reference Drug that is a drug covered under Part D—

(A) Seventy-five percent of the difference between the AMP as reported by the Primary Manufacturer of the selected drug under section 1927 of the Act, or if not reported under section 1927 of the Act, as submitted to CMS in accordance with § 429.200(b)(5), with respect to each of the calendar quarters of the price applicability period that would have applied but for the delay, and the MFP negotiated for the Reference Drug; and

(B) Multiplied by the number of units dispensed under Part D for the Reference Drug in each calendar quarter of the price applicability period that would have applied but for the delay.

(iii) In the case of a Reference Drug that is a drug payable under Part B—

(A) Eighty percent of the difference between the payment amount under section 1847A(b) of the Act, with respect to each of the calendar quarters of the price applicability period that would have applied but for the delay, and the MFP negotiated for the Reference Drug; and

(B) Multiplied by the number of units of the billing and payment code of the Reference Drug administered or furnished under Part B (excluding units that are packaged into the payment amount for an item or service and are not separately payable under Part B) for each calendar quarter of the price applicability period that would have applied but for the delay.

(iv) In the case of a Reference Drug that is a drug covered under Part D and payable under Part B, CMS calculates the rebate amount for Reference Drugs payable under Part B and covered under Part D by summing the rebate amount for the units payable under Part B as specified in paragraph (i)(4)(iii) of this section and the rebate amount for units covered under Part D as specified in paragraph (i)(4)(ii) of this section.

(5) If CMS determines that the Reference Drug transitioned from an extended-monopoly drug to a long-monopoly drug at the time of its inclusion on the selected drug list for an initial price applicability year (as set forth in § 429.110(h)(1)(ii) or (h)(2)), as applicable for the initial year delay—

(i) The rebate calculation as described in paragraph (i)(4) of this section will substitute the MFP negotiated for the

Reference Drug with the amount specified in paragraph (i)(5)(ii) of this section.

(ii) The amount specified in this paragraph is an amount equal to 65 percent of the average non-FAMP for 2021 for the Reference Drug (or the first full year following market entry if there is no non-FAMP for 2021) increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry) to September of the year prior to the selected drug publication date for the initial price applicability year that would have applied but for the Initial Delay Request.

(6) If CMS determines that the Reference Drug transitioned from an extended-monopoly drug to a long-monopoly drug at the time of its inclusion on the selected drug list for an initial price applicability year (as set forth in § 429.110(h)(2)), as applicable for the second year delay—

(i) The rebate calculation as described in paragraph (i)(4) of this section will substitute the MFP negotiated for the Reference Drug with the amount specified at paragraph (i)(5)(ii) of this section that is further adjusted by the annual percentage increase in the CPI-U for the 12-month period ending with July of the calendar year that is 2 years before the initial price applicability year for which the Additional Delay Request was granted.

§ 429.115 Identification of negotiation-eligible drugs.

(a) *Identification.* With respect to each initial price applicability year beginning with initial price applicability year 2029, a qualifying single source drug, identified as set forth in § 429.125, is a negotiation-eligible drug if CMS determines that such qualifying single source drug is on the list of 50 Part D high spend drugs, as set forth in paragraph (a)(1) of this section, or on the list of 50 Part B high spend drugs or both, as set forth in paragraph (a)(2) of this section.

(1) *Part D high spend drugs.* CMS identifies Part D high spend drugs as follows:

(i) CMS removes a qualifying single source drug if it is currently a selected drug.

(ii) For each remaining qualifying single source drug identified in § 429.125, CMS calculates total expenditures under Part D using the methodology set forth at § 429.120(a).

(iii) CMS ranks the remaining qualifying single source drugs by total expenditures under Part D.

(iv) Subject to paragraph (b) of this section and using the ranked list

identified in paragraph (a)(1)(iii) of this section, CMS identifies as Part D high spend drugs the 50 qualifying single source drugs that have the highest total expenditures under Part D.

(2) *Part B high spend drugs.* CMS identifies Part B high spend drugs as follows:

(i) CMS removes a qualifying single source drug if it is currently a selected drug.

(ii) For each remaining qualifying single source drug identified in § 429.125, CMS calculates total expenditures under Part B using the methodology set forth at § 429.120(b).

(iii) CMS ranks the remaining qualifying single source drugs by total expenditures under Part B.

(iv) Subject to paragraph (b) of this section and using the ranked list identified in paragraph (a)(2)(iii) of this section, CMS identifies as Part B high spend drugs the 50 qualifying single source drugs that have the highest total expenditures under Part B.

(b) If two or more qualifying single source drugs have the same total expenditures to the cent (and such total expenditures are the 50th highest among qualifying single source drugs under Part D (as specified in paragraph (a)(1)(iv) of this section) or Part B (as specified in paragraph (a)(2)(iv) of this section), CMS ranks those qualifying single source drugs based on which drug has the earlier approval or licensure date (as applicable) identified at § 429.125(c), until CMS has identified 50 high spend drugs for Part B and 50 high spend drugs for Part D, as applicable.

§ 429.120 Calculation of total expenditures.

(a) *Total expenditures under Part D.* CMS calculates total expenditures under Part D for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug, as the sum of gross covered prescription drug costs for each PDE record for such drug that meets all of the following criteria:

(1) The date of service is during the total expenditures measurement period.

(2) The gross covered prescription drug cost on the PDE record is greater than zero dollars.

(3) The PDE record is considered final action.

(4) The drug coverage status code indicates the PDE record is for a drug covered under Part D.

(5) The compound code indicates the PDE record is not for a compounded drug.

(b) *Total expenditures under Part B.* CMS calculates total expenditures under

Part B for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug, as the sum of the amounts determined under paragraphs (b)(1) and (b)(2) of this section:

(1) Subject to the methodology described in paragraph (b)(3) of this section, the sum of the total allowed charges for each Original Medicare Part B claim for such drug that meets all of the following criteria:

(i) The date of service is during the total expenditures measurement period.

(ii) The claim type code is associated with an Original Medicare Part B claim in an outpatient setting (including but not limited to clinics, Federally Qualified Health Centers, and ambulatory surgical centers), a professional services claim, or a durable medical equipment claim, as determined by CMS.

(iii) The total allowed charges for the claim line is greater than zero dollars.

(iv) The claim is considered final action.

(v) The claim is not billed as a compounded drug.

(vi) The claim is not for a drug or biological product that is bundled or packaged into the payment for another service. In instances where a claim for separate payment is submitted for a drug payable under Part B when such a claim is typically payable under Part B Original Medicare payment rules only as part of a bundled payment, such claim will be considered to be bundled or packaged into the payment for another service and will not be included in the total allowed charges calculation.

(2) Subject to the methodology described in paragraph (b)(3) of this section, the sum of the total allowed charges that would have been applicable under Original Medicare Part B for each MA encounter data record for Part B services for such drug that meets all of the following criteria:

(i) The date of service is during the total expenditures measurement period.

(ii) The claim type code is associated with an MA encounter record in an outpatient setting (including but not limited to clinics, Federally Qualified Health Centers, and ambulatory surgical centers), professional services, or durable medical equipment record, as determined by CMS.

(iii) The reported total number of units on the MA encounter data record line is greater than zero.

(iv) The encounter data record is considered final action.

(v) The encounter data record is not denied.

(vi) The encounter data record is not a chart review record.

(vii) The encounter data record line is not for a supplemental benefit.

(viii) The encounter data record is not reported as a compounded drug.

(ix) The encounter data record is not for a drug or biological product that is bundled or packaged into the payment for another service under Part B Original Medicare. In instances where an encounter data record for separate payment is submitted for a drug payable under Part B when such a claim is typically payable under Part B Original Medicare payment rules only as part of a bundled payment, such claim will be considered to be bundled or packaged into the payment for another service and will not be included in the total allowed charges calculation.

(3) In cases where such drug is assigned to a HCPCS code with other products, CMS calculates the total expenditures under Part B by using ASP sales volume data to apportion Part B expenditures based on the ratio of reported sales volume of the drug compared to reported sales volume of all products assigned to the HCPCS code.

§ 429.125 Identification of qualifying single source drugs.

(a) *General.* Subject to the statutory exclusions codified in paragraph (e) of this section, with respect to each initial price applicability year beginning with initial price applicability year 2029, a qualifying single source drug is a drug covered under Part D, a drug payable under Part B, or both that meets the following criteria:

(1) For drug products, a qualifying single source drug is a drug—

(i) That is approved under section 505(c) of the FD&C Act and marketed in accordance with such approval;

(ii) For which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years have elapsed since the date of such approval, determined as set forth in paragraph (c) of this section; and

(iii) That is not the listed drug for any drug approved and marketed in an ANDA under section 505(j) of the FD&C Act, determined as set forth in paragraph (d) of this section.

(2) For biological products, a qualifying single source drug is a biological product—

(i) That is licensed under section 351(a) of the PHS Act and marketed in accordance with such licensure;

(ii) For which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years have elapsed since the date of such licensure, determined as set forth in paragraph (c) of this section; and

(iii) That is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act, determined as set forth in paragraph (d) of this section.

(b) *Potential qualifying single source drugs.* In identifying qualifying single source drugs under paragraph (a) of this section, CMS first identifies potential qualifying single source drugs as follows:

(1) Subject to paragraph (b)(4) of this section, for drug products, all dosage forms and strengths of the drug with the same active moiety as identified using public sources (such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file), and the same NDA holder, inclusive of all of the following:

(i) Products that are marketed under different NDAs.

(ii) Repackaged and relabeled products that are marketed under such NDA(s).

(iii) Authorized generic drugs, as defined in § 429.20, that are marketed under such NDA(s).

(iv) Multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act that are marketed under such NDA(s).

(2) Subject to paragraphs (b)(3) and (b)(4) of this section, for biological products, all dosage forms and strengths of the biological product with the same active ingredient as identified using public sources (such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file), and the same BLA holder, inclusive of all of the following:

(i) Products that are marketed under different BLAs.

(ii) Repackaged and relabeled products that are marketed under such BLA(s).

(iii) Authorized generic drugs, as defined in § 429.20, that are marketed under such BLA(s).

(iv) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed under such BLA(s).

(3) Subject to paragraph (b)(4) of this section, for purposes of the identification of potential qualifying single source drugs under paragraph (b)(2) of this section for vaccines for infectious disease(s), CMS identifies all dosage forms and strengths of the drug with the same antigen component on such vaccine's labeling.

(4) *Fixed combination products.* Subject to paragraph (b)(4)(i) of this section, for purposes of the identification of potential qualifying single source drugs under paragraphs

(b)(1) and (b)(2) of this section for a drug or biological product that is a fixed combination drug with two or more active moieties, active ingredients, or, for vaccines for infectious disease(s), antigen components, CMS identifies a potential qualifying single source drug using all dosage forms and strengths of the drug or biological product with the same distinct combination of active moieties, active ingredients, or antigen components.

(i) *New Formulations.* If CMS determines that a fixed combination drug with two or more active moieties, active ingredients, or, for a vaccine for infectious disease(s), antigen components shares one or more active moiety(ies), active ingredient(s), or antigen component(s) with another drug or biological product with the same NDA/BLA holder, and such products differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), CMS identifies a potential qualifying single source drug using all dosage forms and strengths of the drug or biological product with the shared active moiety(ies), active ingredient(s), or antigen component(s) and the same NDA/BLA holder.

(c) *Time since approval or licensure.* With respect to initial price applicability years beginning with initial price applicability year 2029, CMS determines if a potential qualifying single source drug, identified as set forth in paragraph (b) of this section, meets the time since approval or licensure criteria set forth in paragraphs (a)(1)(ii) and (a)(2)(ii) of this section, respectively, as follows:

(1) *Time since approval for drugs.* Subject to paragraph (c)(3) of this section, for a drug, at least 7 years must have elapsed between the date of approval of the potential qualifying single source drug and the selected drug publication date with respect to such initial price applicability year. To determine the FDA date of approval of a potential qualifying single source drug that is a drug, CMS uses the date of approval of the FDA application belonging to the NDA holder and containing the active moiety (or in the case of potential qualifying single source drugs identified under § 429.125(b)(4), the distinct combination of active moieties), or, if such drug has more than one FDA application, CMS uses the initial date of approval associated with the earliest-approved

FDA application belonging to the NDA holder and containing the active moiety (or in the case of potential qualifying single source drugs identified under § 429.125(b)(4), the distinct combination of active moieties). For potential qualifying single source drugs identified under § 429.125(b)(4)(i), CMS uses the date of approval of the FDA application belonging to the NDA holder and containing the shared active moiety(ies) identified at § 429.125(b)(4)(i), or, if such drug has more than one FDA application, CMS uses the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing such shared active moiety(ies).

(2) *Time since licensure for biological products.* Subject to paragraph (c)(3) of this section, for a biological product, at least 11 years must have elapsed between the date of licensure of the potential qualifying single source drug and the selected drug publication date with respect to such initial price applicability year. Subject to the exceptions set forth in paragraphs (c)(2)(i) and (c)(2)(ii) of this section, to determine the FDA date of licensure of a potential qualifying single source drug that is a biological product, CMS uses the date of licensure of the FDA application belonging to the BLA holder and containing the active ingredient (or in the case of potential qualifying single source drugs identified under § 429.125(b)(4), the distinct combination of active ingredients), or, if such biological product has more than one FDA application, CMS uses the initial date of licensure associated with the earliest-approved FDA application belonging to the BLA holder and containing the active ingredient (or in the case of potential qualifying single source drugs identified under § 429.125(b)(4), the distinct combination of active ingredients). Subject to the exceptions set forth in paragraphs (c)(2)(i) and (c)(2)(ii) of this section, for a potential qualifying single source drug identified under § 429.125(b)(4)(i), CMS uses the date of licensure of the FDA application belonging to the BLA holder and containing the shared active ingredient(s) identified at § 429.125(b)(4)(i), or, if such biological product has more than one FDA application, CMS uses the initial date of licensure associated with the earliest-approved FDA application belonging to the BLA holder and containing such shared active ingredient(s).

(i) For each unique potential qualifying single source drug that CMS identifies based on its antigen component(s) in accordance with paragraph (b)(3) of this section, CMS

determines the date of licensure using the earliest date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of determining the FDA date of licensure of the potential qualifying single source drug for purposes of implementing paragraph (c)(2) of this section.

(ii) For biological products with an approved NDA that was deemed to be a BLA under section 351 of the PHS Act on March 23, 2020, in accordance with section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed biological products under section 351 of the PHS Act, CMS considers March 23, 2020 to be the date of licensure of the potential qualifying single source drug for purposes of implementing paragraph (c)(2) of this section. For a biological product with an approved application under section 505(c) of the FD&C Act that was deemed to be a BLA under section 7002(e)(4)(B) of the BPCI Act, as amended by the Further Consolidated Appropriations Act of 2020, CMS considers the approval date determined in accordance with section 7002(e)(4)(B) of the BPCI Act to be the date of licensure of the potential qualifying single source drug for purposes of implementing paragraph (c)(2) of this section.

(3) *Certain former orphan drugs.* Notwithstanding paragraphs (c)(1) and (c)(2) of this section to the contrary, for a drug or biological product that met or meets the criteria for the orphan drug exclusion at paragraph (e)(1) of this section as of the date of such drug or biological product's initial approval or licensure identified as set forth in paragraphs (c)(1) and (c)(2) of this section, CMS measures the 7- and 11-year periods described in paragraphs (c)(1) and (c)(2) of this section, respectively, starting from the first day after such initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. CMS identifies this day as the earlier of—

(i) The date on which the FDA approves such drug or biological product for an indication (irrespective of whether approval of such indication was or is withdrawn after its approval) for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act; or

(ii) The date on which an orphan drug designation is withdrawn, if that withdrawal results in the drug or biological product no longer qualifying for the orphan drug exclusion. For

orphan drug designations withdrawn prior to or on August 12, 2013, for which the FDA Orphan Drug Product designation database does not include the date of such withdrawal, CMS uses August 12, 2013, as the date on which the orphan designation is withdrawn for purposes of identifying the first day after the drug or biological product's approval or licensure that such drug or biological product does not qualify for the orphan drug exclusion.

(d) *Bona Fide Marketing of an approved generic drug or licensed biosimilar.* A potential qualifying single source drug is not a qualifying single source drug, if CMS determines that—

(1) Using FDA reference sources including the Orange Book and Purple Book, at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the potential qualifying single source drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the potential qualifying single source drug as the reference product; and

(2) Such generic drug or biosimilar is subject to Bona Fide Marketing when CMS reviews such information at the point in time specified in § 429.130(c)(1).

(e) *Exclusions from qualifying single source drugs.* A potential qualifying single source drug identified in paragraph (b) of this section is not a qualifying single source drug if CMS determines that it qualifies for one or more of the following exclusions:

(1) *The orphan drug exclusion.* A potential qualifying single source drug qualifies for the orphan drug exclusion if, for all dosage forms and strengths of such potential qualifying single source drug, the following criteria are met:

(i) The potential qualifying single source drug is designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act, determined by CMS as follows:

(A) CMS uses data sources such as the FDA Orphan Drug Product designation database; and

(B) CMS only considers orphan drug designations that have not been withdrawn or revoked.

(ii) The only indication(s) approved by FDA for the potential qualifying single source drug are for such designated rare disease(s) or condition(s), determined by CMS as follows:

(A) CMS uses information on FDA-approved indications from publicly available databases and documents (such as, but not limited to, FDALabel,

FDA Online Label Repository, *Drugs@FDA*, and NLM DailyMed); and
 (B) CMS only considers approvals of indications that FDA has not withdrawn.

(2) *The low-spend Medicare drug exclusion.* A potential qualifying single source drug qualifies for the low-spend Medicare drug exclusion if it has combined total expenditures under Part B and Part D, calculated as set forth in paragraph (e)(2)(i) of this section, less than the inflation-adjusted threshold, calculated as set forth in paragraph (e)(2)(ii) of this section.

(i) For a potential qualifying single source drug described in § 429.125(b), CMS calculates combined total expenditures under Part B and Part D as the sum of total expenditures under Part B (calculated as set forth in § 429.120(b)) plus total expenditures under Part D (calculated as set forth in § 429.120(a)).

(ii) Starting from the inflation-adjusted threshold for initial price applicability year 2028 equal to \$212,907,518.30, the inflation-adjusted threshold for an initial price applicability year is equal to the inflation-adjusted threshold for the prior initial price applicability year, increased by the annual percentage increase in the CPI-U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to a given initial price applicability year.

(3) *Plasma-derived product exclusion.* A potential qualifying single source drug qualifies for the plasma-derived product exclusion if it is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling or product information (such as, but not limited to, FDALabel and the FDA Online Label Repository).

§ 429.130 Bona Fide Marketing.

(a) *General.* CMS considers whether an approved generic drug or licensed biosimilar is marketed according to this section based on CMS' evaluation of the following:

(1) Sales and utilization data for the generic drug or biosimilar from the following data sources for the following data periods:

(i) The 12 months of PDE data ending with the last full month of data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section;

(ii) The 12 months of AMP data ending with the last full month of data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section;

(iii) The 4 quarters of ASP data ending with the last full quarter of data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section; and

(iv) The 12 months or 4 quarters of any data source, if applicable to such data source, that is in addition to those data sources listed in paragraph (a)(1)(i) through (iii) of this section and may include, but is not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available databases, ending with the last full month or quarter of data available to CMS (as applicable to the specific data source) at the time CMS reviews such data consistent with paragraph (c) of this section.

(2) Information related to additional factors, including:

(i) Whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain; and

(ii) Whether any licenses or other agreements between a Primary Manufacturer and the manufacturer of the generic drug or biosimilar limit the availability or distribution of the generic drug or biosimilar.

(3) CMS may also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar.

(b) *Conduct holistic inquiry.* In its evaluation of the information described in paragraph (a) of this section, CMS conducts a holistic inquiry based on the totality of the circumstances.

(c) *Timing for CMS review of Bona Fide Marketing.* CMS reviews the information set forth in paragraph (a) of this section that is available at the following times:

(1) *Identification of potential qualifying single source drugs.* For any potential qualifying single source drug for initial price applicability year 2029 and any initial price applicability year thereafter, in January prior to each selected drug publication date.

(2) *Monitoring generic(s) or biosimilar(s) for drugs that were not considered qualifying single source drugs.* For any potential qualifying single source drugs that did not qualify as a qualifying single source drug for initial price applicability year 2029 or any initial price applicability year thereafter because CMS determined that a generic drug was approved using the potential qualifying single source drug as the listed drug or a biosimilar was licensed using the potential qualifying single source drug as the reference product, and such generic drug or

biosimilar is subject to Bona Fide Marketing (consistent with paragraph (a) of this section), periodically during each calendar year, including at least annually in January.

(3) *Identification of selected drugs ineligible to be selected for renegotiation.* For identifying that a drug previously selected for negotiation is not eligible for renegotiation for initial price applicability year 2029 and any initial price applicability year thereafter, in January prior to each selected drug publication date.

(4) *Selected drugs until the negotiation period ends.* For drugs selected for negotiation for initial price applicability year 2029 and any initial price applicability year thereafter, monthly starting in March during the negotiation period for the initial price applicability year for which the drug was selected for negotiation and until November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation.

(5) *Drugs selected for renegotiation until renegotiation ends.* For drugs selected for renegotiation (if any) for initial price applicability year 2029 and any initial price applicability year thereafter, monthly starting in March during the renegotiation period for the initial price applicability year for which the drug was selected for renegotiation and until November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for renegotiation.

(6) *Selected drugs following the negotiation period.* For all drugs selected for initial price applicability year 2029 and any initial price applicability year thereafter after reaching an agreed-upon MFP (consistent with § 429.200(b)(4)), and, starting January 1, 2029, for any drugs selected for initial price applicability years 2026, 2027, and 2028, biannually in March and October, starting in October of the calendar year after CMS and the Primary Manufacturer reached an agreement on the MFP for the initial price applicability year for which the drug was selected originally for negotiation and until CMS determines that a selected drug meets the requirements at § 429.135(b) to cease being considered a selected drug.

(7) *Monitoring generic(s) or biosimilar(s) for selected drugs that are no longer subject to negotiation or that have ceased to be selected drugs.* For drugs selected for initial price applicability year 2029 and drugs selected for any initial price applicability year thereafter (consistent with § 429.200(b)(4)) for which CMS

makes a determination under § 429.135(b), and, starting January 1, 2029, for any drugs CMS determines cease being considered a selected drug for initial price applicability years 2026, 2027, and 2028, periodically during each calendar year, including at least annually in January prior to each selected drug publication date.

§ 429.135 Deselection of a selected drug.

(a) *General.* Each drug selected for negotiation for an initial price applicability year remains a selected drug with respect to such initial price applicability year and each subsequent year beginning before the first year that begins at least 9 months after the date as of which CMS determines that—

(1) Using FDA reference sources including the Orange Book and Purple Book, at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the selected drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the selected drug as the reference product; and:

(2) Such generic drug or biosimilar is subject to Bona Fide Marketing.

(b) *Timing.* For clarity, the following circumstances apply to such selected drug based on the date as of which CMS determines the conditions described in § 429.135(a) are met—

(1) If the date is during the period beginning on the selected drug publication date (as defined in § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for negotiation, then—

(i) The selected drug ceases to be subject to the negotiation process under section 1194 of the Act, as set forth in subpart F of this part;

(ii) The selected drug remains a selected drug for such initial price applicability year only;

(iii) The selected drug will not be replaced with another selected drug for the initial price applicability year that the selected drug is selected; and

(iv) No MFP will be published for, or apply to, such drug.

(2) If the date is during a period beginning on the selected drug publication date (as defined in § 429.20) of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for renegotiation and ending on November 1 of such year, then the selected drug ceases to be subject to the renegotiation process under section 1194 of the Act, as set forth in subpart G of this part.

(3) If the date is during the period beginning on November 2 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for negotiation and ending on March 31 of that initial price applicability year, then—

(i) The selected drug will cease to be a selected drug on January 1 of the year following the initial price applicability year for which such drug was selected for negotiation; and

(ii) The MFP will apply only for the initial price applicability year for which such drug was selected for negotiation.

(4) If the date is during the selected drug's price applicability period and after March 31 of the initial price applicability year for which the selected drug is selected for negotiation:

(i) The selected drug will cease to be a selected drug on January 1 of the year that begins at least 9 months after the date as of which CMS determines the conditions described in § 429.135(a) are met; and

(ii) The MFP will apply until such date that the selected drug ceases to be a selected drug as described in paragraph (b)(4)(i) of this section.

(c) A drug previously selected for negotiation is not eligible for renegotiation if CMS has made a determination described in section 429.135(a), prior to the next selected drug publication date for the initial price applicability year for which any drug could be selected for renegotiation.

(d) *Public notice.* If CMS makes a determination described in paragraph (a) of this section, CMS will announce such determination in a timeframe and manner specified by CMS.

Subpart C—Negotiation Program Agreement

§ 429.200 Entrance into an agreement with CMS.

(a) *General.* The Negotiation Program Agreement between the Primary Manufacturer, as defined in § 429.20, and CMS contains provisions regarding the requirements specified in paragraph (b) of this section, and may contain other provisions as determined by CMS, in accordance with section 1193 of the Act, as necessary for purposes of administering and monitoring compliance with the Negotiation Program.

(1) The deadline for the Primary Manufacturer of a selected drug to enter into a Negotiation Program Agreement with respect to the selected drug is 11:59 p.m. PST on February 28 following the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation.

(2) The negotiation period with respect to a selected drug will begin on the earlier of February 28 following the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation or the date that the Negotiation Program Agreement is fully executed.

(b) *Agreement requirements.* In executing a Negotiation Program Agreement with respect to a selected drug, a Primary Manufacturer agrees to the following:

(1) To comply with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including this part, implementing those provisions and any changes to the Act that affect the Negotiation Program.

(2) To negotiate to determine an MFP for the selected drug with CMS, during the negotiation period for the initial price applicability year for the selected drug, in accordance with section 1194 of the Act, including as described in subpart F of this part.

(3) As applicable, to renegotiate to determine an MFP for the drug selected for renegotiation with CMS, during the renegotiation period for the initial price applicability year for the drug selected for renegotiation, in accordance with section 1194 of the Act, including as described in subpart G of this part.

(4) To provide access to the MFP, including as renegotiated, with respect to the selected drug, during the selected drug's price applicability period, in accordance with section 1193(a)(3) of the Act, including as described in subpart B and subpart I of this part.

(5) To submit to CMS, in a form and manner specified by CMS, the information specified in sections 1191 to 1198 of the Act, the Negotiation Program Agreement, or this part, including, but not limited to, the information as specified at §§ 429.100(d), 429.405, 429.505(b), and, if applicable, 429.615(b)(1), in accordance with sections 1193(a)(4) and 1193(a)(5) of the Act, including as described in subparts B, E, F, and G of this part.

(6) To comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, in accordance with section 1193(a)(5) of the Act, including as described in subpart J of this part.

(c) *Execution of agreement.* The Negotiation Program Agreement must be signed, in a form and manner specified by CMS, by an authorized representative

of the Primary Manufacturer and by CMS.

(d) *Agreement term.* The Negotiation Program Agreement takes effect on the date that the Negotiation Program Agreement is signed both by an authorized representative of the Primary Manufacturer and by CMS. The term of the Negotiation Program Agreement is from such effective date until the Negotiation Program Agreement is terminated in accordance with § 429.205(a), including as described in subpart C of this part.

(e) *Agreement to an MFP.* Upon agreeing to an MFP for a selected drug, CMS and the Primary Manufacturer of a selected drug will formalize the agreement to an MFP through an Addendum to the Negotiation Program Agreement that must be signed, in a form and manner specified by CMS, by an authorized representative of the Primary Manufacturer and by CMS.

§ 429.205 Termination.

(a) *Termination of Negotiation Program Agreement.* The Negotiation Program Agreement terminates effective as of the date of the earlier of—

(1) The first date that the selected drug covered by the Negotiation Program Agreement is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act as described at § 429.135.

(2) The date of termination established in paragraph (b)(5) of this section in connection with a Request to Terminate by the Primary Manufacturer submitted under paragraph (b) of this section.

(b) *Primary Manufacturer-requested Termination.*

(1) A Primary Manufacturer that wishes to terminate a Negotiation Program Agreement may submit in writing a Request to Terminate, in a form and manner specified by CMS. Such Request to Terminate must include:

(A) A request for termination of the Primary Manufacturer's applicable program agreements, and

(B) An attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer shall not seek—

(i) To enter any subsequent applicable program agreement; or

(ii) Coverage for any of its drugs under the Manufacturer Discount Program.

(2) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1), CMS—

(A) Confirms receipt of the Primary Manufacturer's notice; and

(B) Executes the actions with respect to termination of the Primary Manufacturer's applicable program agreements as described in paragraphs (b)(3), (b)(4), and (b)(5) of this section, if applicable.

(3) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1), the Request to Terminate will constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Manufacturer Discount Program in accordance with section 1860D–14C(b)(4)(B)(i) of the Act and § 423.2752(c)(1) of this chapter, and to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with § 423.2752(c)(1) of this chapter.

(4) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1) of this section, the Request to Terminate will also constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and the Medicaid National Drug Rebate Agreement.

(5) Unless a Primary Manufacturer rescinds its Request to Terminate in accordance with paragraph (d) of this section, CMS terminates the Negotiation Program Agreement effective on the first date following the receipt of a Request to Terminate that CMS determines complies with paragraph (b)(1) of this section on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with § 423.2752(c)(1) of this chapter.

(c) *A Decision by the Primary Manufacturer not to execute a Negotiation Program Agreement.*

(1) A Primary Manufacturer that does not wish to enter into a Negotiation Program Agreement in accordance with § 429.200 may submit in writing a Request to Terminate, in a form and manner specified by CMS, that meets the requirements described in paragraph (b)(1) of this section.

(2) In response to the Request to Terminate, CMS takes the steps described in paragraphs (b)(2) through (b)(4) of this section, as applicable.

(d) *Request by a Primary Manufacturer to Rescind the Request to Terminate.* If a Primary Manufacturer wishes to rescind the Request to Terminate it submitted under

paragraphs (b) or (c) of this section, it must file a written request for a hearing, in a form and manner specified by CMS.

(1) Upon such a request from the Primary Manufacturer, CMS provides a hearing concerning termination of the Primary Manufacturer's applicable program agreements, in accordance with sections 1860D–14C(b)(4)(B)(i) and 1927(b)(4)(B)(i) of the Act, as applicable.

(2) Such hearing will be held prior to the effective date of termination of the applicable program agreements with sufficient time for such effective date to be repealed.

(3) Such hearing will be held solely on the papers.

(4) The only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its Request to Terminate prior to the effective date of termination of the applicable program agreements.

(e) *Effect of termination.*

Notwithstanding termination of the Negotiation Program Agreement for a selected drug in accordance with either paragraph (a)(1) or (a)(2) of this section, the Primary Manufacturer is responsible for making the MFP for the selected drug available, in accordance with subpart I of this part, with respect to dispenses, administrations, and furnishings of the selected drug prior to the effective date of termination under paragraph (a) of this section.

Confidentiality, record retention and data requirements and requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities continue to apply.

(f) *Reentry into the Negotiation Program.* A Primary Manufacturer that has terminated the Negotiation Program Agreement for a selected drug in accordance with paragraph (b) of this section and later seeks to re-enter any applicable program agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program during the selected drug's price applicability period would be deemed to have provided an invalid attestation, described in section § 429.205(b)(1)(B), and the Negotiation Program Agreement would once again become operative as of the date of re-entry into the applicable program agreement or coverage for any of its drugs under the Manufacturer Discount Program.

§ 429.210 Other provisions of the Negotiation Program Agreement.

(a) *General.* If any provision of the Negotiation Program Agreement is found to be invalid by a court of law with competent jurisdiction, the Negotiation Program Agreement will be construed in all respects as if any

invalid or unenforceable provision(s) were eliminated, and without any effect on any other provision.

(b) *Update to the Negotiation Program Agreement.* CMS retains the authority to amend the Negotiation Program Agreement to reflect changes in law, regulation, or guidance as applicable.

(c) *Transfer of Negotiation Program Agreement.* If, after entering in a Negotiation Program Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs or BLAs, as applicable, of a selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Negotiation Program Agreement associated with the transferred NDA(s) or BLA(s), including the requirement to provide access to the MFP in accordance with subpart I, unless and until the Primary Manufacturer transfers all the NDAs or BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer in accordance with this paragraph (c).

(1) To transfer responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity, the transferring Primary Manufacturer must—

(i) Transfer all NDA(s) or BLA(s) of the selected drug that it holds to the acquiring entity;

(ii) Provide CMS with documentation of the intended transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, in the form of a novation, at least 30 calendar days before the intended effective date of any such transfer for CMS review and approval. Such novation of the transferring Primary Manufacturer's Negotiation Program Agreement must be signed by the transferring Primary Manufacturer and the acquiring entity and must include, at minimum, the legal name of the acquiring entity, the effective dates of the transfer of ownership of all transferred NDAs or BLAs of the selected drug that the transferring Primary Manufacturer holds and of the transfer of responsibility for all requirements of the Negotiation Program Agreement, a list of all transferring NDAs or BLAs of the selected drug, and agreement that the acquiring entity assumes all obligations and liabilities under the transferring Primary Manufacturer's Negotiation Program Agreement as the successor in interest.

(2) If the transferring Primary Manufacturer submits a novation agreement that meets the requirements of paragraph (c)(1)(ii) of this section and is approved and signed by CMS, the

acquiring entity becomes the successor in interest to the transferring Primary Manufacturer's Negotiation Program Agreement and the Primary Manufacturer of the applicable selected drug as of the novation's effective date of the transfer of responsibility for all requirements of the Negotiation Program Agreement.

(3) The transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the Biosimilar Delay, under section 1192(f) of the Act, unless and until such liabilities are transferred to the acquiring entity as the new Primary Manufacturer, in accordance with paragraph (c) of this section.

Subpart D—Program Administration

§ 429.300 Confidentiality policy and data use.

(a) *Confidentiality of proprietary information.* Information deemed proprietary under this section will only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program.

(b) *Confidentiality policy.* CMS would deem proprietary information, including trade secrets and confidential commercial or financial information, as confidential information exempt from disclosure if the information meets the requirements set forth under Exemption 3 or Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(3), (4)).

(1) CMS would not disclose protected health information or personally identifiable information except in accordance with applicable laws, where received by CMS as set forth in §§ 429.505 and 429.615 or received by CMS in engagements with interested parties specified in §§ 429.515 and 429.620(e).

(c) *Primary Manufacturer data.* The following data when submitted by the Primary Manufacturer as set forth at §§ 429.405 and 429.505(b), and 429.615(b)(1) would be deemed proprietary information by CMS, unless the information is publicly available:

(1) Non-FAMP and associated non-FAMP data collection;

(2) Research and development costs of the Primary Manufacturer for the selected drug;

(3) Current unit costs of production and distribution of the selected drug;

(4) Data on pending patent applications for the selected drug; and

(5) Market data and revenue and sales volume for the selected drug in the United States.

(6) A common Technical File/Drug Master File/“drug dossier” if submitted

with the submission specified at § 429.505(d)(3) or § 429.615(b)(1)(i) (if applicable).

(d) *Publication.* Any information deemed proprietary by CMS or covered by the confidentiality policy, in accordance with paragraphs (a) and (b) of this section, must be redacted from any publications related to the Negotiation Program, including the publication of the MFP, as described in § 429.705.

Subpart E—Establishment of a Single MFP and Determination of the Ceiling

§ 429.400 Establishment of a single MFP for negotiation and renegotiation purposes.

(a) *Establishment of a single MFP for negotiation and renegotiation purposes.* CMS identifies, for purposes of determining offers and counteroffers for use at each step of the negotiation process, as set forth in §§ 429.510 through 429.535, and for use at each step of the renegotiation process, as set forth in § 429.620, a single price for a selected drug, including for a selected drug with multiple dosage forms and strengths.

(1) CMS bases the single price on the cost of the selected drug per 30-day equivalent supply for all formulations weighted across dosage forms and strengths, as set forth in § 429.415.

§ 429.405 Collection of non-FAMP.

(a) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer must submit the following information to CMS in a form and manner specified by CMS by 11:59 p.m. PST on March 1 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation, inclusive of the NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer:

(1) Non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug (as determined in § 429.100(d)) for the four quarters of calendar year 2021 in which the selected drug was sold and non-FAMP data was reported (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021 (when non-FAMP data has not been reported for at least one NDC–11 of the selected drug for at least one quarter in calendar year 2021)), the Primary Manufacturer is required to report the non-FAMP, unit type, and total unit volume for the four quarters of the first full calendar year

following the market entry for such drug); and

(2) Non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug (as determined in § 429.100(d)) for the four quarters of the calendar year prior to the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation.

(b) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, if the information in paragraph (a) of this section is restated due to requirements of 38 U.S.C. 8126 and implementing regulations and guidance issued by the Department of Veterans Affairs, the Primary Manufacturer is required to update the information submitted in accordance with paragraph (a) of this section in a form and manner specified by CMS.

§ 429.410 Determination of the ceiling.

(a) *Limitations on offer amount.* In negotiating the MFP of selected drugs with respect to their initial price applicability year, beginning with initial price applicability year 2029, and in accordance with section 1194(b)(2)(F)(i) of the Act, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act, as determined under this section, subject to § 429.440(b)(4), or is less than the Temporary Floor for Small Biotech Drugs specified in section 1194(d) of the Act, as determined under § 429.440(b)(3), if applicable.

(b) *Determination of the ceiling for the MFP.* With respect to each initial price applicability year beginning with initial price applicability year 2029, the MFP negotiated under the process set forth in §§ 429.510 through 429.535 for a selected drug with respect to the first initial price applicability year of the price applicability period with respect to such drug must not exceed the lower of the amount specified in paragraph (b)(1) or (b)(2) of this section. The ceiling for renegotiation is set forth in § 429.620(b).

(1) The amount determined under this paragraph equals one of the following amounts, as applicable to the selected drug:

(i) For a selected drug that is covered under Part D but is not payable under Part B, the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420.

(ii) For a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, but is not covered under Part D, the payment

amount under section 1847A(b)(4) of the Act, as set forth in § 429.425;

(iii) For a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, and covered under Part D, an amount equal to the combined Part B and Part D amount, as set forth in § 429.430.

(iv) For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and is covered under Part D, the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420.

(v) For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and is not covered under Part D, there is no amount under paragraph (b)(1) of this section.

(2) The amount determined under this paragraph is equal to the applicable percent, as applicable to the selected drug, of the lower of—

(i) The average non-FAMP for calendar year 2021, or, as applicable, the first full year after 2021 for which data is available, adjusted by inflation, as set forth in § 429.435(a)(1); or

(ii) The average non-FAMP for the year preceding the selected drug publication with respect to the first initial price applicability year of the price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available, as set forth in § 429.435(a)(2).

(3) CMS calculates a single amount, a 30-day equivalent supply as described in § 429.415, across all dosage forms and strengths of the selected drug for the amounts set forth in paragraphs (b)(1) and (b)(2) of this section to determine which amount is lowest and will serve as the ceiling for the MFP.

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (b) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.415 Calculation of the 30-day equivalent supply.

(a) *Determination of the 30-day equivalent supply for a selected drug.* CMS calculates the 30-day equivalent supply across all dosage forms and strengths of the selected drug using the following methodologies, as applicable:

(1) *30-day equivalent supply for a selected drug covered under Part D.* For a selected drug that is covered under Part D, CMS uses the methodology in accordance with § 423.104(d)(2)(iv)(A)(2).

(2) *30-day equivalent supply for a selected drug covered under Part B.* For selected drugs that are payable under Part B, CMS determines the 30-day equivalent supply using the following methodology:

(i) For Part B data for the selected drug's HCPCS code(s) that is/are for the year prior to the year of the selected drug publication date with respect to the initial price applicability year (for which the selected drug is selected for negotiation), CMS identifies any subsequent instances of Part B data or any PDE record that:

(A) Is associated with the same beneficiary; and

(B) Is for a drug or biological product with the same active moiety/active ingredient, identified as set forth at § 429.125(b), as the selected drug.

(ii) CMS calculates a “days between services” amount by counting the days between the date of service on the first instance of Part B data and the date of service on the immediately subsequent instance of Part B data or PDE record.

(A) Notwithstanding paragraph (a)(2)(ii) of this section, if the beneficiary does not have a subsequent instance of Part B data or PDE record with the same active moiety/active ingredient, identified as set forth at § 429.125(b), as the selected drug, CMS assigns a “days between services” amount equal to the median “days between services” amount for all other instances of Part B data or PDE records for that selected drug associated with that beneficiary during the applicable claims period.

(B) Notwithstanding paragraph (a)(2)(ii)(A) of this section, if there are no other instances of Part B data or PDE records for that selected drug associated with that beneficiary during the year set forth in paragraph (a)(2)(i) of this section, CMS does not assign a “days between services” amount, and the claim will not be included in the calculations.

(iii) For each instance of Part B data or PDE record, the 30-day equivalent supply for the HCPCS code is equal to the “days between services” (as determined in paragraph (a)(2)(ii) of this section) divided by 30.

(iv) CMS allocates a portion of the HCPCS code's 30-day equivalent supply to each NDC within the HCPCS code for calculations that require a 30-day equivalent supply at the NDC level and will proceed in accordance with paragraph (v) of this section.

(v) To determine the total Part B 30-day equivalent supply at the NDC level, CMS takes the following steps:

(A) As set forth in § 429.100(f), use NDC–11s from the list of NDC–11s of

the selected drug as set forth in paragraph § 429.100(c) to determine which NDC–11s of the selected drug are included in the calculations for the calendar year as set forth in § 429.425(a) that meet the following criteria:

(1) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(2) The NDC–11 does not represent a sample package;

(3) The NDC–11 is assigned to a HCPCS code;

(4) The NDC–11 does not represent a self-administered drug; and

(5) CMS observes any instances of Part B data for the HCPCS code to which the NDC–11 is assigned during the calendar year as set forth in paragraph (a)(2)(i) of this section.

(B) Determine the total billing units sold for each NDC–11 assigned to the HCPCS code (including NDC–11s that do not belong to the selected drug, if applicable) for each quarter of the calendar year set for in paragraph (a)(2)(1) of this section, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(C) For all NDC–11s assigned to the HCPCS code that is associated with the selected drug, sum the total billing units sold for such NDC–11s across all calendar quarters to calculate an annual total billing units sold for all NDC–11s assigned to the HCPCS code.

(D) For each NDC–11 assigned to the HCPCS code that is associated with the selected drug, divide the annual total billing units sold for that NDC–11 by the annual total billing units sold for all applicable NDC–11s of the same HCPCS code.

(E) For each NDC–11 assigned to the HCPCS code that is associated with the selected drug, multiply the 30-day equivalent supply for the HCPCS code (as determined in paragraph (a)(2)(iii) of this section) by the quotient calculated in paragraph (a)(2)(v)(D) of this section, to yield the total 30-day equivalent supply for the NDC–11.

(1) Notwithstanding paragraph (a)(2)(ii)(B) of this section, CMS plans to assign a value of “12” for the 30-day equivalent supply for drugs typically administered one time (for example, some vaccines and cancer therapies).

(b) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (a) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and

in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.420 Determination of the sum of the plan-specific enrollment weighted amounts.

(a) *Data used to calculate the sum of the plan-specific enrollment weighted amount for selected drugs as set forth in § 429.410(b)(1)(i) and (iv).* CMS uses plan sponsors’ reported Part D PDE data and direct and indirect remuneration data for all Part D plans found in such PDE data that meet the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (5) for the year as set forth in paragraph (b)(1) of this section.

(1) As set forth in § 429.100(f), CMS uses NDC–11s from the list of NDC–11s of the selected drug as set forth in paragraph § 429.100(c) to determine which NDC–11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in (b)(1) of this section that meet the following criteria:

(i) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(ii) The NDC–11 does not represent a sample package;

(iii) CMS observes any PDE days’ supply, PDE quantity dispensed, and PDE gross expenditures during the calendar year as set forth in (b)(1) of this section; and

(iv) CMS observes any associated direct and indirect remuneration amounts for the NDC–11 during the calendar year as set forth in (b)(1) of this section.

(v) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (a)(5).

(b) *Determination of the sum of the plan-specific enrollment weighted amounts.* Using the 30-day equivalent supply methodology set forth at 42 CFR 423.104(d)(2)(iv)(A)(2), CMS calculates the sum of the plan-specific enrollment weighted amount for selected drugs as set forth in § 429.410(b)(1)(i) and (iv) to determine the sum of the plan-specific enrollment weighted amounts for across all NDCs of the selected drug by conducting the following steps:

(1) For each Part D plan, CMS identifies the PDE data for the selected drug’s NDC–11s, as identified using the criteria set forth in paragraph (a)(1) of this section, for the most recent year for which all data are available.

(2) For each Part D plan and each NDC–11, CMS separately sums the negotiated price amounts (as defined in 42 CFR 423.100), the ERPOSA (as defined in § 429.20), and units dispensed.

(3) For each Part D plan and each NDC–11, CMS sums the total direct and indirect remuneration amounts found in the Detailed Direct and Indirect Remuneration Report for the year set forth in paragraph (b)(1) of this section and subtracts the total ERPOSA calculated in paragraph (b)(2) of this section.

(4) For each Part D plan and each NDC–11, CMS subtracts the total direct and indirect remuneration amounts minus ERPOSA amount calculated in paragraph (b)(3) of this section, from the total negotiated price amounts calculated in paragraph (b)(2) of this section, and then divide by the total units dispensed also determined in paragraph (b)(2) of this section.

(5) Separately, CMS identifies the total number of individuals enrolled in all Part D plans in December for the year set forth in paragraph (b)(1) of this section and the total number of individuals enrolled in each Part D plan in that same month. The Part D plans included in the calculations of this step will be restricted to Part D plans with at least one PDE record for that NDC–11 identified in paragraph (b)(1) of this section.

(6) For each Part D plan and each NDC–11, CMS divides the total number of Part D beneficiaries enrolled in the Part D plan as identified in paragraph (b)(5) of this section by the total number of individuals enrolled in all Part D plans also as identified in paragraph (b)(5) of this section, and multiplies this quotient by the price per unit, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan (as calculated in paragraph (b)(4) of this section) to arrive at the plan-specific enrollment weighted amount.

(7) For each NDC–11, CMS sums the amounts calculated in paragraph (b)(6) of this section across all Part D plans to calculate the sum of the plan-specific enrollment weighted amounts.

(8) For each NDC–11, CMS multiplies the sum of the plan-specific enrollment weighted amounts (as calculated in paragraph (b)(7) of this section), which are a per-unit price, by the NDC–11 average number of units per 30-day equivalent supply calculated from PDE data for the year set forth in paragraph (b)(1) of this section, (that is, quotient of the total quantity dispensed and the total 30-day equivalent supply as described in paragraph (b)(8)(i)) to yield the price of a 30-day equivalent supply. This calculation results in the sum of the plan-specific enrollment weighted amounts for each NDC–11 identified based on the criteria as set forth in (a)(1) of this section.

(i) For each NDC–11, CMS calculates the quotient of total dispensed and total 30-day equivalent supply to calculate the NDC–11 average number of units per 30-day equivalent supply.

(9) For each NDC–11, CMS divides the total 30-day equivalent supply for that NDC–11 by the total 30-day equivalent supply across all NDC–11s of the selected drug, both calculated from PDE data from the year set forth in paragraph (b)(1) of this section and multiplies this quotient by the sum of the plan-specific enrollment weighted amounts for a 30-day equivalent supply as calculated in paragraph (b)(8) of this section.

(10) CMS sums amounts calculated in paragraph (b)(9) of this section, across all NDC–11s of the selected drug to generate the sum of the plan-specific enrollment weighted amounts for the selected drug for a 30-day equivalent supply.

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (b) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.425 Determination of the payment amount under section 1847A(b)(4) of the Act.

(a) *Determination of the payment amount under section 1847A(b)(4) of the Act.* CMS calculates the payment amount under section 1847A(b)(4) of the Act, which is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation, for a 30-day equivalent supply across all dosage forms and strengths of a selected drug.

(1) As set forth in § 429.100(f), CMS uses NDC–11s from the list of NDC–11s of the selected drug as set forth in paragraph § 429.100(c) to determine which NDC–11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in paragraph (a) of this section that meet the following criteria:

(i) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(ii) The NDC–11 does not represent a sample package;

(iii) The NDC–11 is assigned to a HCPCS code;

(iv) The NDC–11 does not represent a self-administered drug; and

(v) CMS observes any instances of Part B data for the HCPCS code to which the NDC–11 is assigned during the

calendar year as set forth in § 429.425(a).

(vi) The Part B data meets the inclusion and exclusion criteria as set forth in § 429.120(b)(1)(ii) through (vi) and (b)(2)(ii) through (ix).

(2) *Calculating the payment amount under section 1847A(b)(4) of the Act.* CMS calculates the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which any NDC–11 identified in paragraph (a)(1) are assigned, and then assigns such payment amount to each NDC–11 of the selected drug within such HCPCS code.

(i) CMS calculates separately, the annual ASP and WAC amounts for the HCPCS code, by converting quarterly ASP and WAC data for the year set forth in paragraph (a) of this section, for each NDC–11 of a selected drug as set forth in § 429.100(c) that is associated with a HCPCS code, to an annual calendar year ASP and WAC amount for each HCPCS code by taking an average of the reported ASP and WAC amounts for the NDC–11s associated with the HCPCS code across all four quarters of such calendar year, weighted by the total number of billing units in the Part B data for that HCPCS code each quarter.

(A) If the total number of billing units in the Part B data for the HCPCS code are zero for a given quarter, CMS assigns that quarter the lowest positive total units from among the other quarters in the same calendar year for that HCPCS code.

(B) For each of the separate ASP and WAC calculations, if the reported price is negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code in a given quarter for the calendar year as set forth in paragraph (a) of this section, CMS excludes that quarter from the applicable calculation.

(C) If the WAC reported to the ASP portal is negative, zero, missing for all applicable NDC–11s assigned to the HCPCS code for all four quarters of the calendar year as set forth in § 429.425(a) but the reported ASP is positive for at least one of the NDC–11s assigned to the HCPCS code, CMS uses the WAC reported by the Primary Manufacturer of the selected drug to CMS under section 1194(e)(1) of the Act as described in § 429.505(a).

(ii) CMS determines the lesser of the annual ASP and the annual WAC as determined under paragraph (a)(2)(i) of this section to yield the payment amount under section 1847A(b)(4) of the Act for the associated HCPCS code. This amount will apply to all applicable NDC–11s assigned to the associated HCPCS code.

(iii) Notwithstanding paragraphs (a)(2)(i) and (ii) of this section, if ASP,

WAC reported to the ASP payer portal, and WAC reported by the Primary Manufacturer pursuant to section 1194(e)(1) of the Act as described in § 429.505(b)(2) are negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code for all four quarters of the calendar year as set forth in paragraph (a) of this section, CMS takes the average of the published payment limits in the ASP pricing file (or in the OPPS Addendum B file, if it is not available in the ASP pricing file) for the HCPCS code across all four quarters, weighted by the total number of billing units in the Part B data for that HCPCS code for the four quarters as described in paragraph (a)(2)(i) of this section (including the adjustments made when billing units zero) to calculate the payment amount under section 1847A(b)(4) of the Act.

(3) *Allocating HCPCS code-level utilization from Part B data for Part B services.* CMS allocates HCPCS code-level utilization from Part B data across each NDC–11 of the selected drug, identified in paragraph (a)(1) of this section, assigned to such HCPCS code.

(i) CMS allocates HCPCS code-level utilization from Part B data using the proportion of ASP units reported by manufacturers to CMS for each NDC–11 that is assigned to the HCPCS code.

(ii) CMS converts the total billing units in Part B data for the HCPCS code that includes the selected drug to determine the units that are comparable to NCPDP units that are used in PDE records of the total Part B billing units for the NDC–11 of the selected drug using the following steps:

(A) For each NDC–11 assigned to a HCPCS code to which an NDC–11 of the selected drug is assigned for each quarter (including NDC–11s that do not belong to the selected drug, if applicable), calculates the total number of billing units sold for each NDC–11 by multiplying the number of units reported by a manufacturer at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(B) Divides the billing units sold for a NDC–11, as calculated in paragraph (a)(3)(ii)(A) of this section, by the total billing units sold for all NDC–11s within the same HCPCS code.

(C) Multiplies the total billing units from Part B data for the HCPCS code by the quotient calculated in paragraph (a)(3)(ii)(B) of this section, to determine the total Part B billing units for each NDC–11 of the selected drug.

(D) Notwithstanding paragraphs (a)(3)(ii)(A) through (C) of this section, if there are no units as measured on PDE records, the Part B unit type is not converted to a PDE unit type.

(4) *Calculating the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug.* CMS calculates the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of each NDC–11 identified based on the criteria as set forth in paragraph (a)(1) of this section.

(i) For each selected drug, CMS identifies the NDC–11s and the unique HCPCS code(s) associated with the selected drug using the criteria set forth in paragraph (a)(1) of this section.

(A) CMS identifies the annual calendar year set forth in paragraph (a) of this section, for the payment amount under section 1847A(b)(4) of the Act for each HCPCS code and assigns it to each NDC–11 within that HCPCS code.

(ii) CMS sums the converted Part B units from Part B data attributed to each NDC–11 (as calculated in paragraph (a)(3) of this section), across all four quarters of the calendar year as set forth in paragraph (a) of this section to calculate the annual Part B units of that NDC–11.

(iii) CMS calculates the total Part B 30-day equivalent supply in Part B data attributed to that NDC–11 of calendar year as set forth in § 429.425(a).

(iv) CMS calculates the quotient of the annual Part B units in Part B data for each NDC–11 of the selected drug (as calculated in paragraph (a)(4)(ii) of this section), and the total Part B 30-day equivalent supply in Part B data (as calculated in paragraph (a)(4)(iii) of this section) which is the average number of units per 30-day equivalent supply.

(v) CMS multiplies the payment amount under section 1847A(b)(4) of the Act (as determined in paragraph (a)(4)(i) of this section), by the average number of units per 30-day equivalent supply (as calculated in paragraph (a)(4)(iv) of this section), to yield the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for each NDC–11 of the selected drug.

(vi) CMS divides the total 30-day equivalent supply for each NDC–11 (as calculated in paragraph (a)(4)(iii) of this section) by the total 30-day equivalent supply across all NDC–11s of the selected drug and multiplies this quotient by the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC–11 (as calculated in paragraph (a)(4)(v) of this section).

(vii) CMS sums the amounts calculated in paragraph (a)(4)(v)(B) of this section, across all NDC–11s of the selected drug to generate the payment amount under section 1847A(b)(4) of the Act for the selected drug for a 30-day equivalent supply.

(b) CMS does not apply the sequestration payment adjustment (as defined in § 429.20 of this chapter) to the payment amount under section 1847A(b)(4) of the Act as part of this methodology to calculate the payment amount under section 1847A(b)(4) of the Act.

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraphs (a)(2) through (a)(4) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.430 Determination of the combined Part B and Part D amount.

(a) *Determination of the combined Part B and Part D amount.* CMS calculates a single amount referred to as the combined Part B and Part D amount for a selected drug as set forth in § 429.410(b)(1)(iii) using the following methodology.

(1) CMS calculates the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420, and the payment amount under section 1847A(b)(4) of the Act, as set forth in § 429.425, for all dosage forms and strengths of a selected drug that is payable under Part B and covered under Part D as a 30-day equivalent supply by:

(i) Separately calculating the sum of the plan-specific enrollment weighted amounts, as set forth in paragraph § 429.420, and the payment amount under section 1847A(b)(4) of the Act, as set forth in paragraph § 429.425, using the following steps:

(A) If an NDC–11 is only present in PDE data, CMS calculates only the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply for that NDC–11 as set forth in paragraph § 429.420.

(B) If an NDC–11 is only associated with a Part B HCPCS code that is present in Part B data, CMS calculates only the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC–11 as set forth in paragraph § 429.425.

(C) If an NDC–11 is both present in PDE data and is associated with a Part B HCPCS code that is present in Part B data, CMS calculates both the sum of the plan-specific enrollment weighted amount per 30-day equivalent supply and the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC–11.

(1) If an NDC–11 is present in both PDE data and associated with a HCPCS code present in Part B data, CMS treats

each version as a distinct NDC–11 in this step of the calculation.

(ii) For each NDC–11 identified in paragraph (a)(1)(i)(A) of this section present in PDE data, CMS calculates the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply, as set forth in § 429.420(b)(1) through (8), and the total 30-day equivalent supply.

(iii) For each NDC–11 identified in paragraph (a)(1)(i)(B) of this section associated with a HCPCS present in Part B data, CMS calculates the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply, as set forth in § 429.425(a)(4), and the total 30-day equivalent supply.

(2) CMS calculates a combined sum of the weighted averages of the sum of the plan-specific enrollment weighted amounts and the payment amounts under section 1847A(b)(4) of the Act per 30-day equivalent supply for these NDC–11s, using the respective utilization for the NDC–11 in Part B and Part D as described in the following steps:

(i) For each NDC–11 identified in paragraphs (a)(1)(ii) and (iii) of this section, CMS divides the total 30-day equivalent supply for that NDC–11 by the total 30-day equivalent supply across all NDC–11s (both those present in PDE data and those associated with HCPCS present in Part B data) of the selected drug, and multiplies this quotient by either the sum of the plan-specific enrollment weighted amounts or the payment amount under section 1847A(b)(4) of the Act, respectively, per 30-day equivalent supply of that NDC–11.

(A) If an NDC–11 is present in both PDE data and associated with a HCPCS code present in Part B data, CMS treats each version as a distinct NDC–11 in this step of the calculation.

(ii) CMS sums the amounts calculated in paragraph (a)(2)(i) of this section, across all NDC–11s of the selected drug (including both the Part B version and the Part D version of NDC–11s that are present in both PDE records associated with HCPCS codes present in Part B data), to generate the combined sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act for the selected drug for a 30-day equivalent supply.

(3) Paragraphs (a)(2)(i) and (ii) of this section, result in the combined sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act across all NDC–9s of the selected drug.

(b) *Suggestion of Error.* A Primary Manufacturer that believes in good faith

that CMS has made an error in the calculations specified in paragraph (a) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.435 Determination of the applicable average non-FAMP amounts and applicable percent of the average non-FAMP.

(a) *Determination of the average non-FAMP.* CMS calculates and determines the lower of the two applicable average non-FAMP amounts, as set forth in paragraphs (a)(1) and (a)(2) of this section, and determines the applicable percent of the average non-FAMP to apply, as set forth in paragraph (a)(4) of this section, for all selected drugs, subject to § 429.440(b)(4), if applicable.

(1) *Average non-FAMP in calendar year 2021.* As described in section 1194(c)(1)(C)(ii)(I) of the Act, CMS calculates an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021 (or for the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated), increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.

(i) As set forth in § 429.100(f), CMS uses NDC-11s from the list of NDC-11s of the selected drug as set forth in paragraph § 429.100(c) to determine which NDC-11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in (a)(1) of this section that meet the following criteria:

(A) The NDC-11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by Secondary Manufacturer(s);

(B) The NDC-11 does not represent a sample package;

(C) CMS received non-FAMP data for the NDC-11 for at least one calendar quarter in calendar year as set forth in paragraph (a)(1) of this section; and

(D) CMS observes any PDE days' supply and PDE quantity dispensed or any Part B data associated with the HCPCS code to which the NDC-11 is assigned in calendar year as set forth in paragraph (a)(1) of this section.

(E) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (a)(5) or the Part B data meets the inclusion and exclusion criteria as set forth in

§ 429.120(b)(1)(ii) through (vi) and (b)(2)(ii) through (ix).

(ii) CMS uses the non-FAMP price and unit volume data for each NDC-11 that meets the criteria as set forth in paragraph (a)(1)(i) of this section, to be included in this average non-FAMP calculation.

(iii) CMS uses the data that is submitted by the Primary Manufacturer in accordance with section 1193(a)(4)(A) of the Act, as set forth in § 429.405, for each quarter of calendar year 2021 to calculate an annual average non-FAMP per unit for calendar year set forth in paragraph (a)(1) of this section.

(iv) CMS uses 2021 PDE quantity dispensed and days' supply data (or data for the first full year following market entry for such drug if such data is not available for 2021) submitted to CMS at the NDC-11 level by Part D plan sponsors, and total Part B billing units from Part B data and 30-day equivalent supply data at the HCPCS code-level, as applicable, to calculate:

(A) An annual average non-FAMP per unit for each NDC-11 of the selected drug.

(B) The annual average non-FAMP per 30-day equivalent supply for each NDC-11 of the selected drug.

(C) The annual average non-FAMP per 30-day equivalent supply for the selected drug.

(2) *Average non-FAMP for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.* As described in section 1194(c)(1)(C)(ii)(II) of the Act, CMS calculates an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP for the year prior to the selected drug publication date with respect to such initial price applicability year (that is, for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation).

(i) As set forth in § 429.100(f), CMS uses NDC-11s from the list of NDC-11s of the selected drug as set forth in paragraph § 429.100(c) to determine which NDC-11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in (a)(2) of this section that meet the following criteria:

(A) The NDC-11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(B) The NDC-11 does not represent a sample package;

(C) CMS received non-FAMP data for the NDC-11 for at least one calendar quarter during the calendar year and as

set forth in paragraph (a)(2) of this section; and

(D) CMS observes any PDE days' supply and PDE quantity dispensed or any Part B data associated with the HCPCS code to which the NDC-11 is assigned in the calendar year as set forth in paragraph (a)(2) of this section.

(E) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (a)(5) or the Part B data meets the inclusion and exclusion criteria as set forth in § 429.120(b)(1)(ii) through (vi) and (b)(2)(ii) through (ix).

(ii) CMS uses the non-FAMP price and unit volume data for each NDC-11 that meets the criteria as set forth in paragraph (a)(2)(i) of this section, to be included for the calendar year set forth in paragraph (a)(2) of this section using the same methodology described in paragraphs (a)(1)(ii) through (iv) of this section to calculate the average non-FAMP.

(3) *Applicable percent of the average non-FAMP.* For each calendar year set forth in paragraphs (a)(1) and (a)(2) of this section, CMS calculates:

(i) The applicable percent of the average non-FAMP for each NDC-11 of the selected drug as a 30-day equivalent supply (in accordance with the methodology described in § 429.415).

(ii) The applicable percent of the average non-FAMP across the NDC-11s of the selected drug as a 30-day equivalent supply.

(4) To determine the average non-FAMP for each NDC-11 and across all NDC-11s of the selected drug, CMS conducts the following steps separately for the calendar years set forth in paragraphs (a)(1) and (a)(2) of this section:

(i) For each NDC-11 and for each quarter during the calendar year, CMS calculates the non-FAMP per unit by dividing the non-FAMP per package by the total number of NCPDP units per package.

(A) For the calendar year set forth in paragraph (a)(1) of this section only, if the non-FAMP is missing for all NDC-11s of the selected drug for such calendar year, as set forth in § 429.405, then CMS uses the non-FAMP for the quarters of the first full calendar year following the market entry for such drug.

(ii) For each NDC-11 and for each quarter during the calendar year, CMS divides the total unit volume (calculated as the product of the total number of packages sold from manufacturer-reported non-FAMP data and the number of units per package) in that quarter by the total unit volume across all four quarters during the calendar

year (also calculated from manufacturer-reported non-FAMP data), and multiply this quotient by the non-FAMP per unit calculated in paragraph (a)(4)(i) of this section.

(A) For the calendar year set forth in paragraph (a)(1) of this section only, if the non-FAMP is missing for all NDC-11s of the selected drug for such calendar year, as set forth in § 429.405, then CMS uses the non-FAMP and total unit volumes for the quarters of the first full calendar year following the market entry for such drug.

(iii) For each NDC-11, CMS sums the amounts calculated in paragraph (a)(4)(ii) of this section across quarters to calculate the average non-FAMP per unit for that NDC-11 for the calendar year.

(iv) For each NDC-11, CMS divides the total units for that NDC-11 by the total units for all applicable NDC-11s and multiplies this quotient by the average non-FAMP per unit for the calendar year calculated in paragraph (a)(4)(iii) of this section, applying the methodology that follows, as applicable:

(A) For NDC-11s that are present only in PDE data: Total units are defined as the total quantity dispensed for an NDC-11 as determined using the applicable calendar year as set forth in paragraphs (a)(1) and (a)(2) of this section and PDE data identified in § 429.410(b)(5)(iii) and (iv).

(B) For NDC-11s that are only associated with HCPCS codes present in Part B data: Total units are defined as the total Part B units for an NDC-11 as determined using the unit allocation and standardization methodology described for calculating converted Part B units attributed to the NDC-11 as set forth in § 429.425(a)(3).

(C) For NDC-11s that are both present in PDE data and associated with HCPCS codes present in Part B data: Total units are defined as the sum of the total quantity dispensed for the NDC-11 and the total Part B units for an NDC-11 as determined using the unit allocation and standardization methodology described in § 429.425(a)(3).

(v) For the calendar year as set forth in paragraph (a)(1) of this section only: for each NDC-11, CMS then increases the average non-FAMP per unit calculated in paragraph (a)(4)(iv) of this section by the percentage increase in CPI-U (all items; United States city average) as set forth in paragraph (a)(1) of this section.

(A) Notwithstanding paragraph (a)(4)(v) of this section, CMS does not apply a CPI-U adjustment to the average non-FAMP per unit for the calendar year described in paragraph (a)(2) of this section.

(vi) For each NDC-11, after CMS calculates the average non-FAMP per unit for the calendar year (as calculated in paragraph (a)(4)(iv) of this section for the calendar year as set forth in paragraph (a)(2) of this section and as calculated in paragraph (a)(4)(v) of this section for the calendar year as set forth in paragraph (a)(1) of this section), CMS applies the applicable percent specified in section 1194(c)(3) of the Act for the monopoly type which are set forth in paragraphs (A)(1) through (3) of this section and are determined for the selected drug based on its initial approval date as set forth in § 429.125(a)(1)(i) and the initial price applicability year for which the drug is selected for negotiation.

(A) The monopoly types and applicable percent are:

(1) A short-monopoly drug or vaccine, as described in section 1194(c)(3)(A) of the Act, is a selected drug other than an extended-monopoly drug and a long-monopoly drug, for which the applicable percent is 75 percent.

(2) An extended-monopoly drug, as described in section 1194(c)(3)(B) of the Act and defined in § 429.20, for which the applicable percent is 65 percent.

(3) A long-monopoly drug, as described in section 1194(c)(3)(C) of the Act and defined in § 429.20, for which the applicable percent is 40 percent.

(vii) For each NDC-11, CMS then multiplies the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable per paragraph (a)(4)(v) of this section, and with the applicable percent applied as determined in paragraph (a)(4)(vi) of this section by the quotient of total units divided by the total 30-day equivalent supply.

(viii) CMS sums the amounts calculated in paragraph (a)(4)(vii) of this section, across all NDC-11s of the selected drug to calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable per paragraph (a)(4)(v) of this section, and with the applicable percent applied as specified in paragraph (a)(4)(vi) of this section, for the selected drug.

(ix) CMS compares the amount calculated in paragraph (a)(4)(viii) of this section for the applicable percent of the calendar year described in paragraph (a)(1) of this section average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, with the amount calculated in paragraph (a)(4)(viii) of this section for the applicable percent of the calendar year described in paragraph (a)(2) of this section average non-FAMP per 30-day equivalent supply for the

calendar year and determines which is lower.

(b) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (a) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.440 Temporary floor for Small Biotech Drugs.

(a) *Definitions.* For the purposes of this section, the following definitions apply:

(1) *Part B 2021 Manufacturer* means the NDA holder or the BLA holder for the qualifying single source drug on December 31, 2021.

(2) *Part D 2021 Manufacturer* means the entity that either (1) had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A of the Act in effect for the qualifying single source drug on December 31, 2021, or (2) had an arrangement whereby the manufacturer's labeler codes were listed on another manufacturer's Medicare CGDP Agreement, consistent with section 1860D-14A of the Act, in effect on December 31, 2021.

(3) *Part B 2021 Manufacturer and its controlled group* comprises all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer.

(4) *Part D 2021 Manufacturer and its controlled group* comprises all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021.

(b) *General rule.* For a drug selected for negotiation for initial price applicability year 2029 or 2030, or a drug selected for renegotiation for initial price applicability year 2029 or 2030, for which the Primary Manufacturer submits information in accordance with paragraph (b)(1) of this section and CMS determines that such drug meets the requirements set forth in paragraph (b)(2) of this section, CMS will not make an offer (or agree to a counteroffer) for an MFP (as described in § 429.500(b)) that is lower than the Temporary Floor for Small Biotech Drugs, which must be equal to the amount specified in paragraph (b)(3) of this section.

(1) *Temporary Floor for Small Biotech Drugs submission.* For a selected drug to be considered for eligibility for the Temporary Floor for Small Biotech

Drugs, such drug's Primary Manufacturer must submit information to CMS regarding the eligibility criteria described in paragraph (b)(2) of this section as relevant to such drug, in the form and manner specified by CMS.

(2) *Eligibility for the Temporary Floor for Small Biotech Drugs.* To be eligible for the Temporary Floor for Small Biotech Drugs, CMS must determine either that the selected drug is covered under Part D and meets the requirements of the Part D Track set forth in paragraph (b)(2)(i) of this section or that the selected drug is payable under Part B and meets the requirements of the Part B Track set forth in paragraph (b)(2)(ii) of this section.

(i) *Part D Track.* To meet the requirements of the Part D Track, the total expenditures under Part D during 2021 for the selected drug (calculated using the methodology set forth in § 429.120(a), except the date of service as described in § 429.120(a)(1) is during 2021) must be:

(A) Equal to or less than 1 percent of the total expenditures under Part D for all covered Part D drugs during 2021; and

(B) Equal to or greater than 80 percent of the total expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had an agreement in effect under section 1860D–14A on December 31, 2021.

(ii) *Part B Track.* To meet the requirements of the Part B Track, the total expenditures under Part B during 2021 for the selected drug calculated using the methodology set forth in § 429.120(b), except the date of service as described in § 429.120(b)(1)(i) and (b)(2)(i) is during 2021, must be:

(A) Equal to or less than 1 percent of the total expenditures under Part B for all qualifying single source drugs payable under Part B during 2021; and

(B) Equal to or greater than 80 percent of the total expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group that are payable under Part B during 2021.

(iii) *Limitation.* A selected drug will not be eligible for the Temporary Floor for Small Biotech Drugs if the Primary Manufacturer of such drug was acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an

acquisition before 2025, effective January 1, 2025.

(3) *Determination of the Temporary Floor for Small Biotech Drugs.* CMS calculates the Temporary Floor for Small Biotech Drugs with respect to each selected drug that CMS determines to be eligible, under paragraph (b)(2) of this section, as 66 percent of the following amount, as applicable:

(i) Subject to paragraph (b)(3)(ii) of this section, the average non-FAMP in calendar year 2021, calculated using the methodology set forth in § 429.435, increased by the percentage increase in the CPI–U from September 2021 to September of the year prior to the selected drug publication date for which the drug is selected for negotiation or, as applicable, renegotiation.

(ii) In the case that there is not an average non-FAMP available for such drug for 2021, the average non-FAMP for the first full year following market entry, increased by the percentage increase in the CPI–U from December of such first full year following market entry to September of the year prior to the selected drug publication date for which the drug is selected for negotiation or, as applicable, renegotiation.

(4) *Determination of the adjusted ceiling for the MFP exception.* In the event that the ceiling identified in § 429.410(b) (or § 429.620(b) as applicable) for a Small Biotech Drug is below the Temporary Floor for Small Biotech Drugs for such Small Biotech Drug, as described in paragraph (b)(3) of this section, then, notwithstanding § 429.410 (or § 429.620 as applicable), CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the adjusted ceiling determined under paragraphs (b)(4)(i) or (ii) of this section, as applicable, and calculates such adjusted ceiling amount as follows:

(i) CMS excludes the non-FAMP ceiling amount identified under sections 1194(c)(1)(C)(i) or 1194(c)(1)(C)(ii)(I) of the Act from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable, with respect to such selected drug. If the resulting ceiling amount is equal to or above the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410 or § 429.620(b), such resulting ceiling amount applies as the ceiling.

(ii) If the adjusted ceiling determined under paragraph (b)(4)(i) of this section is below the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410 or § 429.620(b), the adjusted ceiling equals the Temporary Floor for Small Biotech

Drugs established in paragraph (b)(3) of this section.

(5) *Notice of determination.* After review of an application made in accordance with paragraph (b)(1) of this section, CMS provides a notice in writing to the Primary Manufacturer, alongside the calculation information provided as set forth in § 429.445(a), of:

(i) A determination of whether the selected drug is a Small Biotech Drug; and

(ii) If the selected drug is eligible for the Temporary Floor for Small Biotech Drugs, the calculation of the Temporary Floor for Small Biotech Drugs set forth in § 429.440(b)(3) and the calculation of the ceiling (or adjusted ceiling, if applicable, set forth in § 429.440(b)(4).

(6) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (b)(3) or (b)(4) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.445 Calculation information and suggestion of error.

(a) *Calculation Information.* CMS provides a Primary Manufacturer with the following, as applicable:

(1) Information on CMS' calculation of the ceiling, as described in §§ 429.410 through 429.435;

(2) The computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug, as described in § 429.700(b) and (c); and

(3) Information on CMS' calculation of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable), as described in § 429.440(b)(3) and (b)(4).

(b) *Timing.*

(1) CMS intends to provide the information specified in paragraphs (a)(1), (a)(2), and (a)(3) (as applicable) of this section:

(i) Following the Primary Manufacturer's submission of data set forth in §§ 429.100(d), 429.405(a), 429.440(b)(1), and 429.505(b)(2); and

(ii) Following the Primary Manufacturer's submission of data set forth in § 429.615(b)(1).

(2) CMS intends to provide the information specified in paragraph (a)(2) of this section:

(i) Following the Primary Manufacturer's submission of data set forth in § 429.100(e); and

(ii) Following the determination by CMS that an NDC with insufficient data, as described in proposed § 429.700(c)(3), has sufficient data as described in § 429.700(c)(4)(i)(B)(2).

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraphs (a)(1), (a)(2), or (a)(3) of this section may submit a Suggestion of Error pertaining to such calculations for CMS' consideration.

(1) A Primary Manufacturer must submit a Suggestion of Error within 10 days of receiving information under paragraph (a) of this section from CMS.

(2) The Suggestion of Error process does not affect a Primary Manufacturer's obligation to comply with Negotiation Program requirements and does not alter or change any timelines or requirements of the Negotiation Program.

(d) *Method and process.* A Primary Manufacturer must submit any Suggestion of Error, as described in paragraph (c) of this section, in a form and manner specified by CMS.

Subpart F—Negotiation Process

§ 429.500 General rule.

(a) CMS has a consistent methodology and process for negotiating MFPs as set forth in this subpart. For purposes of negotiating or renegotiating the MFP of a selected drug in accordance with such methodology and process, CMS:

(1) Aims to achieve agreement on the lowest MFP for each selected drug consistent with section 1194(b)(1) of the Act; and

(2) Considers the factors set forth in section 1194(e) of the Act and § 429.505, as applicable to the selected drug, in determining offers and counteroffers.

(b) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP.

§ 429.505 Negotiation factors.

(a) For purposes of negotiating the maximum fair price of a selected drug with the Primary Manufacturer, CMS considers the Primary Manufacturer-required data specified in § 429.505(b)(2) and evidence about the selected drug and therapeutic alternatives specified in § 429.505(d)(3), as applicable to the drug, as the basis for determining the offers and counteroffers for the selected drug.

(b) *Primary Manufacturer-required data.*

(1) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer must submit the information in paragraph (b)(2) of this section to CMS in a form and manner specified by CMS by 11:59 p.m. PST on

March 1 of the year of the selected drug publication date for the selected drug, inclusive of the NDC-11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

(2) Primary Manufacturer required data includes—

(i) Research and development costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped research and development costs;

(ii) Current unit costs of production and distribution of the selected drug;

(iii) Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;

(iv) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration (FDA), and applications and approvals under section 505(c) of the FD&C Act (21 U.S.C. 355(c) or section 351(a) of the PHS Act (42 U.S.C. 262(a)) for the selected drug; and

(v) Market data and revenue and sales volume data for the selected drug in the United States.

(c) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, a Primary Manufacturer is required to provide updates to the information described in paragraph (b)(2) of this section for the drug selected for negotiation in a form and manner prescribed by CMS if the Primary Manufacturer becomes aware that any of such information has changed or is otherwise inaccurate.

(d) *Evidence about the selected drug and therapeutic alternatives—*

(1) Any interested party, including the Primary Manufacturer of a selected drug, may choose to submit the information set forth in paragraph (d)(3) of this section to CMS in a form and manner specified by CMS.

(2) Interested parties must submit the information in paragraph (d)(3) of this section by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for a selected drug in a form and manner specified by CMS.

(3) Evidence about the selected drug and therapeutic alternatives includes—

(i) The extent to which a selected drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives;

(ii) Prescribing information approved by the FDA for a selected drug and therapeutic alternatives to such selected drug;

(iii) Comparative effectiveness of a selected drug and therapeutic

alternatives to such selected drug, taking into consideration the effects of the selected drug and therapeutic alternatives to such selected drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations; and

(iv) The extent to which a selected drug and therapeutic alternatives to such selected drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

(e) *Limitation on evidence.* CMS will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(1) CMS reviews cost-effectiveness measures used in studies relevant to a selected drug to determine whether the use of the measure is permitted in accordance with section 1194(e)(2) of the Act as described at paragraph (e) of this section, as well as section 1182(e) of the Act and other applicable law.

(2) CMS may use content in a study that uses a cost-effectiveness measure if it determines that the cost-effectiveness measure used is permitted in accordance with section 1194(e)(2) of the Act as described at paragraph (e) of this section, as well as section 1182(e) of the Act and other applicable law.

§ 429.510 Methodology for developing the initial offer.

(a) *Identification of conditions for which the selected drug is used.* CMS identifies the condition(s) for which the selected drug is used that are covered under Part D, payable under Part B, or both.

(1) CMS considers the prescribing information for the selected drug in accordance with section 1194(e)(2)(B) of the Act.

(2) CMS may consider off-label use as defined in § 429.20.

(3) CMS excludes FDA-approved indications and off-label use, if applicable, from its analysis when CMS believes that utilization of the selected drug within such indication(s) and for such uses is intended solely for use in a setting in which the selected drug is not payable under Part B and not covered under Part D.

(b) *Information used to identify a therapeutic alternative(s) for the selected drug.*

(1) CMS identifies the therapeutic alternative(s) for each condition(s) for which the selected drug is used as

determined under § 429.510(a) using any combination of the following, as available:

(i) Information submitted by the Primary Manufacturer and the public as described in § 429.505(b)(2) and (d)(3);

(ii) Prescribing information as approved by the FDA;

(iii) Drug classification systems commonly used in the public and private sector for formulary development;

(iv) Major drug compendia;

(v) Widely accepted clinical practice guidelines;

(vi) Evidence identified through a CMS-led literature review;

(vii) Published drug or drug class reviews;

(viii) Peer-reviewed studies or other clinical evidence and information submitted by the Primary Manufacturer and the public; or

(ix) Medicare claims or other data sets.

(2) The therapeutic alternative(s) may be a brand name drug, a brand name biological product, a generic drug, or a biosimilar, including specific formulations or dosage forms and strengths of such brand name drug, brand name biological product, generic drug, or biosimilar.

(c) *Process for determining the potential therapeutic alternative(s) for a selected drug.*

(1) CMS may consult with FDA, clinicians, patients or patient organizations, and researchers.

(2) When determining a therapeutic alternative(s) for a selected drug, CMS considers:

(i) Off-label use(s) for potential therapeutic alternatives as defined in § 429.20;

(ii) Potential therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action;

(iii) Potential therapeutic alternatives in a different pharmacologic class than the selected drug; and

(iv) Formulations or dosage forms and strengths of a potential therapeutic alternative.

(3) CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug.

(4) CMS prioritizes clinical appropriateness when identifying the therapeutic alternative(s) for a selected drug.

(d) *Determining a starting point for the initial offer.*

(1) CMS determines the price of each therapeutic alternative determined under paragraph (c) of this section:

(i) For a therapeutic alternative covered under Part D, the price is the lower of:

(A) The Net Part D Plan Payment and Beneficiary Liability of the therapeutic alternative;

(B) The MFP of the therapeutic alternative, if applicable; or

(C) The WAC of the therapeutic alternative.

(ii) For a therapeutic alternative payable under Part B, the price is the lower of:

(A) The ASP of the therapeutic alternative;

(B) The MFP of the therapeutic alternative, if applicable; or

(C) The WAC of the therapeutic alternative.

(iii) For a therapeutic alternative that is both covered under Part D and payable under Part B, CMS combines the prices determined in paragraphs (d)(1)(i) and (d)(1)(ii) of this section using an approach similar to the methodology used to combine the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act to calculate the combined Part B and Part D amount, as described in § 429.430.

(2) The prices determined in accordance with paragraph (d)(1) of this section will be expressed as a 30-day equivalent supply.

(i) For a therapeutic alternative(s) covered under Part D, the 30-day equivalent supply will be calculated as described in § 429.415(a)(1), unless CMS determines it is appropriate to apply an alternative methodology under paragraph (d)(2)(iv) of this section.

(ii) For a therapeutic alternative(s) payable under Part B, the 30-day equivalent supply will be calculated as described in § 429.415(a)(2), unless CMS determines it is appropriate to apply an alternative methodology under paragraph (d)(2)(iv) of this section.

(iii) For a therapeutic alternative(s) payable under Part B and covered under Part D, the 30-day equivalent supply will be calculated separately for the prices determined in paragraphs (d)(1)(i) and (d)(1)(ii) of this section using the methodology described in paragraphs (d)(2)(i) and (d)(2)(ii) of this section, unless CMS determines it is appropriate to apply an alternative methodology under paragraph (d)(2)(iv) of this section. The separate prices expressed as a 30-day equivalent supply for the therapeutic alternative as payable under Part B and as covered under Part D are then combined using the methodology described in paragraph (d)(1)(iii) of this section to result in one combined price expressed as a 30-day equivalent supply for the therapeutic alternative.

(iv) For a therapeutic alternative(s) covered under Part D, payable under Part B, or both, for which CMS has determined it is appropriate to apply an alternative methodology, the 30-day equivalent supply may be calculated using a tailored methodology that promotes comparability between the therapeutic alternative(s) and the selected drug.

(3) CMS uses the price(s) determined in paragraph (d)(1) of this section to determine the starting point for developing the initial offer.

(i) If there is no therapeutic alternative for the selected drug or if there is no price(s) of the therapeutic alternative(s) determined under paragraph (d)(1) of this section below the ceiling determined under § 429.410(b), then the starting point for developing the initial offer is the lower of:

(A) The pharmaceutical price for the selected drug as included in the Federal Supply Schedule as managed by the Department of Veterans Affairs per 48 CFR part 38 as most recently submitted by the Primary Manufacturer under § 429.505(b);

(B) The maximum price a manufacturer can charge for a selected drug under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacturer under § 429.505(b); or

(C) The ceiling for the selected drug as determined in § 429.410(b).

(ii) If there is more than one therapeutic alternative for the selected drug, and at least one price determined under paragraph (d)(1) of this section is below the ceiling determined under § 429.410(b), CMS determines a starting point for developing the initial offer within a range based on the lower of the prices listed in paragraph (d)(1) of this section and the ceiling determined under § 429.410(b).

(iii) If there is one therapeutic alternative for the selected drug with a price that is below the ceiling, the price of such therapeutic alternative is the starting point.

(e) *Adjusting the starting point based on section 1194(e)(2) factors.*

(1) CMS uses a qualitative approach to broadly evaluate the body of available evidence related to section 1194(e)(2) factors listed at § 429.505(d)(3) in totality, including any combination of the following, as available:

(i) Information submitted by the Primary Manufacturer and the public as described in § 429.505(b)(2) and (d)(3) and provided in public events described in § 429.515(b), as available;

(ii) Evidence identified through a CMS-led literature review;

(iii) Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug and its therapeutic alternative(s) as determined in paragraph (c) of this section, if any;

(iv) Clinical data;

(v) Other information relevant to the selected drug and its therapeutic alternative(s), if any.

(2) CMS may consult with FDA, clinicians, patients or patient organizations, and researchers.

(3) CMS identifies outcomes of interest to evaluate for each condition identified under § 429.510(a).

(i) The types of outcomes and contextual factors that CMS considers include:

(A) Clinical outcomes;

(B) Patient-centered outcomes, patient experience data, and patient-reported outcomes, if available;

(C) Additional outcomes and contextual factors or patient and caregiver preferences to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternative(s), if any; and

(D) Caregiver perspective to the extent that such perspective reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.

(ii) CMS identifies outcomes using:

(A) A CMS-led literature review; and

(B) Information submitted by the Primary Manufacturer and the public as described in § 429.505(b)(2) and (d)(3) and provided in public events described in § 429.515(b), as available.

(4) Based on the evaluation of evidence described in paragraphs (e)(1) through (3) of this section, CMS adjusts the starting point by considering the applicable evidence related to section 1194(e)(2) factors collectively and within the context of the course of care for each condition for which the selected drug is used.

(i) This assessment includes but is not limited to examining the improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by considering:

(A) The costs of the selected drug and its therapeutic alternative(s); and

(B) The magnitude of differences in outcomes of interest determined in paragraph (e)(3) of this section conferred by the selected drug compared to its therapeutic alternative(s) for each condition for which CMS has identified a therapeutic alternative.

(ii) Notwithstanding paragraph (e)(4)(i) of this section, if a condition

identified under paragraph (a) of this section does not have a therapeutic alternative as identified under paragraphs (b) and (c) of this section, then CMS considers:

(A) The totality of available information described in paragraph (e)(1) of this section;

(B) Any existing treatment option(s) to determine the extent to which the selected drug addresses an unmet medical need as defined in § 429.20 for each identified condition; and

(C) The magnitude of differences in outcomes of interest determined in paragraph (e)(3) of this section conferred by the selected drug to determine the extent to which the selected drug represents a therapeutic advance.

(5) The starting point may be adjusted upward, adjusted downward, or not adjusted based on considerations described in paragraphs (e)(1) through (4) of this section to determine the preliminary price.

(f) *Adjusting the preliminary price based on section 1194(e)(1) factors.*

(1) CMS considers the section 1194(e)(1) factors, specified in § 429.505(b)(2) and provided by the Primary Manufacturer, in totality in determining whether to adjust the preliminary price.

(2) The preliminary price may be adjusted upward, adjusted downward, or not adjusted based on CMS' consideration of the section 1194(e)(1) factors in totality as described in paragraph (f)(1) of this section.

(3) The price resulting from paragraphs (f)(1) and (f)(2) of this section is the initial offer.

(i) Notwithstanding paragraph (f)(3) of this section, if the amount determined in accordance with the process described in this section is above the ceiling as determined in § 429.410(b), then the initial offer will be equal to the ceiling, and if the amount determined in accordance with this section is below the temporary floor for small biotech drugs (as determined in § 429.440(b)), if applicable, then the initial offer will be equal to the temporary floor.

§ 429.515 Engagement with Primary Manufacturers and interested parties.

(a) *Engagement with Primary Manufacturers.* In a form and manner specified by CMS and in accordance with the rules set forth in this § 429.515, CMS hosts up to four optional meetings with Primary Manufacturers of selected drugs that have submitted the information set forth in § 429.505.

(1) *Meeting scope.* The first meeting that CMS offers Primary Manufacturers the option to attend is intended for the Primary Manufacturer to provide

additional context on their data submission of the section 1194(e)(1) factors and section 1194(e)(2) factors as set forth in § 429.505 as CMS begins evaluating the data submission and developing an initial offer as described in § 429.510.

(i) The remaining three meetings that CMS offers Primary Manufacturers the opportunity to attend focus on the section 1194(e)(1) factors and section 1194(e)(2) factors described in § 429.505 and other topics aimed at working towards an agreement on an MFP.

(ii) Notwithstanding paragraph (a)(1) of this section, new manufacturer-required data as described in § 429.505(b)(2) is not considered if it is submitted after the March 1 deadline.

(iii) Discussion of disputes and program policies regarding the negotiation process are considered out of scope.

(2) *Meeting attendance.* Meetings are attended solely by representatives of the Primary Manufacturer and of CMS. The number of attendees are limited as specified by CMS.

(3) *Meeting materials.* For the purposes of each meeting:

(i) Primary Manufacturers may provide the following to be presented and discussed at each meeting in a form and manner specified by CMS:

(A) New information on the section 1194(e)(2) factors

(B) Materials, including pages, slides, and charts and graphs, to facilitate discussion, which must comply with limits on the amount or format of such materials as specified by CMS.

(ii) CMS may request that the Primary Manufacturer provide copies of any presented or discussed materials after the meeting in which they are presented or discussed.

(4) *Meeting timing.* The first optional meeting, if accepted by the Primary Manufacturer, occurs, at a time to be specified by CMS, after the data submission deadline specified in § 429.505(b)(1) and (d)(2) and before the provision of CMS' initial offer, as set forth in § 429.520. Up to three optional meetings are offered by CMS to occur after the provision of CMS' initial offer. If the Primary Manufacturer accepts the meeting invitation(s), such meeting(s) occur, at a time to be specified by CMS, after the provision of CMS's initial offer as set forth in § 429.520 and before the provision of CMS' final offer, if applicable, as set forth in § 429.535.

(5) *Meeting rules.* A Primary Manufacturer—

(i) May maintain a written record of the negotiation process; and

(ii) Is prohibited from making an audio or video recording of any negotiation meeting.

(b) *Engagement with interested parties.* CMS may hold event(s) in a form and manner and at times to be specified by CMS to seek information from patients and other interested parties about selected drugs, therapeutic alternatives to the selected drugs, and other information. CMS may incorporate drugs selected for renegotiation into these events or may hold separate events, as applicable.

§ 429.520 Provision of CMS' written initial offer and concise justification.

(a) *Written initial offer.* CMS provides the Primary Manufacturer with the written initial offer no later than June 1 following the selected drug publication date as defined in § 429.20.

(1) This written initial offer is accompanied by an Addendum to the Negotiation Program Agreement, as described in § 429.200(e), populated with the proposal for the MFP. To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

(b) *Concise justification.* With the written initial offer, CMS includes a concise justification for the written initial offer based on the data set forth in § 429.505. The concise justification:

(1) Includes a qualitative description of the factors from section 1194(e) of the Act as set forth in § 429.505 and a description of the methodology that CMS used to develop the written initial offer as set forth under subpart F of this part.

(2) Provides the Primary Manufacturer with information on the range of evidence and other information considered in accordance with section 1194(e) of the Act that CMS found compelling during the development of the written initial offer.

(3) May include information obtained through events with interested parties as described at § 429.515(b).

§ 429.525 Statutory written counteroffers.

(a) *Primary Manufacturers' statutory written counteroffer.* The Primary Manufacturer must respond in writing within 30 days of receipt of the written initial offer from CMS by either accepting the written initial offer for the selected drug or making a statutory written counteroffer and providing a justification for such counteroffer based on the data set forth in § 429.505.

(b) *Required components.*

(1) Any statutory written counteroffer must:

(i) Provide a proposal for the MFP for the selected drug and a justification for such proposal;

(ii) Respond to the justification provided in CMS' written initial offer; and

(iii) Indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer described in § 429.505, or other available data as described in § 429.505(d), supports the Primary Manufacturer's statutory written counteroffer or otherwise does not support CMS' written initial offer.

(2) Primary Manufacturers must complete an Addendum to the Negotiation Program Agreement, as described in § 429.200(e), and must submit the statutory written counteroffer in a form and manner specified by CMS.

(c) *CMS response to statutory written counteroffer.* CMS responds in writing to a statutory written counteroffer made by the Primary Manufacturer.

(1) CMS considers the statutory written counteroffer and either accepts or rejects it in writing within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later.

(2) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

§ 429.530 Additional price exchange opportunities.

(a) *Additional price exchange opportunities.* CMS and Primary Manufacturers may initiate additional, written offers and counteroffers in a form and manner specified by CMS during the period of time between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the MFP, or at least 8 business days before the deadline by which CMS must issue the final offer, whichever is earlier, via the additional price exchange opportunities described in this section.

(1) The additional price exchange opportunities allow for the optional upload of materials which must comply with limits on the amount or format of such materials as specified by CMS, and include an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer.

(2) Only one written offer or counteroffer per selected drug may be active at a time.

(3) An offering or counteroffering party may archive its written offer or counteroffer in the period before the other party accepts or rejects it, but not afterwards.

(4) Parties do not need to alternate making written offers and counteroffers.

(5) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

§ 429.535 Notification of final offer and conclusion of negotiations.

(a) *Notification of final offer.* In the event neither CMS' initial offer nor the Primary Manufacturer's statutory written counteroffer were accepted, and an MFP was not agreed to during the negotiation meetings or via the additional price exchange functionality, CMS sends the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" and an Addendum with the final offer MFP by September 30 following the selected drug publication date defined in § 429.20.

(1) If a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by October 31 following the selected drug publication date defined in § 429.20.

(2) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

(b) *Conclusion of negotiations.* All negotiations between CMS and the Primary Manufacturer of the selected drug must end prior to November 1 following the selected drug publication date, with respect to the initial price applicability year.

Subpart G—Renegotiation of an MFP

§ 429.600 General rule.

(a) With respect to initial price applicability years beginning with initial price applicability year 2029, the process of renegotiation will include the following actions.

(1) CMS identifies renegotiation-eligible drugs, if any, as described in § 429.605.

(2) CMS selects drugs for renegotiation from among such renegotiation-eligible drugs, if any, as described in § 429.610.

(3) CMS renegotiates the MFP applicable to any such drugs selected for renegotiation in accordance with the process set forth in § 429.620.

(b) Applicability of a renegotiated MFP.

(1) Once the Primary Manufacturer and CMS have agreed upon a renegotiated MFP under the process set forth under § 429.620 with respect to a selected drug, the Primary Manufacturer is responsible for making the renegotiated MFP for the selected drug available, in accordance with subpart I of this part, with respect to dispenses, administrations, and furnishings of the selected drug on or after January 1 of the initial price applicability year for which the selected drug is selected for renegotiation (subject to proposed § 429.135) until termination of the Negotiation Program Agreement in accordance with proposed § 429.205.

(2) CMS applies a renegotiated MFP to all formulations across dosage forms and strengths of the selected drug by applying the methodology set forth at proposed § 429.700, notwithstanding proposed § 429.700(b)(1) and (2)(i) CMS uses the initial price applicability year of the renegotiated MFP to determine the applicable year of data.

(3) The Primary Manufacturer of a selected drug with a renegotiated MFP must provide access to the initial agreed-upon MFP in accordance with section 1193(a)(3), including as described in subpart I of this part, prior to the effective date of the renegotiated MFP as specified in paragraph (b)(1) of this section.

(c) Publication of the list of drugs selected for renegotiation. CMS publishes the drugs selected for renegotiation with respect to an initial price applicability year, if any, consistent with § 429.100(b)(2).

§ 429.605 Eligibility of drugs for renegotiation.

(a) For a selected drug with an agreed-upon MFP from a prior initial price applicability year—

(1) For any selected drugs with an agreed-upon MFP from a prior initial price applicability year for which CMS does not make a determination described in § 429.135(c), CMS reviews such drugs for renegotiation eligibility in accordance with section 1194(f)(2) of the Act as described in paragraphs (b) through (d) of this section.

(b) Selected drugs for which there is a change in monopoly status. With respect to initial price applicability years beginning in 2029, CMS determines a selected drug to be renegotiation-eligible based on a change

in monopoly status as described in paragraph (b)(1) or (2) of this section.

(1) A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if there has been a change in its monopoly status from a drug that is not an extended-monopoly drug, as defined in § 429.20, or a long-monopoly drug, as defined in § 429.20, to an extended-monopoly drug by January 1 of the initial price applicability year for which such selected drug would be selected for renegotiation.

(2) A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if there has been a change in status from a drug that is not a long-monopoly drug, as defined in § 429.20, to a long-monopoly drug by January 1 of the initial price applicability year for which such selected drug would be selected for renegotiation.

(c) Selected drugs for which a new indication is added. A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if a new indication, which may be a new indication added to the FDA-approved labeling or a new off label use, is added for the selected drug since the selected drug was last negotiated or renegotiated, as applicable.

(1) A selected drug will not be determined to be renegotiation-eligible based on the addition of a new indication if the FDA-approved labeling update or off-label use is related to a previously indicated condition.

(2) CMS determines if a new indication has been added as described in paragraph (c)(1) of this section by evaluating:

(i) FDA-approved labeling for the selected drug; and

(ii) Voluntary submissions from the Primary Manufacturer of the selected drug as described in § 429.615, if any.

(A) If a Primary Manufacturer voluntarily submits information through the process described in § 429.615, then CMS may consider off-label use when determining if a new indication has been added for renegotiation eligibility.

(3) To inform CMS determination of renegotiation eligibility under paragraph (c) of this section, a new indication must be added to the FDA-approved labeling for the selected drug on or before a time specified by CMS and any information regarding off-label use must be voluntarily submitted under § 429.615(b) by the same date.

(d) Selected drugs for which there has been a material change in any factor listed in section 1194(e) of the Act. A selected drug with an agreed-upon MFP will be determined to be a renegotiation-

eligible drug if there has been a material change in any factor listed in section 1194(e) of the Act.

(1) A change(s) to any factor listed in section 1194(e) of the Act will be considered to be material if the change(s) would reasonably be expected to meaningfully alter CMS' consideration of the factor within the context of renegotiation offers and counteroffers, including the initial offer as described in subpart F of this part, as compared with CMS' consideration of the factor within the context of offers, including the initial offer, and, if applicable, counteroffers, during the most recent prior negotiation or renegotiation for the selected drug.

(2) CMS reviews information available prior to a time specified by CMS pertaining to section 1194(e)(1) or section 1194(e)(2) factors in accordance with § 429.510(f) to determine if there has been a material change.

(3) CMS considers information provided in voluntary submissions described at § 429.615(a), if any, to determine if there has been a material change.

§ 429.610 Selection of drugs for renegotiation.

(a) Selection of renegotiation-eligible drugs due to a change in monopoly status. All selected drugs determined to be renegotiation-eligible per § 429.605(b) will be selected for renegotiation.

(b) Selection of renegotiation-eligible drugs due to a new indication or a material change in any factor listed in section 1194(e) of the Act. Selected drugs determined to be renegotiation-eligible per § 429.605(c) and (d) will be selected for renegotiation if CMS expects renegotiation is likely to result in a significant change to the previously negotiated or renegotiated MFP of such drug.

(1) CMS expects renegotiation is likely to result in a significant change to the MFP if the criteria described in paragraphs (b)(1)(i) and (1)(ii) of this section are both met.

(i) CMS determines the new indication(s) or material change(s) to any factor(s) listed in either section 1194(e)(1) of section 1194(e)(2) of the Act would be likely to result in a renegotiated MFP that represents at least a 15 percent or greater change to the current MFP of the selected drug upon engaging in renegotiation with the Primary Manufacturer.

(A) The percent change may be an increase or a decrease in the MFP.

(ii) CMS determines that a 15 percent or greater change in the MFP following

renegotiation would have a significant impact on the Medicare program.

(2) To determine if the criteria in paragraph (b)(1) of this section are met, CMS conducts a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug.

(i) The scope of information considered may extend beyond the scope of information reviewed for renegotiation eligibility as described at § 429.605(c) and (d) to include consultations with FDA, clinicians, patients, patient organizations, and researchers, a CMS-led review of the information sources described at § 429.510(b)(1), (c)(1), (e), and (f) pertaining to section 1194(e) factors or any other information to support CMS' determination.

§ 429.615 Data collection to inform renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug.

(a) *Voluntary information submission from Primary Manufacturers to inform renegotiation eligibility and selection for selected drugs.* A Primary Manufacturer of a selected drug may voluntarily submit information to CMS regarding the addition of a new indication to the selected drug or new information regarding the factors listed in section 1194(e) of the Act to CMS in the form and manner and by the deadline specified by CMS. Information submitted by a Primary Manufacturer will be used to inform renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug.

(b) *Data collection from Primary Manufacturers and other interested parties for renegotiation of the MFP.* After publication of the drugs selected for renegotiation, if any, in accordance with § 429.100(b)(2), in a form and manner to be specified by CMS, and by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug was most recently selected for renegotiation:

(1) *Primary Manufacturer-required data.* In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer of a drug selected for renegotiation must submit the following information for such drug for the initial price applicability year for which the drug was selected for renegotiation, inclusive of the NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, to CMS in a form and manner specified by CMS:

(i) The information specified at § 429.505(b)(2)(i) through (v); and

(ii) For drugs selected for renegotiation that were selected originally for negotiation for initial price applicability year 2026 or 2027 and have not previously been selected for renegotiation for initial price applicability year 2028 or thereafter, the information specified below for all NDC–11s of the selected drug payable under Part B, not covered under Part D, and for which the Primary Manufacturer did not include such information with the Primary Manufacturer's data submission for the initial price applicability year for which the selected drug was first selected for negotiation:

(A) Non-FAMP, unit type, and total unit volume for each NDC–11, if available, for the same calendar years for which non-FAMP data was reported in the Primary Manufacturer's data submission for the negotiation period in which the selected drug's MFP was negotiated.

(B) When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in a calendar year, the non-FAMP submitted for that calendar quarter in paragraphs (b)(1)(ii)(A) and (B) of this section should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data.

(2) In accordance with the requirements of its Negotiation Program Agreement as set forth in § 429.200, a Primary Manufacturer is required to update the information submitted in accordance with paragraph (b)(1) of this section if the Primary Manufacturer becomes aware that any such information has changed or is otherwise inaccurate.

(3) Interested parties may submit the data specified in § 429.505(d)(3).

§ 429.620 Renegotiation process.

(a) *General.* CMS establishes a renegotiation process consistent with the negotiation methodology and process established under section 1194(b) of the Act, to the extent practicable.

(b) *Determining the ceiling for renegotiation.* CMS will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. Subject to § 429.440(b)(4), CMS calculates the ceiling for drugs selected for renegotiation using the following process:

(1) With respect to selected drugs negotiated for initial price applicability years 2026 and 2027 and have not been renegotiated in initial price applicability

year 2028 or thereafter, CMS incorporates NDC–11s that are payable under Part B, if applicable. Specifically, CMS:

(i) For a selected drug that is both covered under Part D and payable under Part B, calculates the payment amount under section 1847A(b)(4) of the Act, as set forth in § 429.425, for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation of the previously agreed-upon MFP and the sum of the plan-specific enrollment weighted amounts calculated at the time of the previous negotiation.

(ii) Calculates the average non-FAMP amount(s) used in the calculation set forth in § 429.620(b)(2) using the non-FAMP and Part B utilization data for NDC–11s set forth in § 429.615(b)(1)(i) for the same calendar years for which non-FAMP data was reported during the original negotiation and the non-FAMP and Part D utilization data previously used to calculate the average non-FAMP at the time of the previous negotiation.

(2) CMS updates, as necessary, the applicable percent specified in section 1194(c)(3) of the Act to reflect the monopoly status, which is set forth in § 429.435(a)(4)(vi)(A)(1) through (3), of the drug selected for renegotiation and is determined based on its initial approval date, as set forth in § 429.125(a)(1)(i), and the initial price applicability year for which the drug is selected for renegotiation.

(3) With respect to all selected drugs with an agreed-upon MFP that are renegotiated, CMS, as applicable, updates the amounts considered for the ceiling as set forth in § 429.410, subject to § 429.440(b)(4), for inflation by adjusting for the percent increase in the CPI–U (as defined in § 429.20) from July of the calendar year that is 2 years prior to the initial price applicability year of the most recently published MFP through July of the calendar year prior to the selected drug publication date for the initial price applicability year for which the drug is selected for renegotiation.

(c) *Negotiation factors.* CMS considers the negotiation factors listed at section 1194(e)(1) and (e)(2) of the Act and as set forth in § 429.505 as the basis for determining the offers and counteroffers in the renegotiation process inclusive of information submitted or shared about the factors listed at sections 1194(e)(1) and (e)(2) of the Act in any prior negotiation or renegotiation(s).

(d) *Methodology for developing an initial offer.* CMS follows the process as set forth in § 429.510 to the extent

practicable to develop the initial offer for renegotiation.

(e) *Engagement with Primary Manufacturers and interested parties.* CMS follows the process as set forth in § 429.515 for drugs selected for renegotiation to the extent practicable.

(f) *Provision of CMS' initial offer and concise justification.* CMS follows the process as set forth in § 429.520 to the extent practicable.

(g) *Renegotiation written counteroffers.* The renegotiation written counteroffer follows the process as set forth in § 429.525 to the extent practicable.

(h) *Additional price exchange opportunities.* The additional price exchange opportunities follow the process as set forth in § 429.530 to the extent practicable.

(i) *Notification of final offer and determination that renegotiations have finished.* CMS follows the process as set forth in § 429.535 to the extent practicable.

(j) *Application of the MFP across dosage forms and strengths.* CMS applies the renegotiated MFP across dosage forms and strengths as set forth in § 429.600(b)(2) to the extent practicable.

(k) *Publication of the MFP.* For drugs for which there is agreement on a renegotiated MFP, CMS publishes the renegotiated MFP and related information as set forth in § 429.705 to the extent practicable.

(l) *Establishment of MFPs after the negotiation deadline.* CMS follows the process set forth in § 429.710 in circumstances where a renegotiated MFP is agreed upon after the deadline for the conclusion of negotiations as set forth in § 429.535(b) to the extent practicable.

Subpart H—Implementation of the MFP

§ 429.700 Application of the MFP across dosage forms and strengths.

(a) *General principles for MFP application.* CMS has the administrative duty to establish procedures to compute and apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation, package size, or package type of such drug.

(1) A single MFP will be applied across NDC–9s and HCPCS codes, as set forth in § 429.100(d), as applicable, for a 30-day equivalent supply and will be used to calculate an MFP per unit for each NDC–9 of the selected drug and an MFP per billing unit for each billing and payment code associated with the selected drug, as applicable.

(b) *Procedures to compute and apply the MFP across dosage forms and*

strengths. CMS calculates and applies the MFP across dosage forms and strengths as follows:

(1) *Calculate Annual WAC per Unit.* For each selected drug and calendar quarter of the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation, CMS—

(i) For each NDC–11—
(A) Divides the WAC quarterly units by the total WAC annual units (as reported by the Primary Manufacturer under § 429.505(b)(2)(v)); and

(B) Multiplies the quotient determined in paragraph (b)(1)(i)(A) of this section by the quarterly WAC per unit for such NDC–11 (as reported by the Primary Manufacturer under § 429.505(b)(2)(v)) to calculate the weighted quarterly WAC per unit.

(ii) For each selected drug, sums the resulting weighted quarterly WAC per unit amounts from paragraph (b)(1)(i)(B) of this section for all NDC–11s to calculate the annual WAC per unit.

(2) *Calculate average number of units per 30-day equivalent supply.*

(i) For each NDC–11, CMS calculates the total units dispensed/administered, as reported on PDE data or Part B data for the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.

(A) For NDCs only present in PDE data: total units dispensed/administered are defined as the total quantity dispensed for an NDC–11, summed across the calendar year.

(B) For NDCs only associated with HCPCS codes present in Part B data: total units dispensed or administered are defined as the total billing units sold for an NDC–11 as determined using the unit allocation and standardization methodology described in § 429.425(a)(3), summed across the calendar year.

(C) For NDCs that are both present in PDE data and associated with HCPCS codes present in Part B data: total units dispensed/administered are defined as the sum of the quantity dispensed for the NDC–11 and the total billing units sold for the NDC–11 as determined using the unit allocation and standardization methodology described in § 429.425(a)(3), summed across the calendar year.

(ii) For each NDC–11, CMS divides the total units dispensed/administered, as calculated in paragraph (b)(2)(i) of this section, by the total 30-day equivalent supply, as determined using the 30-day equivalent supply methodology described at § 423.104(d)(2)(iv)(A)(2) for Part D and

at § 429.415(a)(2)(v) for Part B, to calculate the average number of units per 30-day equivalent supply.

(3) *Calculate WAC per 30-day equivalent supply ratio.*

(i) For each NDC–11, CMS multiplies the annual WAC per unit, calculated as described at paragraph (b)(1) of this section, by the average number of units per 30-day equivalent supply, as described at paragraph (b)(2) of this section, to calculate the WAC per 30-day equivalent day supply for that NDC–11.

(ii) For each NDC–11, CMS divides the total 30-day equivalent supply from paragraph (b)(2)(ii) of this section for such NDC–11 by the total 30-day equivalent supply summed across all applicable NDC–11s within an NDC–9 and then multiplies such quotient by the amount calculated in paragraph (b)(3)(i) of this section to calculate the weighted WAC per 30-day equivalent supply per NDC–11.

(iii) For each NDC–9, CMS sums the resulting amounts from paragraph (b)(3)(ii) of this section across all NDC–11s to calculate the WAC per 30-day equivalent supply for that NDC–9.

(iv) For each NDC–9, CMS divides the total 30-day equivalent supply for that NDC–9 by the total 30-day equivalent supply summed across all NDC–9s and then multiplies this quotient by the resulting amount from paragraph (b)(3)(iii) of this section to calculate the weighted WAC per 30-day equivalent supply per NDC–9.

(v) CMS sums the resulting amounts from paragraph (b)(3)(iv) of this section across all NDC–9s of the selected drug to calculate the WAC per 30-day equivalent supply for the selected drug.

(vi) For each NDC–9, CMS divides the amount from paragraph (b)(3)(iii) of this section by the amount from paragraph (b)(3)(v) of this section to calculate the WAC per 30-day equivalent supply ratio for that NDC–9.

(4) *Calculate NDC–9 MFP per Unit and MFP per Billing Unit.*

(i) To determine the NDC–9 MFP per unit, CMS takes the following steps:

(A) For each NDC–9, CMS multiplies the single MFP for the selected drug by the amount resulting from paragraph (b)(3)(vi) of this section to calculate the MFP per 30-day equivalent supply for that NDC–9.

(B) For each NDC–9, CMS divides the amount resulting from paragraph (b)(4)(i) of this section by the quotient of the total number of units dispensed/administered divided by the total 30-day equivalent supply to calculate the NDC–9 MFP per unit at the NCPDP unit (for example, tablet).

(ii) For NDC-11s associated with HCPCS codes present in Part B data, CMS further converts the MFP per NCPDP unit of each NDC-9 into an MFP per billing unit using the following steps:

(A) For each NDC-9, CMS converts the resulting amount from paragraph (b)(4)(i)(B) of this section to an NDC-11 MFP per billing unit, as necessary. First by multiplying NDC-9 MFP per unit calculated in paragraph (b)(4)(i)(B) of this section by the manufacturer submitted total NDC-11 package NCPDP unit quantity, for NDC-11s associated with a HCPCS code, to get an NDC-11 MFP per package. Then, by dividing this product by the HCPCS billing units per package for that NDC-11 to get an NDC-11 MFP per billing unit.

(B) For each NDC-11, CMS sums the units reported by manufacturers in the ASP portal for all quarters for the calendar year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation for each NDC-11 associated with a given HCPCS code.

(C) For each NDC-11, CMS divides the resulting amount from paragraph (b)(4)(ii)(B) by the sum of units reported by manufacturers in the ASP portal for all quarters for the calendar year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation for all NDC-11s that share the same HCPCS code and belong to the selected drug.

(D) For each NDC-11, CMS multiplies the resulting amount from paragraph (b)(4)(ii)(A) of this section by the resulting amount from paragraph (b)(4)(ii)(C) of this section.

(E) For each HCPCS code, CMS sums the resulting amount from paragraph (b)(4)(ii)(D) of this section across all NDC-11 associated with the HCPCS code to yield the MFP per billing unit.

(c) *Application of the MFP to NDC-11s and HCPCS codes associated with a new NDA or BLA of the selected drug, new NDC-11s and HCPCS codes for existing NDAs or BLAs of the selected drug, and NDC-11s of the selected drug with insufficient PDE, Part B data, or WAC data for the calendar year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.* CMS applies the MFP to NDCs associated with new NDAs or BLAs of the selected drug, new NDC-11s and HCPCS codes for existing NDAs or BLAs of the selected drug, and to NDCs of the selected drug with insufficient PDE, Part B data, or WAC data as follows:

(1) *NDC-11s and HCPCS Codes associated with new NDAs or BLAs of the selected drug.* If the Primary Manufacturer of a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety/active ingredient/antigen component (or in the case of a potential qualifying single source drug identified under § 429.125(b)(4), the distinct combination thereof), as identified as set forth at § 429.125(b)(1) through (4), as the selected drug, CMS—

(i) Uses available information to determine the 30-day equivalent supply and the WAC ratio; and

(ii) Includes the NDCs and HCPCS codes associated with the new NDA or BLA, as set forth in § 429.100(c), as appropriate, on the list of NDCs and HCPCS codes of the selected drug and requires that the MFP apply to such NDCs and HCPCS codes.

(2) *New NDC-11s and HCPCS codes for existing NDAs or BLAs of the selected drug.* If new NDC-11s and HCPCS codes for existing NDAs or BLAs of the selected drug are marketed after the initial calculation of WAC ratios, as set forth in paragraph (b)(3) of this section, CMS—

(i) Uses available information to determine the 30-day equivalent supply and the WAC ratio; and

(ii) Includes the new NDCs and HCPCS codes, as set forth in § 429.100(c), as appropriate, on the list of NDCs and HCPCS codes of the selected drug and requires that the MFP apply to such NDCs and HCPCS codes.

(3) *NDC-11s of the selected drug with insufficient data.* If an NDC-11 (or all NDC-11s assigned to a HCPCS code) that has been included on the list of NDCs of the selected drug under § 429.100(c) lacked sufficient PDE, Part B data, or WAC data for the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation, CMS—

(i) Uses available information to determine the 30-day equivalent supply and the WAC ratio; and

(ii) Includes the NDCs and HCPCS codes, as appropriate, on the list of NDCs and HCPCS codes of the selected drug and requires that the MFP apply to such NDCs and HCPCS codes.

(4) To determine the 30-day equivalent supply and the WAC ratio using available information for NDC-11(s) (and all NDC-11s assigned to a HCPCS code) of the selected drug described at paragraphs (c)(1) through (c)(3) of this section, CMS takes the following steps:

(i) Determines whether there is an existing NDC that is comparable to such

NDC (or comparable to the NDCs associated with such HCPCS code) with sufficient data for the MFP application calculations to be performed as set forth in paragraph (b) of this section.

(A) If an existing, comparable NDC exists, CMS uses the quotient of total units dispensed or administered to 30-day equivalent supply (adjusted as necessary to reflect dosing or unit type differences between the comparable NDCs and the new NDCs as described at paragraphs (c)(1) and (c)(2) of this section or NDCs with insufficient data as described at paragraph (c)(3) of this section), as described at paragraph (b)(2) of this section, and the WAC ratio, as described at paragraph (b)(3) of this section, that was calculated for the existing, comparable NDC for the application of MFP to the new NDC or NDC that lacks sufficient data.

(B) If a comparable NDC does not exist, CMS imputes the quotient of total units dispensed or administered to 30-day equivalent supply using sources such as the FDA-approved label and other sources associated with the new NDC as described at paragraph (c)(1) or (c)(2) of this section or NDC that lacks sufficient PDE, Part B data, or WAC data as described at paragraph (c)(3) of this section, but uses a WAC ratio of 1.0 to apply the MFP to the new NDC as described at paragraph (c)(1) or (c)(2) of this section or NDC that lacks sufficient PDE, Part B data, or WAC data, but uses a WAC ratio of 1.0 to apply the MFP to the NDC that lacks sufficient PDE, Part B data, or WAC data as described at paragraph (c)(3) of this section.

(1) When CMS accrues sufficient data for NDCs for which CMS imputed the quotient of total units dispensed or administered to 30-day equivalent supply as described at paragraph (c)(4)(B) of this section, CMS adjusts the MFP application by updating the quotient of total quantity dispensed or administered to 30-day equivalent supply based on observed PDE data and Part B data for existing NDCs (or NDCs associated with such HCPCS code) that lacked sufficient WAC, PDE data, or Part B data to be included in the initial calculation of WAC ratios (described in paragraphs (a) and (b) of this section), and new NDCs (and all NDC-11s assigned to such HCPCS code) launched after the initial calculation of WAC ratios.

(2) CMS determines that sufficient data was accrued as follows:

(i) One year has elapsed since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B data.

(ii) The NDC or HCPCS code has accrued the same number of units

dispensed/administered as the NDC–11 that had the fewest units dispensed/administered at the time that the WAC ratios were originally calculated.

(ii) If a new NDC (or NDC that lacks sufficient PDE, Part B data, or WAC data) is assigned to a HCPCS code for which CMS has already calculated an MFP per billing unit, the MFP per billing unit for that HCPCS code will not change, and the new NDC (or NDC that lacks sufficient PDE, Part B data, or WAC data) will be subject to that existing MFP per billing unit.

(d) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraphs (b) and (c) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.705 Publication of the MFP.

(a) *Publication.* With respect to an initial price applicability year for which a drug is selected for negotiation or renegotiation, as applicable, CMS publishes by November 30 of the year that is 2 years prior to such initial price applicability year the MFP for each such drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP.

(1) CMS publishes all of the following on the CMS website:

- (i) The selected drug.
- (ii) The initial price applicability year.
- (iii) The MFP file which contains the single MFP for a 30-day equivalent supply of the selected drug, NDC–9 MFP per unit price and HCPCS code dosage price and is updated annually to show the inflation-adjusted MFP for the selected drug as set forth in paragraph (a)(2)(i) of this section.

(iv) Whether an MFP between a Primary Manufacturer and CMS is not agreed upon.

(v) Whether a drug is no longer a selected drug and the reason for that change.

(2) For each selected drug and for each year subsequent to the first initial price applicability year of the price applicability period (unless renegotiation occurs as set forth under subpart G of this part), CMS publishes an updated MFP no later than November 30 of the year that is 2 years prior to such subsequent year.

(i) The updated MFP for each selected drug is equal to the MFP that was published for such drug for the previous year, increased by the annual percentage increase in the CPI–U for the 12-month period ending with the July

immediately preceding such November 30.

(3) In the case of a selected drug with respect to an initial price applicability year for which the MFP is agreed upon after the MFPs are published for other selected drugs in accordance with § 429.710, CMS publishes the MFP no later than 30 days after the date such MFP is so agreed upon.

(b) *Explanation for the MFP.* CMS publishes explanations for the MFPs no later than March 1 of the year prior to the initial price applicability year.

(1) The explanation for the MFP of each selected drug, or drug selected for renegotiation, subject to the requirements for treatment of confidential and proprietary information described in proposed § 429.300 includes:

(i) The narrative explanation of the MFP;

(ii) Redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable; and

(iii) The redacted information submitted by a Primary Manufacturer, as set forth in § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as set forth in § 429.505(d)(3) or § 429.615(b)(3), as applicable.

(2) If agreement upon an MFP is not reached for a selected drug, neither an MFP nor an MFP explanation is published. CMS indicates on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug as set forth in paragraph (a)(1)(iv) of this section.

§ 429.710 Establishment of MFPs after the negotiation deadline.

If actions or delays by the Primary Manufacturer delay the negotiation process such that the MFP may be agreed to after the end of the negotiation period as described in § 429.535(b), CMS continues to engage in the negotiation process set forth in subpart F of this part. In accordance with the requirement to have a consistent methodology and process for negotiating MFPs, CMS follows timelines consistent with the negotiation process set forth in subpart F of this part and takes the time to complete the established process so described as appropriate for the selected drug.

(a) If actions or delays by the Primary Manufacturer delay the negotiation process, when CMS initiates or resumes the negotiation process, CMS applies the consistent methodology and process with respect to the selected drug based

on its status at the time the negotiation process occurs, including with respect to renegotiation, as applicable, as described in subpart G of this part.

(b) If the manufacturer and CMS have completed each step of the negotiation process as detailed in subpart F of this part, including the issuance of a final offer in accordance with § 429.535(a), and then, after the statutory end of the negotiation period as described in § 429.535(b), the Primary Manufacturer of a selected drug wishes to agree to an MFP, the Primary Manufacturer must notify CMS in writing that it would like to accept the final offer from CMS.

Subpart I—[Reserved]

Subpart J—Manufacturer Compliance and Oversight

§ 429.900 Monitoring manufacturer compliance.

(a) *Monitoring and assessment.* CMS monitors and evaluates Primary Manufacturer compliance with the Negotiation Program Agreement as described in § 429.200, including compliance with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including this part, implementing those provisions and any changes to the Act that affect the Negotiation Program.

(b) *Primary Manufacturer cooperation with CMS compliance monitoring activities.* Primary Manufacturers must cooperate with CMS compliance monitoring activities. In accordance with the Negotiation Program Agreement as set forth in § 429.200, Primary Manufacturers must cooperate with CMS monitoring and evaluation of Primary Manufacturer compliance as specified in subsection (a), including, but not limited to, providing complete and accurate responses to CMS written requests for clarifications, corrections, and additional information, and complying fully with all requests for corrective action, in a form and manner specified by CMS. Such requests will include a date by which the Primary Manufacturer must submit a complete, accurate, and relevant response, or take any other corrective action requested. Non-responsive, incomplete, or inaccurate responses will not be considered compliant. Failure to provide a timely, accurate, and complete response is a violation of the Negotiation Program Agreement as described in § 429.200, and may result in the Primary Manufacturer being subject to a civil monetary penalty as described in § 429.1005.

(c) *Actions to address Primary Manufacturer noncompliance.* If CMS concludes that the Primary Manufacturer is noncompliant with one or more of the requirements of the Negotiation Program Agreement, including all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including this part, implementing those provisions and any changes to the Act that affect the Negotiation Program, CMS may take one or more of the following actions:

(1) Provide a written notice to the Primary Manufacturer of the violation(s).

(2) Request the Primary Manufacturer take specific corrective action to address the noncompliance, in a form and manner, and by the deadline specified by CMS.

(3) Impose a civil monetary penalty on the Primary Manufacturer as set forth in subpart K of this part.

Subpart K—Civil Monetary Penalties

§ 429.1005 Violations of the Negotiation Program Agreement.

(a) *General.* CMS must impose a civil monetary penalty on a Primary Manufacturer that has entered into a Negotiation Program Agreement as set forth in § 429.200, and that fails to comply with a requirement determined by CMS to be necessary for the purposes of administering and monitoring compliance with the Negotiation Program including without limitation the requirement to submit information in accordance with section 1193(a)(4) of the Act.

(b) *Determination of the civil monetary penalty amount.* CMS must impose a civil monetary penalty for such violation as set forth in § 429.1005(a) in the amount of \$1,000,000 as adjusted annually under 45 CFR part 102, for each day of such violation as set forth in § 429.1005(a).

(c) *Accrual of civil monetary penalty.* The civil monetary penalty accrues for each day of such violation as set forth in § 429.1005(a), starting on the first day of such violation, until—

(1) The Primary Manufacturer has provided all required information or otherwise taken any corrective action determined by CMS to be necessary to address such violation, including, as applicable, providing documentation to evidence that the Primary Manufacturer has provided all past due information; or

(2) The Negotiation Program Agreement is terminated as described in § 429.205(a).

(d) *Notice.* When a civil monetary penalty is imposed under this section, CMS sends a notice to the Primary Manufacturer in accordance with § 429.1020(a) after the civil monetary penalty stops accruing under § 429.1005(c).

§ 429.1010 Provision of false information related to the biosimilar delay and Temporary Floor for Small Biotech Drugs.

(a) *General.* CMS must impose a civil monetary penalty as follows:

(1) On a Biosimilar Manufacturer for each item of false information the Biosimilar Manufacturer knowingly provides to CMS for use in applying the aggregation rule described at § 429.110(c)(1)(iv)(A).

(2) On a Primary Manufacturer for each item of false information the Primary Manufacturer knowingly provides to CMS for use in applying the test to determine if a selected drug is eligible for the Temporary Floor for Small Biotech Drugs described at § 429.440(b)(2).

(b) *Determination of the civil monetary penalty amount.* CMS must impose a civil monetary penalty in the amount of \$100,000,000 as adjusted annually under 45 CFR part 102, per item of false information described in § 429.1010(a).

(c) *Notice.* When a civil monetary penalty is imposed under this section, CMS sends a notice to the Biosimilar Manufacturer or Primary Manufacturer, as applicable, in accordance with § 429.1020(a).

§ 429.1015 Failure to pay a biosimilar delay rebate.

(a) *General.* CMS must impose a civil monetary penalty on a Reference Manufacturer that fails to pay the rebate amount set forth in § 429.110(i)(4) by the payment deadline as set forth in section § 429.110(i)(2) for such selected drug.

(b) *Determination of the civil monetary penalty amount.* CMS must impose a civil monetary penalty for each violation described at § 429.1015(a) in an amount equal to 10 times the amount of the biosimilar delay rebate as set forth at § 429.110(i)(4) that the Reference Manufacturer failed to pay.

(c) *Notice.* When a civil monetary penalty is imposed under this section, CMS sends a notice to the Reference Manufacturer in accordance with § 429.1020(a).

§ 429.1020 Notice and appeal procedures.

(a) *Notice of imposition of civil monetary penalties.* If CMS makes a determination to assess a civil monetary penalty described in this subpart K, CMS sends a written notice of its

decision to impose a civil monetary penalty to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) For civil monetary penalties imposed in accordance with § 429.1005, the start date of the penalty accrual.

(4) For civil monetary penalties imposed in accordance with § 429.1005, the end date of the penalty accrual.

(5) The total amount of the penalty assessed.

(6) The date the penalty is due.

(7) The manufacturer's right to a hearing as specified under 42 CFR part 423, subpart T.

(8) Information about where to file the request for a hearing.

(b) *Collection.*

(1) A manufacturer must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS as set forth in paragraph (a) of this section.

(2) In the event a manufacturer requests a hearing, in accordance with 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (b)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(c) *Appeal procedures for civil monetary penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil monetary penalty until the affected party has had notice and the opportunity for a hearing. Any appeal proceedings will be governed by the provisions of 42 CFR part 423, subpart T.

(1) Primary Manufacturers may appeal the following determinations, subject to the limitations on administrative and judicial review in section 1198 of the Act:

(i) A CMS determination to assess a civil monetary penalty under §§ 429.1000 through 429.1015.

(ii) The calculation of the amount of the civil monetary penalty.

(2) If CMS decides to impose a civil monetary penalty, CMS provides the manufacturer with notice in accordance with the process set forth in paragraph (a) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil monetary penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(d) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil monetary penalties under this section to the same extent that they apply to a civil monetary penalty or procedures under section 1128A of the Act.

(e) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and fails to pay either the biosimilar delay rebate amount owed or the total sum of civil monetary penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid

amount of the rebates and civil monetary penalties owed by the manufacturer.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 488 and 489

Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflicts of Interest, and Related Provisions; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 488 and 489

[CMS–3367–FC]

RIN 0938–AU88

Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflicts of Interest, and Related Provisions

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period sets forth provisions to strengthen the oversight of Medicare national accrediting organizations by addressing conflicts of interest, establishing consistent standards, processes, and definitions, and updating the validation and performance standards systems. Additionally, this final rule with comment period revises the psychiatric hospital survey process, adds a limitation on terminated deemed providers and suppliers when reentering the program, and provides technical corrections for End-Stage Renal Disease facilities and Transplant Programs.

DATES:

Effective date: These regulations are effective on June 16, 2027.

Comment date: To be assured consideration, comments on sections VI., “Collection of Information” and VII., “Regulatory Impact Analysis” must be received at one of the addresses provided below, by August 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3367–FC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov/docket/CMS-2024-0016>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3367–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3367–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: CAPT Scott J. Cooper, USPHS, (410) 786–9465 or AO_Applications@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Executive Summary

A. Purpose

The Centers for Medicare & Medicaid Services (CMS) seeks to protect the health and safety of all patients who receive services from Medicare- and Medicaid-participating providers and suppliers, including those facilities that are accredited by CMS-approved accrediting organizations (AOs). We continue to review and revise our

patient health and safety requirements and our survey process requirements to ensure that these regulations effectively drive the quality and safety of the care our beneficiaries and all patients receive from these accredited providers and suppliers.

In 2015, we published a final rule in the **Federal Register** entitled, “Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures” (80 FR 29796), hereinafter referred to as the “2015 AO final rule” to clarify and strengthen the oversight of AOs, specifically to provide additional criteria for AOs that apply for, and are granted, recognition and approval of an accreditation program (see section “II. Background” of this final rule with comment period for additional background information). Since 2015, CMS has continued to evaluate the effectiveness of these regulatory changes and the performance of AOs. In our proposed rule, published February 15, 2024 (89 FR 11996), we proposed multiple provisions to further strengthen our oversight and enforcement capabilities of the AOs. The need for these provisions is based on multiple factors, which include: (1) direct observation and review of the AOs’ accreditation programs for those AOs with CMS-approved deeming programs; (2) media reports and complaints against facilities that are deemed; (3) the CMS validation program and analysis of disparity rates between State survey agencies (SAs) and the AOs; and (4) our performance evaluations of AOs. Section IV. of the proposed rule discussed each of the proposed provisions. More specifically, the preamble provided background and analysis of why CMS proposed additional provisions and revisions to existing requirements. CMS is responsible for the oversight of the national AOs’ Medicare accreditation programs, and for ensuring that providers or suppliers under CMS-approved deeming programs by the AOs meet the baseline quality and patient safety standards required by the Medicare conditions (please refer to section “II. Background” of this final rule with comment period for additional information). Based on several years of experience and data analysis, we proposed the revisions and the new requirements in the February 15, 2024, proposed rule to strengthen our oversight of AOs.

B. Summary of the Major Provisions

- We proposed at § 488.1 to add the definitions of “geographic regions”, “national in scope”, “outcome disparity

rate”, “process disparity rate”, and “unannounced survey”. In addition, we proposed to revise the definition of “national accrediting organization,” and remove the definition of “rate of disparity”.

- We proposed to establish a new requirement at § 488.4(a)(1) that would require the AOs that accredit Medicare-certified providers and suppliers to include the language of the applicable Medicare Conditions of Participation (CoPs), Conditions for Coverage or Conditions for Certification (CfCs), or requirements (collectively referred to as “Medicare conditions”) set forth in the applicable CMS regulations for each provider and supplier type as their minimum accreditation requirements. However, the AOs would be free to establish additional accreditation requirements that exceed Medicare conditions, as permitted by section 1865(a)(1) of the Social Security Act (the Act).

- We proposed to add language at § 488.4(a)(2) regarding use of a comparable survey process approved by CMS, as outlined and contemplated in § 488.5.

- We proposed to add a new regulation at § 488.4(b) that would state that if Medicare terminated the participation agreement of a Medicare-certified provider or supplier, then CMS would no longer recognize the facility’s AO accreditation for deemed compliance. At proposed § 488.4(b)(2), we would require a terminated provider or supplier to meet all requirements set forth at § 489.57 before their new agreement for participation in the Medicare/Medicaid program can be approved.

- We proposed to require AOs to develop a crosswalk between their accreditation standards and the Medicare conditions, at proposed § 488.5(a)(3).

- We proposed to strengthen the requirements at § 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), § 488.5(a)(4)(vii), § 488.5(a)(4)(xi), § 488.5(a)(5) and § 488.5(a)(6) related to the comparability of survey processes as mentioned above. We also proposed changes under § 488.5(a)(5)(viii)(A) related to survey reports. These strengthened requirements would be applicable to initial and renewal applications, effective 1 year after the effective date of the rule.

- We proposed at § 488.5(a)(8)(i) through § 488.5(a)(8)(iv) to require that AO surveyors complete the applicable CMS online surveyor trainings.

- We proposed to add a requirement at § 488.5(a)(10) that the AOs must provide, as part of their initial and

renewal applications, specific policies and procedures that would address how the AOs would prevent and address conflicts of interest. We proposed that AOs provide information on a number of specific policies and procedures regarding conflicts of interest.

- We proposed to revise requirements under § 488.5(a)(12) related to the AO procedures for investigating and responding to complaints against accredited facilities.

- We proposed revisions to § 488.5(a)(13) related to the AO's accreditation status decision-making process, to strengthen the comparability of the survey processes.

- We proposed to add a new requirement at § 488.5(a)(21) that would require an AO to submit a statement with its initial or renewal application certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been involuntarily terminated from the Medicare/Medicaid program, the AO agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5 business days from receipt of said written notice.

- We proposed at § 488.5(a)(22) to require an AO submit a declaration from each surveyor disclosing any interests or relationships the surveyor may have in or with another survey agency or in or with a healthcare facility the AO accredits (as defined in § 488.5(a)(10)).

- We proposed at § 488.8(a)(2) to expand the types of accreditation survey validation activities included in CMS' performance review.

- We proposed at § 488.8(a)(4) to require an AOs submit a plan of correction that would be subject to a public reporting requirement, when the AO's performance on survey activities identify disparity concerns, either through the outcome disparity rates or process disparity rates.

- We proposed at new § 488.8(i) to place restrictions on the fee-based consulting services provided by AOs to the healthcare providers and suppliers they accredit. At § 488.8(i)(1), we proposed that an accrediting organization or its associated fee-based consulting division or company may not provide fee-based consulting services to any healthcare provider or supplier prior to an initial accreditation survey. At § 488.5(i)(2), we proposed to prohibit AOs from providing fee-based consulting services to healthcare providers and suppliers they accredit within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. At § 488.5(i)(3), we proposed that AOs may

not provide fee-based consulting services to a healthcare provider or supplier in response to a complaint received by the AO regarding that provider or supplier.

- At § 488.8(i)(4), we proposed circumstances in which the restrictions to the provision of AO fee-based consulting services would not apply.

- We proposed at § 488.8(i)(5) to require AOs to provide specific information to CMS on a bi-annual basis about the fee-based consulting services they provide.

- We proposed at § 488.8(i)(6) to take actions against AOs for the provision of prohibited fee-based consulting services.

- We proposed at § 488.8(k) that when an AO owner, surveyor, or other employee, currently or within the previous 2 years, has an interest in or relationship with a healthcare facility that the AO accredits, the AO would be required to take steps to prevent the surveyor from having any involvement with the survey of that facility; having input into the results of the survey and accreditation for that facility; having involvement with the pre- and post-survey activities for that facility; and having contact with or access to the records for the survey of that healthcare facility.

- We proposed at § 488.9(b) to revise the types of validation programs by adding a new type of validation survey to be conducted by SA or CMS surveyors.

- We proposed a new paragraph § 489.20(z) which would require a terminated provider attempting to re-enroll to follow the terms of proposed new § 489.57(b) noted below.

- We proposed to redesignate the current § 489.57(a) and (b) and add a new paragraph (b) at § 489.57, to require that Medicare-certified providers or suppliers that have been involuntarily terminated from the Medicare and/or Medicaid program must meet several requirements before CMS will approve their new Medicare agreements. Proposed § 489.57(b)(1) would place the terminated provider or supplier under the oversight of the SA for a reasonable assurance period (with the length of time to be determined by CMS) for the purpose of demonstrating compliance with the Medicare conditions. Proposed § 489.57(b)(2) would require the provider or supplier to remain under the exclusive oversight of the SA until the SA has certified and/or CMS has determined its full compliance with all Medicare conditions, and CMS has approved the new agreement for participation in the Medicare/Medicaid program. Proposed § 489.57(b)(3) would

require that while a provider or supplier was terminated from the Medicare program, under the oversight of the SA, and when a new agreement for Medicare participation was pending, CMS would not accept or recognize deeming accreditation of that provider or supplier from a CMS-approved accrediting organization.

- We also proposed to remove the reference at § 488.4(a)(2) (inadvertently proposed as a revision to the proposed recodification at § 488.4(a)(4)) that currently excludes end-stage renal disease (ESRD) facilities from the opportunity for accreditation, to reflect a change included in the Bipartisan Budget Act of 2018 (Pub. L. 115–123). Consistent with this same provision, we also proposed to remove the reference restricting transplant programs from utilizing an accreditation option.

- We proposed to integrate the acute care hospital and psychiatric hospital survey processes for SAs to ensure that there was a systematic and integrated survey of psychiatric hospital quality and safety. We also proposed to expand the acute care hospital accreditation program for AOs to include current psychiatric hospital accreditation standards that would require AOs with existing CMS-approved hospital programs to expand their existing hospital programs to include survey activities of psychiatric services in psychiatric hospitals.

- We solicited comments on whether CMS should limit the number of times an AO could submit an incomplete initial application for a new accreditation program. We sought comment on this question because we recently received several incomplete applications which required multiple pass backs due to the applicant's failure to provide information about issues, such as their financial viability, survey processes which appeared not to be operationalized, or similar concerns.

- We note that the regulations have some minor phrasing changes related to updated style guidelines.

II. Background

A. Legislative History

To participate in the Medicare program, providers and suppliers of healthcare services must, among other things, be in substantial compliance with the applicable statutory requirements of the Social Security Act (the Act), as well as CMS' regulatory requirements related to the health and safety of patients. These health and safety requirements are generally called CoPs for most providers; Requirements for Participation for skilled nursing

facilities (SNFs) and Medicaid Nursing Facilities (NFs) (collectively, long-term care facilities); and CfCs for Ambulatory Surgical Centers (ASCs), Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), ESRD facilities, and some types of suppliers (collectively referred herein as Medicare conditions). A Medicare-certified provider or supplier that does not comply with the Medicare conditions risks having its Medicare provider or supplier agreement terminated. Medicaid service providers or suppliers that are required by CMS or the State to have Medicare approval would also be affected.

In accordance with section 1864 of the Act, the SAs or other appropriate local agencies, under an agreement with the Secretary of the Department of Health and Human Services (the Secretary), perform surveys of healthcare providers and suppliers to assess their compliance with the applicable Medicare conditions for the purpose of certification for participation in the Medicare/Medicaid program. There are several types of surveys conducted, including initial certification, recertification, and complaint surveys. The SAs and CMS also perform surveys in certain circumstances for the providers and suppliers that are accredited by an AO and deemed to meet Medicare requirements. For example, the SA performs complaint surveys for healthcare providers that are accredited by an AO, if the complaint was received by the SA directly. The SA also performs surveys of AO-accredited healthcare providers that have had their participation in the Medicare program terminated, that wish to be surveyed by the SA instead of an AO, and for the purpose of validation of the results of an AO's surveys. Rules, regulations, and guidance for the certification process performed by the SAs are discussed in the CMS State Operations Manual (SOM) ¹ or communicated via Quality, Safety & Oversight (QSO) policy memorandums.²

Some provider types may only be surveyed by the SA and cannot use AOs while others cannot be surveyed by SAs pursuant to statute but can only participate in Medicare if accredited by a CMS-approved AO. We refer readers to section "III. Summary of the

Proposed Provisions, Public Comments, and Responses to Comments on the Proposed Rule" of this final rule with comment period for additional information. For those providers participating via State survey, based on the SA's certification of a provider's compliance or noncompliance and recommendation, CMS determines whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program. Additionally, section 1865(a) of the Act allows most healthcare facilities to demonstrate their compliance with the Medicare conditions through accreditation by a CMS-approved program of an AO, in lieu of being surveyed by SAs for certification. This is referred to as "deeming" accreditation. This is because CMS-approved AOs are recognized by the Secretary as having accreditation programs with accreditation standards that meet or exceed those of Medicare. Therefore, any provider or supplier that is accredited by an AO under a CMS-approved accreditation program is deemed by CMS to have also complied with the applicable Medicare conditions or requirements. The AOs perform initial, re-accreditation, follow-up, and certain complaint surveys.

In December 2020, Division CC, section 407 of the Consolidated Appropriations Act of 2021 (CAA, 2021) (Pub. L. 116–260), amended Part A of Title XVIII of the Act to add a new section 1822 to the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. CMS issued implementing regulations for SAs and AOs in the CY 2022 Home Health Prospective Payment System Rate Update (HH PPS) final rule (86 FR 62240). The HH PPS rule finalized changes to increase and improve transparency, oversight, and enforcement for hospice programs under SA and AO oversight. Additionally, the HH PPS final rule in part requires hospice program AOs to measure and reduce inconsistency in the application of survey results among all surveyors. The HH PPS final rule: (1) requires AOs with CMS-approved hospice programs to use the same survey deficiency reports as the SAs (Form CMS–2567, "Statement of Deficiencies" or a successor form) to report survey findings; (2) requires comprehensive training and testing of SA and AO hospice program surveyors; and (3) prohibits SA and AO surveyors from surveying hospice programs for which they have worked in the last 2 years (and by which there might be a

perceived or actual conflict of interest for these surveyors).

CMS is responsible for: (1) providing ongoing oversight of AO accreditation programs to ensure that a provider or supplier accredited by an AO meets the required Medicare conditions; (2) ensuring that an AO has formalized procedures to determine whether the healthcare facilities deemed under its accreditation programs meet the AO's accreditation standards (which must meet or exceed the applicable Medicare program requirements); and (3) ensuring that the AO's accreditation standards and practices for surveying providers and suppliers meet or exceed the Medicare conditions and practices for granting approval.

For some provider and supplier types, accreditation is voluntary and seeking deemed status through an accreditation organization is an option, not a requirement, for these Medicare-certified providers and suppliers. A provider or supplier has the choice to seek deeming status and accreditation from an AO with a CMS-approved program or certification through the SA survey process. A nationally recognized AO may have accreditation services which are not specifically related to Medicare-participation or Medicare conditions and an AO may offer accreditation services to a provider or supplier which Medicare does not recognize for deeming status, such as long-term care facilities. The AO may also provide accreditation with a deeming option, which is that their deemed program is recognized and approved by CMS to meet or exceed the Medicare program requirements. We refer readers to section "III.K. Require the AOs that Accredited Medicare-Certified Providers and Suppliers to Use Medicare Conditions; and Strengthened Survey Process Comparability" of this final rule with comment period for additional context.

AOs typically charge healthcare facilities a fee for the accreditation services they provide. AOs generally offer at least two accreditation options, which include non-CMS approved accreditation, and accreditation for the purpose of participating in the Medicare program. By "non-CMS approved accreditation" we mean accreditation that is offered by the AOs with an accreditation program but is not approved by Medicare, and which is not used for Medicare purposes. Such accreditation could be used for individual State accreditation purposes or additional professional accreditations that a provider or supplier seeks for business purposes, such as The Joint Commission's (TJC's) Nursing Care

¹ CMS Internet Only Manual, Pub. 100–07, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS1201984>.

² <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions>.

Center accreditation for skilled nursing facilities, which is not recognized by CMS as an option for deemed status.

This final rule with comment period will apply only to the AOs with CMS-approved programs that accredit Medicare-certified providers and suppliers and those entities they accredit. The provisions of this final rule will not apply to the following parties: (1) healthcare providers and suppliers that are not currently accredited by AOs, such as, but not limited to, nursing homes and comprehensive outpatient rehabilitation facilities (CORFs); (2) healthcare providers and suppliers that are certified by the SAs, such as those who elect not to be deemed through an AO; (3) AOs that accredit non-certified suppliers; (4) non-certified suppliers; and (5) AOs that accredit laboratories (under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)).

B. Regulatory Overview of CMS' Rules Regarding AO Programs

The current regulations at 42 CFR 488.4 set forth the general provisions for CMS-approved accreditation programs for Medicare-certified providers and suppliers. 42 CFR 488.5 sets out application and re-application procedures for national AOs that seek to obtain CMS approval of their accreditation programs, often called "deeming authority."

The AO application and re-application procedures set forth at § 488.5 for Medicare-certified providers and suppliers task CMS with the responsibilities of approval and oversight of the AOs' accreditation programs while ensuring that the accredited providers and suppliers meet or exceed the Medicare conditions.

CMS conducts a thorough review of each accreditation program application submitted by an AO for CMS approval. This review establishes the "comparability" of the AOs accreditation standards with Medicare, to determine whether the AO's standards meet or exceed the Medicare conditions. The application review process also includes a review of the AO's survey processes and procedures, the AO's surveyor training, and their policies and procedures for the oversight and enforcement of provider or supplier entities they accredit. The application review team also reviews the qualifications of the AO surveyor staff. In addition, CMS reviews the AO's financial status, to determine their solvency and potential for longevity of operations.

Section 488.5(e)(1) requires that we publish a notice in the **Federal Register** when we receive a complete initial or renewal application from a national AO seeking CMS approval of its accreditation program. The **Federal Register** notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides a 30-day public comment period. CMS has 210 days from the receipt of a complete application to publish notice of approval or denial of the application. Upon approval, any provider or supplier subsequently accredited by the AO's approved program would be deemed by CMS to have met the applicable Medicare conditions and would be referred to as having "deemed status."

C. Congressional Report on the Oversight of National AOs and CMS-Approved Accreditation Programs

We are required by section 1875(b) of the Act to submit an annual Report to Congress³ on CMS' oversight of national AOs and their CMS-approved accreditation programs. This report contains information related to the AOs' activities in a fiscal year (FY) and provides a comparison of these activities to the activities of previous years. Within this report, we also measure the "disparity rate," which is a comparison rate based on AO findings of non-compliance during an accreditation survey and the SA findings of non-compliance for the same facilities found during a look-back validation survey.

For certain types of healthcare facilities, there are three levels of adverse findings on an SA survey: immediate jeopardy (IJ); condition-level deficiencies; and standard-level deficiencies. Sections 488.1 and 489.3 define immediate jeopardy as a situation in which the provider's or supplier's non-compliance with one or more of Medicare requirements, conditions of participation, conditions for coverage or certification "has caused or is likely to cause, serious injury, harm, impairment, or death to a resident or patient." When investigating a potential immediate jeopardy situation, surveyors must find that there is non-compliance by the provider or supplier, that serious harm has occurred or is likely to occur, and that immediate action needs to be taken by the provider/supplier (see Appendix Q of the SOM for additional guidance). A condition-level deficiency means that for that particular requirement under a

Medicare condition of participation or condition for coverage, also known as a CoP or a CFC respectively, the facility's noncompliance is such that it substantially limits the provider's or supplier's capacity to furnish adequate care or adversely affects the health and safety of patients (§ 488.24(b)). Surveyors may determine that a deficiency under a single standard alone may have substantially limited a facility's capacity to furnish adequate care and/or adversely affected the health and safety of the facility's patients such that it rises to the level of a condition-level deficiency. The manner and degree of the deficient practice is considered to determine whether there is substantial noncompliance (that is, a condition-level deficiency) or not. A standard-level deficiency means that the provider is out of compliance with one or more aspects of a regulatory condition or requirement that is not severe enough to rise to the level of a condition-level deficiency. A condition-level deficiency, however, is considered more serious in nature and could lead to a facility being terminated from the Medicare and Medicaid programs for non-compliance. Immediate jeopardy citations are condition-level deficiencies that pose immediate jeopardy to patient health and safety. On a validation survey, when the SA cites a condition-level deficiency for which the AO has not cited a comparable deficiency, the deficiency is considered by CMS to have been missed by the AO and is a factor in determining the AO's "disparity rate" for each facility type. The identification of one missed condition-level deficiency by the AO results in the entire survey being counted toward the disparity rate. The number of disparate surveys is divided by the total number of validation surveys performed with respect to that AO by various SAs, to determine the AO's disparity rate.

According to the most recent report, the FY 2020 Report to Congress,⁴ average disparity rates for all CMS-approved AO programs for the following facility types for the most recent year in the report (FY 2019) are: Hospitals (42 percent); Psychiatric hospitals (45 percent); Critical Access Hospitals (46 percent); Home Health Agencies (HHAs, 8 percent); Hospices (19 percent) and Ambulatory Surgical Centers (34 percent). From FY 2018 to FY 2019, hospitals, HHAs and ASCs had the only decreases in disparity rates, with a decrease of 5 percentage points, 11

³ The most recent Report to Congress may be accessed at <https://www.cms.gov/files/document/qso-22-06-ao-clia.pdf>.

⁴ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-17-AO-CLIA.pdf>.

percentage points, and 7 percentage points, respectively. The disparity rates for psychiatric hospitals increased by seven percentage points from FY 2018 to FY 2019. The disparity rates for Critical Access Hospitals (CAHs) and hospices increased by 5 percentage points and 3 percentage points respectively from FY 2018 to FY 2019. The findings and other information are consistent with previous reports, and no other notable changes were observed in the FY 2020 Report to Congress covering the FY 2019 period of activities. We note the impact of the COVID-19 public health emergency (PHE) in relation to the decreased representative validation survey sample size and disparity rates during FY 2020, and the continued suspension of look-back validation surveys since that point.

D. CMS Validation Survey Pilot

As part of our ongoing efforts to enhance transparency and our oversight of the AOs, in 2018, CMS began a pilot for integrated validation surveys for accredited hospitals, known as the Validation Redesign Program (VRP) pilot. In a VRP pilot survey, the SA teams accompany the AO survey teams on a reaccreditation survey for an accredited facility for the purpose of evaluating the AO surveyors' competency at performing surveys and overall effectiveness during the survey process. The initial findings of the VRP pilot were discussed in the proposed rule at sections IV.J. and IV.L.3. CMS plans to continue to refine the validation process over the next several years to enhance AO oversight and verify that providers/suppliers under deemed status are in compliance with the Medicare conditions and focus surveys on key quality concerns while reducing provider/supplier burden.

A national AO seeking approval of its accreditation programs in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed 6 years. (See §§ 488.5(a), (e)(2)(i)). An AO must submit a renewal application if it wishes to seek re-approval of its accreditation program(s) before the expiration date of its current CMS approval. Review of the AO's renewal application in a timely manner allows CMS to ensure that there would not be a lapse in accreditation for the providers and suppliers accredited by the AO. Requiring the AO to submit a renewal application periodically allows CMS to ensure that the providers or suppliers accredited by that AO meet or exceed the Medicare conditions.

E. Overview of Transparency and Oversight of Accrediting Organizations

In September 2017, an article in the Wall Street Journal⁵ raised concerns regarding the performance and transparency of AO surveys and noted potential conflicts of interest between an AO's accreditation services and its consulting services. As a result of this article, CMS initiated an investigation into these allegations.

F. Prior Rulemaking—Accrediting Organizations Conflicts-of-Interest Request for Information (RFI)

CMS is aware, from the information submitted with their applications, that some AOs with CMS-approved accreditation programs are also providing fee-based consultative services to Medicare-participating healthcare facilities. Our understanding is that typical AO fee-based consultative services include, but are not limited to, the following:

- Assistance for clinical and non-clinical leaders (including administrators) in understanding the AO standards and Medicare conditions for compliance;
- Review of facility standards and promised early intervention and action through simulation of a real survey, such as a mock survey with comprehensive written reports of findings;
- Review of a facility's processes, policies, and functions;
- Identification of, and technical assistance for, changing and sustaining areas in need of improvement; and
- Educational consultative services.

CMS acknowledges that independent fee-based consulting is a valuable resource that can help providers and suppliers improve the quality and safety of the care they provide. This does not mean that the providers or suppliers who elect not to receive fee-based consulting from an AO that offers it, or that providers or suppliers that are accredited by an AO that does not offer this service would not provide safe, quality care.

There are many third-party consultants that offer fee-based consulting across all provider and supplier types. The availability of third-party fee-based consultants give providers and suppliers access to this educational service, if their AO does not provide fee-based consulting. If a

provider's/supplier's AO already offers fee-based consulting, third-party consultants can offer such providers and suppliers with an alternative, allowing providers and suppliers to compare the effectiveness and quality of consultants to address their needs within their cost limitations. The provider or supplier may also be able to negotiate a price for educational services provided by a third-party consultant, while this may not be an option with the AOs that offer fee-based consulting. It is important to note there would be no conflict of interest associated with the use of third-party fee-based consultants because these consultants do not also make compliance determinations about the provider or supplier.

Fee-based consulting services offered by AOs are not prohibited by law or regulation. However, CMS is concerned that an AO's provision of such fee-based consulting results in perceived or actual conflicts of interests because of the contractual and financial relationship that exists between the healthcare provider and the AO, which is a private entity that profits from the performance of the inherently governmental function of regulating healthcare providers through accreditation.

Because of this, on December 20, 2018, we published a Request for Information (RFI) in the **Federal Register** entitled, "Medicare Program: Accrediting Organizations Conflict of Interest and Consulting Services; Request for Information" (83 FR 65331), hereinafter referred to as "2018 AO Conflict-of-Interest RFI", in response to increasing concern about potential conflicts of interest created by the accreditation and consultative activities of the AOs. Specifically, we solicited public comments to determine whether offering consultative services to the same entities an AO accredits may create actual or perceived conflicts of interest between an AO's accreditation program and its consultative program. We stated that this dual function may undermine, or appear to undermine, the integrity of the accreditation programs and could erode public trust in the safety of providers and suppliers that have been accredited by CMS-approved AOs. We further acknowledged that certain consulting services offered by some of the AOs, such as quality improvement work and training of facility staff, may be beneficial to some facilities and result in improvements in operations or the quality of care furnished and may be provided with the best of intentions. We stated that circumstances could arise where an AO has recommended a facility for deemed status through their accreditation

⁵ The Wall Street Journal, "Watchdog Awards Hospitals Seal of Approval Even After Problems Emerge" Stephanie Armour (September 8, 2017) <https://www.wsj.com/articles/watchdog-awards-hospitals-seal-of-approval-even-after-problems-emerge-1504889146>.

service, while the consultancy service of the AO was generating revenue assisting the same facility in passing the AO's own accreditation surveys. Some AOs have indicated that they establish firewalls between the arms of their businesses, but we stated that these firewalls may not be sufficient to ensure that no conflicts of interest result from these activities.

We further stated that, similar to quality improvement organization (QIO) and external quality review organization programs, any AO with a Medicare-approved accreditation program has assumed a position of public trust and is responsible for acting on behalf of the public, because the AO is performing a function that assists in the Federal government's enforcement programs. We also expressed our view that AOs voluntarily take on this position and responsibility when they seek accreditation approval from CMS to accredit providers and suppliers for participation in Medicare. Because of the responsibility to maintain public trust and public health, we continually ensure that all entities and programs, including AOs and their accreditation programs that require CMS approval, be held to high standards of ethical conduct so that everyone can have complete confidence in the integrity of Federal government certification. We stated that the AOs' decisions to accredit facilities must be made without regard to any additional services that a Medicare provider or supplier might obtain through the AO or its subsidiaries. We stated that this policy would ensure and maintain public trust in the Medicare certification program.

In the 2018 AO Conflict-of-Interest RFI, we solicited public comments to gather information for potential future rulemaking and to obtain insight on mechanisms to address this potential conflict of interest. We were specifically interested in ways to potentially modify § 488.5(a), which sets out the required information to be submitted with an AO's application. For example, § 488.5(a)(10) states that the application information from the AO include the organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

We stated that potentially expanding § 488.5(a)(10) by adding provisions that would require the AOs to disclose information about any consultative services they offer to facilities could further enhance our oversight of AOs.

In addition, we solicited comments on the following issues:

- With respect to fee-based consultative services provided by AOs to the facilities they accredit—
 - ++ How are these services provided and communicated to the facilities?
 - ++ Are potential conflicts of interest disclosed?
- Are there other entities that could provide this training besides the AOs?
- Whether commenters perceive a conflict of interest in AOs providing fee-based consultative services to the facilities they accredit.
- Whether the ability of an AO to collect fees for consultation services from entities they accredit could degrade the public trust inherent in an AO's CMS-approved accreditation programs.
- What the appropriate consequences or impacts should be, if a conflict does exist.
- What firewalls may exist within an AO between accreditation and consultation services, or what firewalls would be prudent, to avoid potential and actual conflicts of interest.
- Examples of positive and negative effects which may arise as a result of a conflict of interest.
- What the potential impact, financially and overall would be if CMS were to finalize rulemaking which would restrict certain activities that might give rise to a real or perceived conflict of interest.
- When and/or under what circumstances it would be appropriate for AOs to provide fee-based consultative services to the facilities which they accredit.
- Whether, and if so under what specific circumstances, CMS should review a potential conflict of interest, and what factors CMS should look at to determine if a conflict of interest exists.
- A list describing under what circumstances the AOs or interested parties would believe there to be a conflict; and under which circumstances a conflict does not exist.
- The type of information which would be considered necessary, useful and/or appropriate in proving or refuting our hypothesis of a connection between the use of consultative services and preferential treatment of accredited providers and suppliers. (See 83 FR 65335.)

We received 128 public comments in response to the 2018 AO Conflict-of-Interest RFI. Approximately half of the commenters (consisting primarily of AOs and healthcare facilities that use consulting services) supported the use of AO consulting services and stated that there is no conflict of interest associated with fee-based consulting. The other half of the commenters

(consisting of individuals, provider associations, medical advocacy groups and one AO) stated that the provision of fee-based consulting by the AOs creates a conflict of interest.

Several commenters stated that the benefits derived from AO fee-based consulting far outweigh any potential or actual conflict of interest that may result. Many commenters believe that AO consulting services allow the facility to seek information and guidance that helps them understand, interpret and comply with the Medicare conditions and regulatory requirements. These commenters stated that use of the AO's fee-based consulting services helped to improve the safety and quality of the care provided by the healthcare facility.

Many commenters stated that there are already implemented checks and balances between CMS and the AOs that are sufficient to ensure that no conflicts of interest occur between the AOs and their accredited facilities. These commenters stated that the AOs have robust firewall policies and procedures in place to prevent conflicts of interest related to fee-based consulting. Many commenters also stated that CMS has a specific AO fee-based consulting firewall policy in place and that this policy is adequate to prevent any conflicts of interest. However, CMS does not currently have such a policy.⁶

Several commenters stated that AOs are commissioned to ensure compliance with the Medicare conditions. These commenters stated that a big part of compliance is not only being punitive but informational/educational. One commenter suggested that AOs are in a unique position to provide this education and technical assistance because they understand the complexity of the Medicare conditions. One commenter stated that if AO fee-based consulting services were not provided, facilities could see additional deficiencies cited due to misinterpretation of requirements and multiple rounds of surveys, generating still more cost to the facility.

Several commenters stated that the financial benefit derived by the AOs from providing fee-based education is not significant. Some of these commenters also stated that the AOs gained no benefit from the success or results of accreditation whether they had assisted the provider to deliver better services or not.

⁶In section IV.B.6. of the proposed rule, we proposed to require any AO that provides fee-based consulting services, or its associated fee-based consulting division or company, have written fee-based consulting "firewall" policies and procedures.

One commenter stated that they are not aware of other organizations that would be capable of educating and advising healthcare providers in a similar fashion as the AOs' consulting services. Several other commenters expressed concern about having fee-based consulting services provided by an independent third-party. These commenters stated that, while there are other entities besides the AOs, such as QIOs, that could provide training, the focus would solely be on quality rather than the outcome of an accreditation.

Many commenters stated that the integrity of the accreditation process is of utmost concern for regulators, providers, and patients alike and that AOs should position themselves to be above reproach regarding overseeing patient care and quality of services that healthcare facilities provide, so as to retain the trust of patients and the public. Several commenters suggested that anything that may undermine the integrity of accreditation programs or the public trust in CMS accredited providers and suppliers be considered and addressed. One commenter stated that the ability of AOs to provide both survey services and consulting services is a conflict of interest, which results in a decreased level of trust among providers, Medicare, and the public.

Many commenters expressed concern about the financial and contractual relationship that exists between AOs and the healthcare facilities they accredit. These commenters expressed concern that the existence of a financial relationship between AOs and healthcare providers casts a veil of doubt over the entire CMS hospital accreditation process, eroding the public trust in CMS to maintain the standard of care at our nation's hospitals and to ensure that Medicare patients are receiving safe, therapeutic care. One commenter opined that the business connection between the provider and the AO creates a relationship that the AO could have an incentive to manipulate.

In addition, several commenters expressed concern about the significant financial interest the AOs have in the provision of fee-based consulting. One commenter stated that since AOs are being paid by the healthcare facilities for both accreditation services as well as consulting services, it is obviously in their financial interest to keep the healthcare facilities accredited and not to create too much dissatisfaction to incite the organization to seek another AO. Several commenters expressed concern that this financial relationship might provide the incentive for the AOs to ignore or downplay deficiencies

during the survey of a consultative client to increase the apparent efficacy of its consulting services. Or, perhaps, an AO could exaggerate the deficiencies on surveys to increase the apparent value of the consulting services to providers. Because of the previously stated concerns, several commenters suggested that CMS prohibit the AOs from providing fee-based consulting to the healthcare providers and suppliers they accredit.

G. Conflicts of Interest—The AO Owner's, Surveyor's, and Other Employee's Interest in or Relationship With a Healthcare Facility That the AO Accredits

It is typical for an individual healthcare professional, such as a physician or nurse, to have concurrent employment relationships with more than one healthcare provider. Many healthcare professionals, such as physicians, physician assistants, and nurse practitioners have multi-setting practices or are employed at more than one healthcare facility. For example, a registered nurse (RN) may work on staff at a hospital but also work at other hospitals through a medical staffing agency. In addition, as employees of a healthcare facility, these healthcare professionals could possibly gain a financial interest in the healthcare facility through means such as being a contributor to the construction costs of a new wing of the facility or buying stock in the facility or its parent corporation. Management employees could be awarded stock or stock options for the facility or its parent corporation as part of their compensation and benefits package.

AOs frequently hire surveyors that are also employed at one or more outside healthcare settings because the professional associations, expertise, knowledge and skills held by these healthcare practitioners make them an asset as a surveyor. This might include, for example, an RN who is employed by a hospital and also works as a surveyor for an AO. This employment scenario does not generally violate CMS policy or regulations. Furthermore, an AO surveyor having other employment does not, in and of itself, necessarily create a conflict of interest. However, if the AO provides accreditation services to the healthcare facility that employs the AO surveyor, this could cause a conflict of interest if that surveyor is permitted to have any involvement in the survey process for that healthcare facility.

CMS has recently encountered two situations in which an AO's surveyor was also employed by the healthcare facility that was being accredited by the

AO. In one of these situations, an AO surveyor was also employed in an administrative position at a rehabilitation facility that was being surveyed by the AO. This situation was not disclosed to CMS by the AO. Currently, CMS has no specific regulations that would prohibit a conflict of interest related to an AO surveyor's relationship with a healthcare facility that the AO accredits, except for home health agencies and hospice programs.

Section 488.5(a)(10) of our regulations requires that an AO provide, with its application seeking CMS approval of its accreditation program, "the organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions." However, § 488.5(a)(10) does not provide requirements for specific types of information or requirements that should be contained in the AO's conflict-of-interest policies and procedures. This regulation does not specifically prohibit or define conflicts of interest and based on the comments to the 2018 AO Conflict-of-Interest RFI, CMS proposed to revise this regulation to more specifically address situations that should be included in the AO's conflict-of-interest policy.

As noted previously, the SAs and AOs perform similar work. Section 4008 of the SOM describes examples of scenarios that would be conflicts of interest for SA surveyors who have an outside relationship with a facility that is surveyed by the SA.⁷ Currently, section 4008 of the SOM applies only to SA surveyors and not AO surveyors.

Scenarios in which an AO surveyor has a relationship with a healthcare facility that their AO accredits could represent a conflict of interest. As CMS has no specific regulations that would proactively address such conflicts of interest for AOs that accredit healthcare providers other than home health agencies and hospice programs, we proposed establishing several requirements to help mitigate such conflicts of interest in section IV.B.7. of the proposed rule.

⁷ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c04pdf.pdf>.

H. Public Comment on Whether it Is a Conflict of Interest for AO Board Members or Advisors To Have an Interest in, or Relationship With, a Healthcare Facility that the AO Accredits

As previously stated, it could be a conflict of interest when an AO surveyor is involved with the survey of a facility with which that surveyor has an employment, financial, business or other interest or relationship. We note that in most cases, the AO board members do have interests in or relationships with the healthcare facilities the AO accredits. In many cases, the board members of the AOs frequently hold upper management positions of a healthcare facility the AO accredits, such as chief executive officer (CEO), director, or President. In the proposed rule, we sought public comment as to whether it would be a conflict of interest for an AO board member, AO advisor, or CEO or other executive team members to also have a relationship with a healthcare organization accredited by such AO. An AO advisor would be an advisory committee member, advisor to the CEO, or an advisor to the board of directors. We refer readers to the revisions related to an AO owner's, surveyor's or other employee's interest in, or relationship with, a healthcare facility the AO accredits in section III.J. of this final rule with comment period.

We received comments in response to our request for public comments on whether it is a conflict of interest for AO board members or advisors to have an interest in or relationship with a healthcare facility that the AO accredits. The comments and responses can be found in section III.D. of this final rule with comment period.

III. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Proposed Rule

As stated in section "I. Executive Summary" and section "II. Background" of this final rule with comment period, there are several provisions related to oversight of AOs that we believe require strengthening since we issued the 2015 AO final rule. Over the last several years, we have worked closely with the AOs to establish and implement an AO Liaison program in which we meet with each AO regularly (at least on a quarterly basis). These meetings and discussions have provided an avenue for CMS to also receive feedback on existing Medicare conditions and our interpretive guidelines and allowed us an opportunity to clarify our

expectations for the AOs. Most importantly, this experience has helped us to identify areas of our AO oversight regulations in need of revision so that we might more clearly articulate the requirements for all AOs with CMS-approved accreditation programs. Therefore, we have become aware of the need to clarify, reorganize, and amend our regulations to support a more efficient and effective oversight process.

The proposed rule, titled "Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions" (89 FR 11996 through 12064), was published in the **Federal Register** on February 15, 2024, with a comment period that ended on April 15, 2024. We received approximately 250 individual public comments from 58 separate commenters on our proposals, including comments from AOs; ESRD facilities; national renal groups, nephrologists, and patient organizations; patients and care partners; manufacturers; healthcare systems; and nurses.

In this final rule with comment period, we provide a summary of each proposed provision, a summary of the public comments received and our responses, the policies and requirements we are finalizing for AOs (including those for preventing AO conflicts of interest), and other related provisions we are finalizing in this rule.

A. General Comments in Support of the Proposed Rule

Comment: Many commenters supported the provisions of the proposed rule. They stated that the rule aims to protect patients, strengthen oversight of AOs to ensure that the highest quality of care is being delivered to all patients. Commenters also stated that this rule will help to ensure that all AOs conduct their work in a consistent, rigorous, and unbiased manner. The proposals made in the rule, if finalized, will prevent conflicts of interest, streamline survey processes and ensure more consistency between AOs and CMS or SA surveyors. One commenter supported the proposed rule because they believe it is imperative that as CMS seeks to improve oversight and transparency of AOs, it avoids introducing unnecessary obstacles to the ability of providers to seek accreditation through these AOs. One commenter the proposal made in the proposed rule and further suggested that CMS be more aggressive in their effort to strengthen the requirements and process for deeming hospices eligible for Medicare certification given the ongoing challenges related to hospice fraud,

waste, and abuse. Another commenter supported the proposed rule because it will help the public know which healthcare facilities to choose from and to be confident that any accredited facilities they do choose will provide high-quality care.

Response: We thank these commenters for their support of the provisions of the proposed rule.

B. Comments Expressing General Opposition to the Proposed Rule

Comment: Two commenters believe the proposed oversight will require additional administrative work from CMS, which one commenter believes is already concerned with existing staffing levels and which the other commenter believes is only now returning to normal workloads after the COVID-19 PHE.

Response: We appreciate these commenters' concerns for the administrative burden on CMS staff to implement the provisions of this rule. We will consider the potential for additional burden to CMS staff when implementing these provisions. We anticipate a fully developed workflow for the increased AO oversight provisions prior to implementation of the rule.

Comment: One commenter opposed the provisions in the proposed rule because they believe the extent of changes proposed are vast and far reaching; they stated that many provisions contain ambiguities and needed additional clarification.

Response: We thank this commenter for their comment. We appreciate this commenter's concern for clarity. However, we are not able to respond to this comment because the commenter did not provide enough detail about the provisions they think were excessively far-reaching and/or unclear.

Comment: Several commenters oppose the proposed rule because they believe that CMS does not have the statutory authority to make such proposals. One commenter stated that the Congress delegated only limited authority to CMS to grant private AOs the ability to "deem" that a provider or supplier meets or exceeds the Medicare conditions and that CMS' limited authority to regulate AOs must be tied to the statutory purpose.

Another commenter believes that the Congress has not granted CMS the authority to determine the AO's service offerings or to regulate any aspects of the AO's operations, governance structure, or business practices. In proposing that AOs only be allowed to provide certain services at certain times, the commenter believes CMS has exceeded its authority under the statute,

venturing into operational grounds with which the Congress never intended the agency to interfere.

Response: We respectfully disagree. CMS is using the authority established by the Congress under section 1865 of the Act to establish certain requirements for AOs in this rule. The Congress gave CMS broad authority for oversight over the AOs.

Comment: One commenter recommended that instead of implementing all of the provisions in the proposed rule, we instead select provisions for implementation that receive the least amount of negative public comments, then at a later date, update the proposed changes that may be viewed by some as more burdensome and imprecisely drafted, followed by the issuance of a RFI with an extended comment period that allows time for detailed and evidence-based responses. The commenter believes this segmented approach will allow both CMS and the AOs to focus on perfecting the selected changes without being overwhelmed and overly burdened by the number of changes implemented at one time.

Response: We thank the commenter for their recommendations but respectfully disagree with this approach to finalizing the rule we proposed in February 2024. We note that we did publish an RFI on December 20, 2018 (83 FR 65331), seeking public input on our oversight of AOs, particularly with regard to AO conflict-of-interest issues. We carefully considered the information received on the 2018 RFI as well as the public comments received on the February 2024 proposed rule as we developed this final rule with comment period.

C. Add Definition of “Unannounced Survey” to § 488.1

We proposed to add a new definition of “unannounced survey” to § 488.1. The definition of “unannounced survey” would be consistent with the definition of “unannounced” contained in the Merriam-Webster dictionary, which is “without previous notice or arrangement and therefore unexpected”. Adding this definition of “unannounced survey” would support the existing requirements set out at § 488.5(a)(4)(i) and in our sub-regulatory guidance. This proposal clarifies and codifies existing requirements under § 488.5(a)(4)(i), which requires that surveys must be unannounced, which means that the facility must be unaware of the survey until the time that the survey team arrives, and that the provider or supplier would not receive notice of the survey until the survey team arrives at the facility. Our long

standing policy behind the term “unannounced survey” is within Chapter 2, Section 2700A of the SOM, outlining the expectation that all surveys of providers and suppliers (other than clinical laboratories) must be unannounced to the provider or supplier being surveyed. This means that the provider or supplier to be surveyed would not receive notice of the survey until the survey team arrived at the facility for the survey, as is also currently the AO’s process for complaint surveys. The proposed definition for “unannounced survey” would also state that unannounced surveys must be scheduled by the AO in a manner so that their timing and occurrence will not be predictable to the healthcare facility being surveyed.

One of the primary reasons surveys conducted by either the SA or the AO are required to be unannounced is to prevent the provider or supplier from making unusual preparations for the survey that would not represent the ongoing typical condition of the provider, and the true nature and quality of care provided. Examples of these activities would include unusual cleaning activities, painting, clearing obstructions from halls and entrances, denying leave to staff during that time or calling staff back to inflate staffing availability, and re-reviewing medical records outside of what is normally done. If a provider or supplier knows the exact time a surveyor will be onsite, it may temporarily adjust its typical practices such as staffing, which would provide an unrepresentative picture to surveyors of the quality of care typically provided to patients or residents. Any notice to facility leadership via organizational websites, emails, or phone calls prior to surveyors arriving onsite is considered a violation of CMS regulations.

In 2009, CMS clarified this expectation in the Survey & Certification Policy Memorandum 09–41,⁸ to advise that announcing of surveys was in conflict with CMS regulations. In the effort to align AO survey processes with CMS survey processes (which are followed by the SA surveyors), as outlined in section IV.C. of the proposed rule, we determined that additional clarity regarding this prohibition was needed. Defining the term “unannounced survey” within the regulation as opposed to our SOM (sub-regulatory guidance) would provide clarity regarding our expectations, and

would mirror the processes used by the SAs, who do not announce their surveys (except for clinical laboratories); as noted, any AO practice of announcing surveys could undermine the integrity of the survey process. While we recognize that some AOs may have provided up to a 60-minute advance notice of the survey team arriving onsite for initial and reaccreditation survey activities, this practice is inconsistent with the processes followed by our SAs and inconsistent with the AOs’ own survey processes for complaint surveys (which are always unannounced). Therefore, in accordance with § 488.5(a)(4)(i), which requires unannounced surveys, as well as our long-standing policy in Chapter 2, Section 2700A of the SOM, we proposed to define “unannounced survey” to clarify through this definition that all surveys of providers and suppliers (other than clinical laboratories) must be unannounced and any advance notice to facilities would be prohibited. This definition would ensure clarity in the requirement that applies to AOs as well as SAs and further support our initiative to bring consistency to survey practices as outlined in section IV.C. of the proposed rule.

Furthermore, the definition of “unannounced survey” ensures that the timing of recertification surveys is also unpredictable. AOs generally complete comprehensive re-accreditation surveys of their client providers and suppliers every 32 to 36 months. However, some providers or suppliers have informed us that they know when an AO is scheduled to survey the facility—the AO may schedule the facility for survey within the same week or month every survey cycle, or has narrowed its schedule via the use of blackout days, or informed the facility close to the time of the survey via administrative contact from the AO, such as payment collection, confirmation or change of address notification or other facility-AO specific information. All of these practices undermine the integrity of the unannounced survey process.

We received several comments, with a majority of the comments in general support of our proposed definition. The comments and our responses to the comments are set forth below.

Comment: We received several comments supporting our proposal for unannounced surveys, restricting blackout dates and ensuring the unpredictability of surveys. One commenter stated that an unannounced survey will enable the surveying organization to more effectively assess the organization in its normal state, identify areas of risk and subsequently

⁸ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS1223113>.

improve patient care. One commenter supported our proposed definition of “unannounced survey”, highlighting that unannounced surveys would not only provide more consistency among AOs and SAs, but also may impact the proliferation of fraudulent hospices. Another commenter stated that announcing any survey allows companies time to prepare and that unannounced surveys will ensure that surveyors receive honest results. One commenter also stated that all surveys should be unannounced without the facility being aware of the survey until the arrival of the survey team. One commenter also stated that among CMS’ proposals for increased comparability, the most important aspect was use of the unannounced survey to avoid rigging of the system.

Response: We appreciate the commenters support of the proposed definition of “unannounced surveys”. We agree that adding the definition will help ensure more consistency among AOs and SAs and the integrity of survey results.

Comment: We received one comment noting that the proposed definition of “unannounced surveys” and the preamble discussion within the proposed rule are consistent with CMS’ 2023 notice letter to AOs (discussing unannounced surveys and blackout dates). The commenter stated that CMS overestimated the actions facilities could take to improve the results of an impending survey on short notice. The commenter urged CMS to consider allowing hospitals a 24-hour notice of the survey to ensure appropriate staff would be available during the survey and to maximize access to hospital leadership and other staff who could answer surveyor questions. The commenter suggested that this would allow for a more efficient survey process and that survey results would be more useful and reflective of the care provided by the facility. The commenter stated that a 24-hour window would not allow sufficient time to make outcome-changing preparations. Finally, the commenter also suggested that when AOs combine complaint investigations with the required 36-month reaccreditation survey the type of survey is frequently not identified by the surveyor. The commenter implied that this process is confusing for hospital staff and risks conflating the results and urges CMS to ensure surveyors clearly identify the purpose of the survey with outreach to hospital staff to address issues which may arise.

Response: While we appreciate the commenter’s concern, we note that we proposed to add a definition, which

does not change the requirement at § 488.5(a)(4)(i) that was discussed in the 2023 letter the commenter mentioned, which is a letter from our Quality, Safety & Oversight Group Director that was sent to the AOs through our AO liaisons. Surveys are intended to assess the daily operations of the facility at any time. Facilities should always have processes in place to ensure continuity of care and operations in the event that leadership is not available or onsite. Therefore, we believe that advance notice could give leadership an opportunity to appear involved in the facility, when in normal operations, leadership could be absent or not as involved as made out to appear. Additionally, a 24-hour notice could allow for a facility to increase staffing for the day of the survey or clean areas of the facility which otherwise would have not been changed. As for the commenter’s concern that when complaint investigations are incorporated into a recertification/reaccreditation survey, we note that Chapter 5 of the SOM allows both SAs and AOs to combine complaint investigations into the next survey activity if the complaint was triaged as low-priority. However, we understand the commenter’s concerns for the need of a transparent process and believe that adding a regulatory definition for “unannounced survey” will further that goal.

Comment: We received several comments raising concerns about unannounced surveys and the potential for this to disrupt operations. One commenter specifically stated that unannounced surveys disrupt the daily operations of healthcare facilities, potentially affecting patient care and staff workflows. The commenter also stated that this is a resource burden where facilities may need to allocate more resources to maintain constant readiness for survey. Another commenter stated that some individuals who support regulatory surveys may not work onsite at the facility and that certain departments such as infection prevention, quality or others may be covered by individuals working in multiple locations, especially in rural locations. Alternatively, one commenter stated that surveys should not be delayed more than 30 minutes of the reported opening time. Finally, two commenters also advised that notification on the initial day of survey is critical to ensure key members are present, negate interruptions in the facility’s operations, and ensure coordination, especially for multi-site institutions. One of the two commenters

specifically stated that same-day notification would protect patient and workforce safety.

Response: While we appreciate the commenters’ concerns, we note that CMS has expected that all survey activities from the SAs and AOs are to be unannounced and has reiterated this expectation in § 488.5(a)(4)(i), the SOM, and other subregulatory guidance.⁹ This long-standing requirement ensures that surveyors can observe a facility’s daily operation and that facilities do not make adjustments to pass the survey, as implied by the commenter. Surveyors are flexible and are required to work around the facility’s schedules and its daily requirements to provide patient care. For instance, if a Registered Nurse is assisting a survey team with record reviews but needs to see patients, the expectation is that patient care takes priority over survey activities. Similarly, should a facility have staff which support the daily operations but may be off-site, surveyors will wait for their arrival and conduct other survey activities during that time, or even conduct telephone interviews should the individual not be able to travel to the facility on the survey date(s). We agree with the one commenter related to delay of survey activities upon arrival beyond 30 minutes should not be the norm; however, we believe that the facility’s verification of the survey team and beginning the survey processes (including the facility gathering required documentation) should not be significantly slowed. Surveyors may delay the formal entrance conference to await leadership or staff the facility may want present, especially in situations with multiple locations.

Comment: One commenter advised that unannounced surveys and the inability to provide blackout dates would pose challenges for hospitals and accreditation specialists. Specifically, the commenter suggested that blackout dates and announced surveys offer crucial preparation time, the ability to allocate resources efficiently, conduct self-assessments and identify deficiencies proactively. The commenter also stated that lack of prior knowledge of the survey amplifies stress among the facility’s staff and hampers productivity and morale in a hospital setting. The commenter also suggested that announcing survey activities in advance would allow for continuous improvement and ensure high standards of care.

⁹ <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/cms1223113>.

Response: We thank the commenter for expressing concerns related to unannounced surveys and blackout dates. While we understand unannounced survey activities can pose a challenge, this has been a long-standing requirement. Unannounced survey activities are intended to assess a facility's quality of care provided on any given day and to prevent the provider or supplier from making special preparations for the survey that would not represent the ongoing typical condition of the provider and true nature and quality of care provided, such as increasing staffing that would not usually be scheduled; adjusting records and practices; and unusual cleaning or changes to its physical environment. We do not want to provide an opportunity for facilities to demonstrate a different picture to surveyors from how the facility normally operates. Additionally, we expect that facilities are survey-ready, meaning always in compliance with the Medicare conditions, at all times. Therefore, allowing facilities to choose dates that they wish not to be surveyed further compromises a true depiction of how the facility operates on any normal business day. Related to the commenter's suggestion that announced surveys allow for continuous improvement and ensure high standards of care, we believe by adding the definition of "unannounced survey" and continuing the requirement for unannounced surveys should have no bearing on facilities providing high-quality care to patients.

Comment: We received two comments raising concerns specific to our discussion and restriction of blackout dates. One commenter stated that prohibiting blackout dates would make it very difficult for organizations to successfully support survey activities while maintaining day-to-day operations. The commenter stated that organizations may not always have the bandwidth to support multi-day regulatory surveys, as staff or leaders must escort surveyors, answer questions, and attend meetings all while supporting and providing patient care. Another commenter voiced significant concerns with the prohibition of blackout dates, highlighting the drastic workforce shortages as the result of the COVID-19 pandemic and a strained health system. This commenter implied the burden associated with staff having to provide care to patients while providing support to surveyors and that the ability for a facility to request blackout dates, as well as pre-survey contact with the AO, ensures that the

facility has the necessary resources, to include staff, files, manuals, and policies, when the survey team arrives. Additionally, the commenter raised concerns related to unannounced surveys, as some facilities may be supported by individuals who cover multiple locations.

Response: We appreciate the commenters' concern related to blackout dates and the challenges which could arise regarding adequate staff to support the survey teams. The existing regulations 42 CFR 488.5(a)(4)(i) require unannounced surveys, as well as our long-standing instructions in Chapter 2, Section 2700A of the SOM. If a provider or supplier knows the exact time a surveyor will be onsite, even shortly before their arrival, it may temporarily adjust its potentially noncompliant and typical practices (for example, regarding staffing). This can lead to findings that are not representative of the quality and the safety typically provided to the facility's patients. Allowing facilities to request dates when they wish not to be surveyed is not consistent with our survey expectations. Furthermore, some AO blackout date policies provide the caveat that the wishes of the facility may not be guaranteed, we believe this practice is inconsistent with the requirements and policies for unannounced surveys and the expectation that a provider/supplier must be always "survey ready". If an AO learns that a facility has a situation that would decrease the efficacy of an onsite survey (such as a sole practitioner who will not be at an ASC and no surgeries will be performed that day), the AO may pick an alternate date. This decision, however, rests with the AO and should not be driven by the facility. We appreciate the commenter's concerns surrounding staffing shortages in a post COVID-19 environment and the challenges for supporting survey activities. Surveys are intended to assess the normal day-to-day operations of a facility and are not intended to be disruptive. We recognize staff participating in survey activity may need to pause assisting surveyors to provide patient care or manage the facility's operation. Surveyors and processes are intended to be flexible when onsite and patient care and safety is our number one priority. However, it is imperative to use unannounced surveys to assess the daily operations at the facility, and to also ensure that patients receive quality care and sufficient staff are available to the patients to provide a safe environment.

Comment: We received several comments raising concerns related to the physical security and safety of staff.

One of the commenters noted that AOs had adopted pre-arrival notifications because health systems experienced incidents of individuals impersonating surveyors accessing a facility with fake credentials; the commenter also cited Bureau of Labor Statistics data showing an increase in the number of healthcare workers physically attacked. Another commenter noted that violence against healthcare workers is on the rise, and pre-arrival notification would allow proper identification of surveyors. A few commenters also stated that a 30-minute to 60-minute pre-arrival notice would not allow sufficient time for usual preparations to be made. Another commenter echoed the comment regarding safety risks and stated that The Joint Commission's process for pre-notification includes a survey agenda, letter of instruction, biography, and picture of the surveyors for facilities to verify and validate the surveyors are legitimate. Another commenter stated that pre-survey notifications allow facilities to maintain the physical security of the facility. This commenter stated that notification ensures that health systems can inform their security personnel and receptionists to expect the survey team.

Response: We appreciate the concerns related to unauthorized individuals who may attempt to gain entry using fake credentials, however, we note that this occurrence has not been reported by any non-deemed facilities under various SAs' jurisdictions. SAs present credentials at the time of arrival for authentication and entry into the facility. We would expect AOs present their credentials as is currently customary upon arrival. Furthermore, allowing a one-hour notification to the facility could provide sufficient time for the facility to adjust schedules or make certain environmental changes which would not represent the true picture of the facility. Additionally, with respect to the one AO's process for notification (including photographs, biographies, and a survey agenda), AOs may implement these types of processes upon arrival and entry to the facility. Facilities are not restricted from verifying the survey team, whether the survey team is from the SA or an AO; facilities may request that surveyors wait until identification and verification is complete. Furthermore, we note that complaint surveys are unannounced, therefore arrival procedures and processes should not be different for initial or reaccreditation surveys. We encourage AOs to develop processes to ensure the integrity of unannounced surveys is maintained, while accounting

for processes which allow facilities additional time to verify surveyor identities.

Comment: One commenter, while in general support of the proposed provision, also urged CMS to include instructions or guidance to surveyors to be prepared with all the necessary identify verification documentation immediately upon arrival and to allow some period of time for hospitals to verify those identities before commencing the survey. This commenter emphasized the importance of safety of patients and staff.

Response: We appreciate the commenter's general support of unannounced surveys, and we appreciate the commenter's concerns on verification of identities. As outlined in the SOM program appendices, surveyors are already expected to present their identification upon entry at the facility. For example, Hospital Appendix A, Task 2 states "The entire survey team should enter the hospital together. Upon arrival, surveyors should present their identification." AOs must have comparable processes. Furthermore, we note that some AOs have already put identify verification processes in place, such as upon entry of the surveyor, the surveyor lead uploads identification information and survey notifications into portals accessible by their deemed facilities. We encourage AOs to develop processes that ensure identity verification and arrival procedures that align with CMS' expectations of unannounced surveys.

Comment: We received several comments related to the predictability of surveys and the requirement that AOs conduct surveys at least every 36 months. One commenter suggested that facilities roughly are aware of the timeframe of their reaccreditation window. Multiple commenters observed that the requirement for surveys every 36 months makes surveys somewhat predictable.

Response: We thank the commenters for their concerns, and we agree that while an accreditation/deeming cycle provides some level of predictability, surveys must be unannounced with no prior notice of arrival to the facility to maintain the integrity of the survey process. The intent of the proposed provision and definition of "unannounced survey" is to ensure an AO's administrative contact with facilities is variable and does not specifically address or imply the survey dates or month.

Comment: We received several comments related to pre-survey contact for administrative purposes. One commenter also stated that

administrative contact an AO has with its deemed facility is critical to ensuring that the size and complement of survey teams, and the length of surveys, are appropriate. This commenter stated that contact prior to survey ensures that the AO has the facility's application information, list of documents that will be required during the survey, contact information, hours of operation, and surgical schedules. The commenter stated that this maximizes the efficiency of the survey process. Another commenter stated that small, solo practitioner, and low-volume ambulatory surgical centers (ASCs) may operate with significantly smaller staff or may be closed during regularly scheduled hours due to illnesses of staff or due to vacations or personal matters of the practitioner. The commenter suggested CMS did not account for these operational challenges for pre-survey contact and pre-arrival notifications. One commenter stated that the proposed definition of "unannounced survey" is counterproductive and penalizes responsible providers from engaging with the AO for a productive survey. This commenter stated that communication between the AO and the provider is crucial to seamless execution of an unannounced survey and that surveys are resource-intensive, therefore by prohibiting preparatory dialogue would waste valuable time during the survey. The commenter also stated that pre-communication does not compromise the integrity of the survey process; operational preparations, including the logistical and operational scope of the survey should occur in advance for an efficient survey process.

Response: We appreciate the commenters' concerns related to pre-survey contact, specifically administrative contact with a facility. Our proposal aims to ensure administrative contact with facilities prior to surveys is variable. We are not restricting AOs from contacting facilities to verify application details or request additional information, such as their current operating hours, upcoming surgical schedules, any extension locations, or providing the facilities with an agenda. However, contact prior to survey to gather additional information must not suggest when the survey will occur. For example, facilities due for a survey in December (near the end of their accreditation cycle), should not be contacted each September and surveys should not always be scheduled exactly in the same weeks of November or December. We note that the proposed provisions do not intend to limit an AO from

communicating with their respective organizations prior to the survey to gather certain administrative information, such as operating hours and surgery schedules. The intent is for AOs to vary their preparatory contacts in a manner which is unpredictable and to ensure onsite surveys are unannounced. AOs must survey facilities at least every 36 months; therefore, we would expect any contact to be made 6 months, 3 months, 1 month or 2 weeks prior to onsite surveys randomly. We also appreciate the commenter's concerns and those challenges which may present due to small volume provider types with limited hours of operation, such as ASCs that operate once a week or a few times a month. We believe these requirements would not inhibit an AO from gathering needed information to facilitate planning for an unannounced survey.

Comment: We received one comment that the proposed definition for "unannounced survey" does not reflect the flexibility of Section 2700A of the SOM. The commenter stated that flexibilities allowed by the SOM include a provision stating that non-long-term care facilities (other than home health) may be given advance notice in certain situations; and that our proposed definition does not reference the SOM, furthering the concern that the advance notice provision could be removed from future SOMs (for example, in effort to align with regulatory text). Another commenter recommended that CMS retains a window for notice of the survey the morning of and retain blackout dates to protect time for emergency preparedness and key activities requiring staff and resources.

Response: We appreciate the commenter's concern related to the proposed definition of "unannounced survey" and our subregulatory guidance in Chapter 2, Section 2007A of the SOM. The subregulatory guidance provides for exceptions in limited circumstances. We recognize that in emergency events, a survey could disrupt the facility's ability to appropriately respond. However, CMS believes that emergency events would be unforeseen and not predicted and SAs and AOs will generally assess whether any survey activity would be feasible; the facility would not need to provide blackout dates in such cases.

Comment: We received one comment suggesting inconsistent implementation of unannounced surveys with one AO, which has led to confusion. The commenter urged CMS to clarify its requirement for unannounced surveys, including recognition that some

inpatient facilities could experience crisis scenarios that would not allow leadership to concurrently respond to an on-site survey in a timely manner.

Response: We appreciate the commenter's concerns, and we note that the proposed provisions aim to clarify expectations for unannounced survey activities across all AOs. We recognize that in managing emergency events or crises that leadership may not be available during the survey. However, we expect facilities to designate an individual for daily operations should leadership be unavailable.

Comment: While generally supportive of the definition and proposals, we received three comments which provided further recommendations for improving the unannounced survey process and encouraged CMS to consider these additional areas in subregulatory guidance. For example, two commenters stated to ensure the unannounced process works effectively, that CMS consider requiring providers to ensure a "duly authorized W-2 employee member of management" or a designated alternate be onsite at all times the office/facility is open. These commenters suggested that this would ensure an individual knowledgeable of company operations that has access to materials needed by surveyors is present, in turn limiting the potential for independent consultants to appear and act as the representative of the owner. Finally, the commenters also suggested that CMS consider "adding authorized W-2 employee" on the CMS-855 enrollment application as another category for management which could allow SAs and CMS to identify and monitor those individuals who appear as managing employees for multiple facilities and identify potentially fraudulent operations. Another commenter recommended CMS set clear expectations that an authorized employee be onsite when the facility opens to ensure survey activities are not delayed, as delays could limit the surveyor's ability to conduct a robust survey which could benefit lower performing agencies. This commenter suggested promoting prompt start times.

Response: We appreciate the commenter's support for our definition of "unannounced survey." We agree that leadership and a representative knowledgeable of the facility is important during the survey process and during the daily operations of the facility. We believe that when facility leadership is not onsite or on personal time off, the facility's governing body or leadership should appoint a knowledgeable individual able to provide continuity of care and

operations for the facility; this individual should be able to provide SA and AO surveyors with the information needed and guide the survey processes. As noted in many CMS program appendices of the SOM, such as Appendix A Task 2 for hospitals, CMS guidance to survey teams states "If the Administrator (or person in charge) is not onsite or available (for example, if the survey begins outside normal daytime Monday through Friday working hours), ask that they be notified that a survey is being conducted. Do not delay the survey because the Administrator or other hospital staff is/are not on site or available." We expect surveyors to begin survey activities upon arrival, and to notify staff and management that a survey is currently taking place. Surveyors may delay the entrance conference of the survey for leadership to arrive and begin requesting documentation from the facility while waiting. As for requiring prompt survey start times, we agree with the commenter, yet we also recognize the need for flexibilities to allow staff who may not be present at the time of the survey team arrival to travel to the facility. Surveyors aim to be flexible to ensure robust surveys are conducted with the appropriate staff. We encourage healthcare facilities to have the appropriate leadership and staff present during a survey.

Comment: We received one comment, while in general support of unpredictability and unannounced surveys, that recommended unannounced surveys only apply to follow-up surveys when a provider or supplier has been previously cited for deficiencies. This commenter suggested that this approach would work for a common purpose to achieving excellence and that unannounced surveys as part of a follow up survey of a corrective action would be more appropriate. This commenter suggested this would build a level of trust and support, encourage facilities to excel in quality and allow a safe space for exploration to ensure health and safety standards are met, as opposed to penalizing poor performance or actively seeking mistakes.

Response: We agree with the commenter that the intent of an unannounced survey is not to give the impression that surveyors are there to observe mistakes. The intent of an unannounced survey is to ensure the facility is always providing quality and safe patient care and to assess the daily operations of a facility against the Medicare requirements. Surveys by both SAs and AOs are not punitive but rather are an opportunity to identify

deficiencies and mitigate potential harm to patients as well as staff.

Unannounced surveys will provide a better assessment of the day-to-day operations at the facility. Furthermore, without an accurate assessment during an initial or recertification/reaccreditation survey and only requiring unannounced surveys as part of the plan of correction process for condition-level deficiencies (45-day revisit to the facility) would not accurately capture the normal daily operations of the facility and allow for unusual preparations hindering the integrity of the survey process.

Final Decision: The requirement for unannounced surveys has been a long-standing requirement that ensures the integrity of the survey process and provides surveyors a clear depiction of the day-to-day operations of the facility without preparatory adjustments which may not reflect the true quality of care being provided to patients. While we appreciate some of the commenter's concerns surrounding physical security as well as the need for preparation for the survey, both at the facility level as well as from AOs gathering necessary information pre-survey, we are hereby finalizing the definition of "unannounced survey" without changes.

D. Conflicts of Interest

In the proposed rule, we cautioned that AOs that provide fee-based consulting would not be allowed to raise their accreditation fees or otherwise raise costs for the provider or supplier because of the provision of survey-related education (90 FR 12009).

We proposed changes to § 488.5(a)(10) to require AOs to have policies and procedures for the prevention and handling of conflicts of interest, and to notify CMS when those conflicts of interest arise, because on several occasions, AOs have failed to notify CMS of such conflicts of interest. These changes would broaden our oversight of the AOs' handling and reporting of conflicts of interests. Additionally, by requiring the AOs to provide CMS with more specific information about their conflict-of-interest policies and procedures, CMS would be afforded a more comprehensive look at how the AOs plan to handle specific scenarios that CMS would deem to be conflicts of interest. These proposed requirements would require those AOs that did not have policies and procedures to prevent, address, and handle conflicts of interests to develop and use them.

The proposed requirements at § 488.5(a)(10)(iii) for the submission of the AO's policies and procedures to

avoid conflicts of interest (as defined in paragraph (a)(10)(v) of this section) included more detailed examples of possible scenarios that could be conflicts of interest for accrediting organization owners, surveyors, or other employees than those examples currently set forth in section 4008 of the SOM, which provide examples of potential conflicts of interest for SA surveyors.

A more detailed conflict-of-interest requirement is not necessary for the SA surveyors because SA surveyors, who are State employees, are generally required to report incidences of conflicts of interest to the SA management, who is tasked with taking the appropriate action. Additionally, State employees are generally prohibited from taking certain types of conflicting outside employment as a matter of course, so it is much less likely for such conflicts of interest to be an issue for them and their management. By contrast, AOs are more likely to encounter conflicts of interest. For example, AO owners, board members, surveyors and other employees might also be employed by healthcare facilities that are surveyed and accredited by that AO. Therefore, the proposed requirements for AOs were more detailed and prescriptive than those for SAs.

We also note here that we proposed two, slightly different, definitions of “immediate family member” at § 488.5(a)(10)(iii)(I) and at § 488.8(k)(2) (89 FR 12060 and 12062 through 12063). While we believe that the two definitions are legally and functionally equivalent, to avoid confusion over the minor language differences we have decided to standardize the definition in both provisions so that the language is the same. Therefore, we are making minor changes to the definition of “immediate family member” at § 488.8(k)(2) to now conform with the language we are finalizing at § 488.5(a)(10)(iii)(I). We do not believe that these minor changes to § 488.8(k)(2) in this final rule with comment period are substantively different than what we proposed, and therefore do not require a new round of public comment or a waiver of proposed rulemaking.

We received the following general comments about the conflict-of-interest proposals made in the proposed rule that are not associated with a specific conflict-of-interest proposed provision. We have grouped these comments by general topic.

Comments Stating General Support for the Conflict-of-Interest Proposals

Comment: Many commenters supported the proposals that would prevent conflicts of interest, streamline survey processes, and ensure more consistency between AOs and CMS or SA surveyors. Commenters also voiced strong support for ensuring that organizations responsible for issuing standards, guidelines, education, training, and evaluations of performance are not adversely affected by competing interests in real or perceived conflicts of interest.

Response: We thank the commenters for their support of our AO conflict-of-interest proposals.

Comments Expressing General Opposition to the Conflict-of-Interest Proposals

Comment: One commenter stated that CMS has made multiple proposals intended to prevent conflicts of interest and recommended that CMS limit its conflict-of-interest (COI) proposals to sharing COI policies and the COI log during a corporate onsite review or at the agency’s request. One commenter opined that the AOs should have the opportunity to investigate and verify the existence of a conflict of interest before providing notification to CMS.

Response: Limiting our proposals to only requiring that AOs share their conflict-of-interest policies during application reviews would be insufficient to fully identify and address AO conflicts of interest. We agree that the AOs should be allowed to investigate and verify conflicts of interest before reporting them to CMS. No proposals included in the proposed rule prohibit an AO from verifying conflicts on the part of its owners, surveyors, and other employees before notifying CMS of these conflicts.

Comment: One commenter stated that they were perplexed as to why CMS is not proposing the same conflict-of-interest requirements for SAs. This commenter also pointed out that, in the proposed rule, CMS stated that it believes a more detailed conflict-of-interest requirement is not necessary for the SA surveyors because SA surveyors, as State employees, are generally required to report incidences of conflicts of interest to the SA management, who are tasked with taking the appropriate action. CMS also opined that AOs are more likely to encounter conflicts of interest.

This commenter further stated that, while they agree that the nature of the business relationship between AOs and providers inherently creates greater

opportunity for conflicts of interest, they believe nearly all the same situations CMS proposes as conflict-of-interest definitions are potentially present with SA surveyors.

This commenter also pointed out that in the proposed rule, CMS defined “conflict of interest” as a situation in which an AO, its owner(s), surveyors, or other employees, or the AO’s successors, transferees, or assigns, or the immediate family members of the AO owners(s), surveyors, and other employees, have an employment, business, financial or other type of interest in or relationship with a healthcare facility the AO accredits. CMS would deem a conflict of interest to have occurred if one of the stated parties either knowingly or unknowingly exploited their interest in or relationship with that provider or supplier.

Response: We agree that there are potential conflicts of interest for surveyors or other employees of the SA division conducting surveys, and for the immediate family members of these individuals, if there is an employment, business, financial or other type of interest in or relationship between a health facility the SA surveys and its surveyors and other SA employees and/or their applicable immediate family members. However, in response to the comment questioning why CMS did not propose the same conflict-of-interest requirements for SAs, CMS does not believe that additional Federal conflict-of-interest requirements are necessary for SAs as they are for AOs because individual State laws, rules, and regulations regarding conflicts of interest apply to each SA and its employees.

Comment: One commenter appreciated CMS’ diligence in preventing conflicts of interest during the accreditation process and agrees that the proposed language will mitigate inappropriate biases from affecting the survey processes. However, this commenter also recommended that CMS establish language that prohibits SA surveyors from surveying any facility where they were employed the previous 2 years, including facilities that are part of a larger health system. This commenter further opined that this is imperative in eliminating all conflicts of interest from surveyors, regardless of the agency that employs them.

Response: SAs make their own policies and procedures regarding staff matters such as the handling of staff conflicts of interest and the Federal government typically does not interfere in internal State decisions.

Nevertheless, consistent with Agreements between states and CMS under section 1864 of the Act, CMS holds the SAs responsible for assuring that any surveys for Medicare/Medicaid certification meet all Federal requirements, including conflict of interest requirements. Also, Chapter 4, Sections 4008 and 4008A of the SOM address the issue of conflicts of interest on the part of SA employees. Section 4008 of the SOM contains suggestions as to how the SA could handle such conflicts of interest. Section 4008A provides examples of conflict-of-interest scenarios on the part of SA employees that are similar to those we set forth in the proposed rule (89 FR 12005).

Comment: One commenter stated that they have been proactive in taking steps to prevent real or perceived conflicts of interest to maintain the integrity and rigor of the accreditation process. This commenter also stated that they implemented strong firewall and COI policies to prevent any perceived or actual conflict of interest between its fee-based consulting company and accreditation divisions. This commenter stated that they strongly disagree with CMS' proposals to place limitations on fee-based consulting services provided by AOs to Medicare-certified providers and suppliers they accredit because of concerns related to conflicts of interest.

Response: We note that in this final rule with comment period we have not prohibited AO fee-based consulting in its entirety; we have placed some limited restrictions on this service to help mitigate the conflicts of interest associated with specific AO consulting services and the timing of those services.

Comment: One commenter observed that the restricted periods, prior to the initial survey and 12 months prior to each reaccreditation survey, are exactly when education is needed. This commenter further stated a belief that: (1) healthcare providers new to healthcare should attend workshops that provide the interpretation of regulations; (2) these workshops serve as a guide for businesses looking to navigate the complex world of healthcare regulations; (3) by attending these workshops, organizations could gain valuable insights and knowledge on compliance requirements; and (4) this knowledge would enable them to operate efficiently and effectively within the healthcare industry. This commenter further stated that, in addition to attending the workshops, the healthcare providers could also purchase workbooks and tools that could further assist them in

understanding and implementing regulatory requirements.

Another commenter stated their view that the proposed rule would prohibit AOs from providing support and guidance to the facilities that they accredit in the months directly preceding a reaccreditation survey, when it is most needed. The commenter argued that AOs provide the most effective guidance to the facilities that they accredit because they are intimately familiar with the specific requirements of their standards. The commenter believed that the proposed rule would seek to disadvantage a facility by preventing the accrediting AO from providing valuable education during a critical period. In the commenter's view, the proposed rule places unnecessary obstacles in a facility's path to the provision of high-quality care.

Response: The restrictions on consulting do not prohibit the AOs from providing consulting services or workshops to the providers and suppliers they accredit prior to a reaccreditation survey. Consulting services, as defined in § 488.1, must not be provided within 12 months prior to the next scheduled re-accreditation survey pursuant to § 488.8(i)(2). This means, for example, that the AOs would still be able to provide consulting, including workshops, to the providers and suppliers they accredit during the 24 months after each accreditation survey was completed in a 36-month accreditation cycle.

We believe that, after an accreditation survey, an AO's consulting services would be geared towards helping the facility correct deficiencies and non-compliance with the AO's accreditation standards that were detected during the survey. We further believe that the best time for an AO to provide such consulting services would be within the 24-month period after an accreditation survey has been completed. During this period, the survey findings are fresh in the minds of the facility management and compliance team and there would be an impetus to address and correct the deficiencies cited. We further believe if the AO provides consulting services to address deficiencies and compliance concerns early in the 3-year accreditation period, the AO could work with the affected provider or supplier, at their own pace, to implement long-lasting and sustainable changes that would address the deficiencies identified. On the other hand, if the AO waited until 12 months prior to the next accreditation survey due date to provide consulting, it might only result in the implementation of quick temporary

solutions or corrective action just prior to the next accreditation survey.

Comment: One commenter stated that CMS' proposal to prohibit receiving fee-based consulting services from an AO at any time before an initial accreditation survey or in the 12 months before a reaccreditation survey would restrict the ability of many health systems to receive necessary education and could delay their ability to be accredited in a timely manner.

Response: We respectfully disagree with this commenter's contention that our restrictions on AO consulting, as finalized, will prohibit providers and suppliers that are seeking accreditation by an AO that provides consulting from seeking consulting prior to the initial survey. This is because these providers and suppliers would be permitted to seek fee-based consulting from a third party at any time, without restrictions. Also, any provider or supplier already accredited by any AO can seek consulting services from another AO provided that AO does not accredit the provider or supplier at the time the consulting services are furnished.

Comment: One commenter noted that, under the proposal, providers would not have the benefit of receiving education from the creator of the standards who could best teach the requirements of compliance. The AO standards include not only regulatory language but also AO-specific requirements. Many organizations seek Medicare certification through an AO versus the State Agency because of the valuable education that the AO provides. The type of education provided often distinguishes one AO from another. Restricting the provision of fee-based education diminishes competition, and forces each AO to provide the exact same product.

Response: General education provided by an AO would not necessarily constitute a conflict of interest and is not entirely prohibited under this rule, regardless of whether it is fee-based education. Section 488.8(i)(4) finalized here allows AOs to provide general education as well as fee-based consulting services at specific times and under certain conditions. However, any AO fee-based education that meets the definition of fee-based consulting services finalized here and does *not* meet the timing and condition requirements at § 488.8(i)(4) would be prohibited by this rule.

Comment: One commenter opposed the proposals that would limit the ability of health systems to receive fee-based consulting services from their AO for the following reasons:

- AOs are uniquely situated to provide consulting services with firewalls in place that prevent conflicts of interest.

- Fee-based consulting services can include educating health system staff on the CoPs and guiding them on how best to comply with them.

- Fee-based consulting services play an important role in assisting providers with their compliance with CoPs and their quality and patient safety improvement efforts.

- Fee-based consulting can assist health systems in improving the safety and quality of the care they provide to their patients.

Response: In our view, the restriction on fee-based consulting will not completely prohibit providers and suppliers accredited by the AOs from obtaining fee-based consulting. These providers and suppliers will only be restricted from receiving AO fee-based consulting from their AO prior to their initial survey and during the 12 months immediately preceding their reaccreditation survey. The accreditation period for most providers and suppliers is 36 months; therefore, the providers and suppliers would be able to receive AO fee-based consulting during the first 24 months of the 36-month accreditation period. In addition, providers and suppliers may seek fee-based consulting at any time from third party consultants because there is no conflict of interest associated with the fee-based consulting provided by third parties.

Comment: One commenter stated that if CMS' proposals are finalized, overall survey costs will increase, due to factors such as limited consulting resources or increased interruptions in hospital operations.

Response: We disagree that these requirements as finalized in this rule will inevitably lead to increased overall survey costs due to the factors the commenter noted. While the rule puts specific limitations on an AO that provides consulting services to a facility that the AO accredits, the rule does not prohibit an accredited facility from using the consulting services provided by other AOs that do not accredit the facility or by third-party consultants, and thus does not limit the overall consulting services that might be available to facilities. Without further clarification by the commenter, we are not clear why they believe that this rule would cause interruptions in a hospital's or other facility's operations.

Comment: One commenter supports the proposed definition of conflict of interest.

Response: We thank this commenter for their support of our proposed definition.

Comment: One commenter noted that proposed § 488.5(a)(10)(iii)(I) would provide that an immediate family member of an AO surveyor who was employed in a healthcare facility that was accredited by the AO would be deemed a conflict of interest. This commenter further observed that, by contrast, the United States (U.S.) Federal government does not restrict immediate family members from working in different facets of the government or as a contractor to the government.

Response: This commenter is correct that the proposed regulations would prohibit an AO owner, AO surveyor or other AO employee from having any involvement in the survey process for the healthcare facilities in which they, or their immediate family members, have a relationship or interest that existed within 2 years prior to the AO owner's, surveyor's or other employee's employment by the AO. If such a situation were to exist, it would be a conflict of interest. We have proposed to add the provisions at §§ 488.5(a)(10)(iii)(I) and 488.8(k) to prevent such conflicts of interest, including those involving immediate family members as defined at § 488.8(k)(2), from occurring. The commenters' reference to multiple family members working for governmental entities is not comparable to the scenario in which an AO surveyor might be expected to change his assessment to benefit the facility family member because family members working for different government agencies generally are not able to provide benefits for each other.

Comment: One commenter disagreed with the proposed definition of "immediate family member". This commenter noted that this proposed definition closely resembles that used in reference to the professional courtesy exception for physician and healthcare entity referral prohibitions, Securities and Exchange Commission restrictions on transactions with related persons, and laws related to campaign contributions.

This commenter stated that such an expansive definition of "immediate family member" as used for the purposes of securities transactions and campaign contributions would be inappropriate for application to healthcare conflict-of-interest considerations.

Response: We used the same definition of "immediate family member" that we finalized for hospices

in the CY 2022 Home Health Prospective Payment System Rate Update (86 FR 62368 and 62426), which is codified at § 411.351. While this definition may be the same or similar to other rules for other subject matter, this does not make it inappropriate for use in a healthcare setting.

A definition of "immediate family member" is necessary because, at § 488.5(a)(10)(iii), we proposed to require the AOs to provide policies and procedures for the prevention and handling potential or actual conflicts of interest that could arise from situations in which an AO owner, surveyor, or other employee has a business, employment or financial interest in or relationship with another survey agency or healthcare facility to which the AO provides accreditation services.

At proposed § 488.5(a)(10)(iii), we stated that such interests or relationships would include but not be limited to, "(I) *Having members of their immediate family engaged in any of the above stated activities.*" Moreover, at § 488.8(k), we proposed that it would be a conflict of interest if AO employees, surveyors, and other employees have a member of their immediate family employed at a healthcare facility that is accredited by the AO. We made this proposal because it is possible that one of the subject individuals could either consciously or unconsciously exploit their interest in or relationship with that provider or supplier. Also, allowing an AO owner, surveyor or other employee that has an interest in or relationship with or that has an immediate family member that is employed by or has an interest in or relationship with (as defined by proposed § 488.5(a)(10)(iii)) a healthcare facility that is accredited by the AO would not only be inappropriate but could result in inaccurate survey results and/or preferential treatment of the facility. We say this because if an AO owner, surveyor or other employee has a family member employed at a healthcare facility that is accredited by the AO, that AO owner, surveyor or other employee may have a bias towards or against that facility which could have an effect on the survey results.

An AO surveyor, owner, or other employee that has an interest in or relationship with a healthcare facility the AO accredits might have additional motivation to improperly give that healthcare facility notice about the survey ahead of the scheduled survey date. Surveys are required to be unannounced to prevent the facility from preparing for the survey by activities such as unusual cleaning activities, painting, clearing obstructions from halls and entrances,

covering up and hiding deficiencies, coaching staff, and otherwise preparing in advance for the survey. If the survey is unannounced, the healthcare facility is not able to make advance preparations so that the survey team is able to assess the facility in its usual condition and observe the typical standard of care provided.

If an AO owner, surveyor or other employee has an immediate family member that is employed by a healthcare facility that is accredited by the AO, that immediate family member might provide confidential or proprietary information about the healthcare facility to the AO owner, surveyor or other employee that the AO would not otherwise be entitled to receive. The immediate family member employed at a healthcare facility accredited by the AO could also provide information about incidents that have occurred at the facility, safety and quality concerns or other issues. This would be a problem because this unfiltered information may be damaging to the facility for several reasons. First, this person may have incomplete or inaccurate information. Second, the information provided by the family member could affect the course of the survey, the survey findings and objectivity of the survey results.

Comment: One commenter stated a concern that the conflict of interest on the part of some extended family members included in the definition of “immediate family member” are unlikely to be known in many instances.

This commenter was concerned that, while a potential conflict could exist if conflicts with immediate family members are known to the AO, there is no requirement within this proposed rule that the information *actually* be known for a conflict to exist because the proposed rule (89 FR 12005) says “unknowingly exploited interest”.

To illustrate their concern, the commenter provided the following scenario:

- An AO surveyor resides in Washington and has a brother-in-law that resides in Georgia.
- The surveyor only speaks to her brother-in-law every other year at Thanksgiving.
- The AO at which the surveyor is employed accredits a small ASC in Tennessee (fictional “Anytown ASC”).
- The AO surveyor performs a survey of Anytown ASC in Tennessee in May 2024.
- The surveyor’s brother-in-law has an ownership interest in Anytown ASC in Tennessee that his sister-in-law is surveying. This interest was obtained in January 2023.

- The AO surveyor was not aware that her brother-in-law obtained an ownership interest in Anytown ASC in January 2023.

This commenter requested that CMS reconsider the definition of “immediate family member” to address its appropriateness, reasonableness, and applicability.

Response: We have proposed to require AOs provide annual surveyor declarations of conflicts of interest and also that AO owners, surveyors, and other employees be prohibited from having involvement in the survey process for any healthcare facility accredited by the AO with which they or their immediate family members have an interest or relationship. While these proposals are silent on this issue, it is implied that the AOs will only be required to report and act on known conflicts of interest. We certainly cannot hold AOs, their owners, surveyors, and other employees accountable for any conflicts of interest of which they are unaware. Therefore, we do not believe that it is necessary to revise the proposed definition of “immediate family member.”

This does not mean that the AOs, their owners, surveyors, and other employees can ignore such potential conflicts of interest. AOs, owners, surveyors, and other employees have a duty to investigate whether they or their immediate family members, as defined in the proposed rule at § 488.5(a)(10)(iii), might have applicable conflicts of interest. AOs will be required to obtain surveyor conflict-of-interest information on an annual basis. AO surveyors and other employees will be required to take reasonable steps to determine whether they have interests in or relationships with healthcare facilities accredited by the AO, both on their part and on the part of their immediate family members.

If an AO, AO owner, surveyor, and other employee should reasonably have known about a conflict of interest on their part or the part of an immediate family member and it is not reported to CMS on a surveyor declaration, or an AO owner, surveyor, or other employee was permitted to have involvement with the survey process for a healthcare facility for which they reasonably should have known they had an interest in or relationship with, CMS has the option to place the AO on a CMS-approved accreditation program review pursuant to § 488.8(c).

Comment: One commenter requested that CMS clarify the applicability of the proposed requirement for information to be submitted with the AOs’ conflict-of-

interest policies and procedures to different types of AO employees.

Response: Our proposal for information to be submitted with the AOs’ conflict-of-interest policies and procedures applies to the AO and not any specific individual or group of AO employees. This proposal requires that the AO provide more specific information with the conflict-of-interest policies and procedure it provides to CMS with the initial and all subsequent renewal applications for CMS approval of the AOs accreditation programs.

However, § 488.5(a)(10)(iii) does require an AO to submit information to CMS regarding its policies and procedures for the prevention and handling of potential or actual conflicts of interest and it does specify that these conflicts of interest are those that could arise from situations in which an accrediting organization owner, surveyor, or other employee has an interest in or relationship with a SA or with a healthcare facility to which the accrediting organization provides accreditation services. In response to the commenter’s request for clarity as to whom the requirements for such information would apply, § 488.5(a)(10)(iii) provides examples of the interest and relationships with a healthcare facility that would be a conflict of interest on the part of an AO owner, surveyor or other employees, including:

- being employed as a SA surveyor;
- being employed in a healthcare facility that is accredited by the AO;
- having an ownership, financial or investment interest in a healthcare facility that is accredited by the AO;
- serving as a director of or trustee for a healthcare facility that is accredited by the AO;
- serving on a utilization review committee of a healthcare facility that is accredited by the AO;
- accepting fees or payments from a health facility or group of health facilities that is/are accredited by the AO;
- accepting fees for personal services, contract services, referral services, or for furnishing supplies to a healthcare facility that is accredited by the AO;
- providing consulting services to a healthcare facility that the AO accredits;
- having members of their immediate family engaged in any of the stated activities; and
- engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

Section 488.8(k) provides that it would also be a conflict of interest if an AO owner, surveyor or other employee

has an immediate family member that has an interest in or relationship with a healthcare facility accredited by the AO. In such a scenario, the AO owner, surveyor, or other employee should not be permitted to have any involvement with the survey process for the healthcare facility at which their family member is employed or has an interest or relationship.

2. Comments Generally Supporting the Proposal for Information To Be Submitted With an AO's Conflict-of-Interest Policies and Procedures

Comment: Five commenters supported the proposed requirement that the AOs provide, as a part of their initial and renewal application, specific policies and procedures that would address how the AO addresses and prevents conflicts of interest. One commenter stated that proposed revision to § 488.5(a)(10) for information to be submitted with the AOs' conflict-of-interest policies and procedures are common sense updates on unintended gaps in the accreditation ecosystem. This commenter further stated that if these unintended gaps are not fixed, opportunities for conflicts of interest will persist in the system. One commenter stated that the requirement that the AOs provide, as part of their initial and renewal applications, specific policies and procedures that would address how the AOs prevent and address conflicts of interest would put pressure on AOs to create firewalls to address these concerns. One commenter expressed support for the proposed requirements for AOs that do not have policies and procedures to prevent, address and handle conflicts of interest to develop and use them. One commenter expressed support for the proposal for expansion and revision of conflict-of-interest policies and procedures. This commenter stated that these AO conflict-of-interest improvements would secure the overall fairness and transparency of the survey process. One commenter supported CMS' efforts to increase oversight of AO conflicts of interest while providing a requirement that does not impose additional burden on providers. One commenter stated that § 488.5(a)(10) is already a requirement for approval of an AO. This commenter further opined that the proposed requirement could strengthen our policies to reflect the high standards of their AO. One commenter fully supported our proposal to require the AOs to provide more specific information in the conflict-of-interest policies and procedures they submit to CMS. This commenter stated that the requirement will protect the

integrity of the survey process and provide guidance to surveyors.

Response: We thank these commenters for their support of our proposal at § 488.5(a)(10) to require the AOs to submit more specific information with their conflict-of-interest policies. Robust and strictly enforced firewall policies and procedures can help mitigate the effects of conflicts of interests. We believe that it is important for the AOs that provide fee-based consulting to have fee-based consulting firewall policies and procedures. We thank these commenters for their support of our proposed requirement at § 488.5(a)(10) that the AOs submit policy and procedure to address conflicts of interest.

3. Comments Generally Opposing the Proposal for Information To Be Submitted With an AO's Conflict-of-Interest Policies and Procedures

Comment: One commenter stated that requiring AOs to turn over their conflict-of-interest policies and logs over to CMS would require the AOs to share proprietary information and internal business operations.

Response: We respectfully disagree with this commenter. We are not sure what this commenter considers to be proprietary information and internal business operations. However, we do not consider the AOs conflict-of-interest policies and procedures or information about AO conflicts of interest to be proprietary information. AOs are already required by our regulations to provide their accreditation standards and all policies and procedures related to the accreditation and survey processes (including those related to detecting and handling conflicts of interest) to CMS as part of their initial and renewal applications they submit seeking approval for their accreditation program. For example, § 488.5(a)(10) already requires AOs to provide their "policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions."

Although we do not believe that the surveyor declarations and reports containing information about the fee-based consulting services provided would fall under the category of proprietary information or internal business operations, we have no plans to publish this information. It is our intent, to the extent permissible by law, that the information collected be for internal CMS use only.

Comment: One commenter requested clarification on how the revised

requirements at § 488.5(a)(10), if finalized, will be different from the existing requirement of this regulation.

Response: In the proposed rule (89 FR 12005), we discussed the difference between the existing regulation and the revised requirements at § 488.5(a)(10). Section 488.5(a)(10) currently requires that the AO submit "*the organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in decisions.*" This requirement does not require the AO to address any specific areas or issues in their conflict-of-interest policies and procedures. In addition, the AOs only need to submit this information to CMS with their initial and renewal applications, which is currently every 6 years or less, as established by CMS.

Comment: One commenter recommended that CMS ensure that the new policies the AOs will need to develop do not unintentionally result in disruptions to providers seeking to become accredited or maintain accreditation.

Response: We do not anticipate that the accreditation process will be disrupted by the revised requirements at § 488.5(a)(10)(i) to § 488.5(a)(10)(v). All AOs that accredit Medicare-certified providers and suppliers will be required to submit conflict-of-interest policies and procedures that comply with the requirements of proposed § 488.5(a)(10)(i) to (v). To be approved by CMS, all AOs are required to have some type of conflict-of-interest policies and procedures; however, prior to this proposed rule CMS did not have any minimum requirements for the contents of these COI policies. This means that the AOs will simply need to update their existing COI policies and procedures to comply with the new requirements.

Final Decision: After consideration of all comments received regarding the proposed requirement for AOs to submit specific information with the conflict-of-interest policies and procedures they submit to CMS with their initial and each subsequent renewal application, we have decided to finalize the requirements with a minor clarifying revision to § 488.5(a)(10)(iii) to change the proposed language of "... potential or actual conflicts of interest that could arise from situations in which an accrediting organization owner, surveyor, or other employee has an interest in or relationship with another State survey agency or a healthcare facility to which the accrediting organization provides accreditation

services” [emphasis added] by changing the word “another” to “a” and adding the words “with a” so that the finalized provision reads “... situations in which an accrediting organization owner, surveyor, or other employee has an interest in or relationship *with a State survey agency or with a healthcare facility* to which the accrediting organization provides accreditation services” [emphasis added]. We are making this revision in this final rule with comment period to clarify the requirement.

Additionally, commenters requested that we establish a clear definition of the AO consulting services on which we will be placing the proposed restrictions and provided us with an example of such a definition for purposes of this rule. We have used this definition from the public comments as the basis for the definition of “fee-based consulting services” that we are including in this final rule with comment period. We discuss this definition in more detail in section III.D.3. of this final rule with comment period.

E. Comments on the Proposed Requirement That AOs Obtain and Submit Surveyor Declarations of Any Interest in and Relationships With Healthcare Providers the AO Accredits to CMS on an Annual Basis (Proposed § 488.5(a)(22))

A conflict of interest may exist when an AO surveyor has interest(s) in or relationship(s) with a healthcare facility the AO accredits. We believe that requiring AOs to obtain and submit declarations detailing such interests and relationships would ensure that CMS would be notified of potential or actual conflicts of interest AO surveyors might have with the providers and suppliers the AO accredits. Such notice would allow CMS to be aware of the existence of these potential or actual conflicts of interest, some of which would preclude a surveyor from participating in survey activities (see § 488.8(j) discussion at section IV.B.6. of the proposed rule) and some of which would not.

We proposed to add a new provision at § 488.5(a)(22) that would require the AO to obtain declarations from all surveyors employed or contracted to the AO regarding any employment, business, financial or other interests in or relationships they have with the healthcare facilities the AO accredits. We proposed that AOs would initially be required to submit the surveyor declarations with their initial application for CMS approval of their accreditation programs. We further proposed to require that the AOs update the surveyor declarations on an annual

basis, and that the information from the annual updated surveyor declarations be submitted to CMS no later than December 31st each year. Annual updates would be necessary because a surveyor’s interests in and relationships with healthcare facilities the AO accredits could change over time. This requirement would ensure that the information contained in the surveyor declarations remains up-to-date and accurate. We proposed that this provision at paragraph (a)(22) would be become applicable beginning 1 year after the effective date of the final rule with comment period. We further proposed to require the AOs to begin submitting their surveyor declaration information on or before the December 31st date that occurs after the proposed applicable date of this requirement.

We received the following comments regarding this proposal. We group the comments and our responses by topics for clarity.

a. General Comments About the Proposal To Require AOs To Submit Surveyor Conflict-of-Interest Declarations

Comment: One commenter supported our proposal to require AOs to obtain and submit surveyor declarations of any interest in and relationships with healthcare providers the AO accredits to CMS on an annual basis for the following reasons:

- Organizations entrusted with the public’s well-being must disclose their affiliations to ensure impartiality and maintain public trust.
- Any suggestion of impropriety or conflict of interest could compromise the integrity of the accreditation process, emphasizing the paramount importance of full transparency.
- Prioritizing excellence, quality, and integrity over financial interests is crucial.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter stated that they have always required the completion of conflict-of-interest statements from all their staff as a standard compliance practice. The commenter further stated that they are diligent in managing and enforcing their conflict-of-interest processes as a first-line measure in controlling any threat to their accreditation program’s integrity. Another commenter stated that they require the completion of a conflict-of-interest statement in the following instances:

- All staff complete a COI statement at the time of hire; senior leadership staff additionally sign a COI statement annually.

- Board of Director members sign a COI statement at the time of board appointment and annually throughout their term.

- Surveyors sign a COI statement at the time of hire, annually, and if new conflicts of interest arise.

Response: We thank this commenter for their comment. We further commend this commenter on their commitment to preventing, detecting, and managing conflicts of interest.

b. Comments in Support of the Proposal for AOs To Submit Surveyor Conflict-of-Interest Declarations

Comment: Two commenters supported our proposal to establish processes for ensuring that AO surveyors do not have conflicts of interest in the review process, including surveyor relationships with a healthcare facility or another survey agency.

Response: We thank these commenters for their support of this proposal.

Comment: One commenter stated that they already have a strict surveyor conflict-of-interest process. The commenter further stated that requiring a declaration from each surveyor is unnecessarily burdensome to their established process.

Response: We thank this commenter for their comment and note their concern about the burden related to this proposal. Please see section VI. Collection of Information of this final rule with comment period for more information about the burden associated with this rule.

Comment: One commenter supported our proposal to require the AOs to provide conflict-of-interest information on past employees and other areas.

Response: We believe this commenter is referring to our proposal to require the AOs to collect surveyor conflict-of-interest declarations and submit them to CMS on an annual basis. If so, we thank this commenter for their support of this proposal. We would like to point out that this requirement, as finalized, doesn’t require the AOs to collect conflict-of-interest information about past employees or areas other than current interests in or relationships the AO’s surveyors may have in any healthcare providers or suppliers accredited by the AO.

Comment: One commenter had several questions about this proposal including:

How are new hires and terminated surveyor declarations to be handled throughout the year? Are the submissions to be electronic? What does CMS intend to do with this information? For instance, would CMS review each

one of the declarations annually and would declarations of “no conflict of interest” be confirmed? If so, how would this be accomplished?

Response: We will provide subregulatory guidance on submission and compliance when this requirement becomes effective.

Comment: One commenter stated that they require all employees to complete annual COI declarations regarding any employment, business, financial, or other interests in or relations they have with healthcare facilities that this AO accredits. The AO expressed concerns with the proposal to require AOs to submit surveyor COI declarations to CMS because these declarations have personal information that may violate employee confidentiality or other privacy laws if shared publicly. This commenter recommended that CMS modify this proposal to require only a review of AO surveyors’ COI declarations at the time of the CMS corporate onsite review for each AO. This commenter stated that their suggested alternative would still allow CMS to achieve its stated goal and that there was no reason for CMS to require AOs to unnecessarily disclose sensitive information. This commenter also stated that the AO should not be required to submit the surveyor conflict-of-interest disclosures to CMS because they would contain sensitive information.

Response: Our rule, as finalized, will require the AO to submit declarations from all surveyors the AO employs, describing any employment, business, financial or other interests in or relationships they have with the healthcare facilities the AO accredits. Even if this is sensitive or confidential information, it is necessary for enforcement of our policy and, to the extent permitted by law, we would keep this information internally and not publish it or provide it to any outside source. Proprietary commercial information and trade secrets are protected from public disclosure under FOIA Exception 4 (5 U.S.C. 552(b)(4)).

e. Recommended Changes to Proposal That AOs Submit Surveyor Declarations

Comment: One commenter recommended that CMS modify this proposal to allow the AOs to submit 100 percent of surveyor COI declarations for year one after the final rule with comment period implementation date. Thereafter, for each calendar year, AOs would only submit COI declarations for new surveyors and updated COI declarations for surveyors where a baseline COI declaration was submitted in year one.

Another commenter suggested that implementing and managing a COI declaration process might complicate the survey process and increase the administrative burden on AOs and complicate the survey process by requiring additional resources. This commenter recommended that CMS make the implementation of the surveyor declaration process as minimally burdensome as possible on all entities.

Several commenters expressed support for the proposed requirement for collection of surveyor declarations on an annual basis but requested that AOs be allowed to keep the declarations and not be required to submit them to CMS. One of these commenters suggested that CMS review them during the corporate office visit as part of each AO’s initial/renewal application rather than requiring the AO to submit them to CMS on an annual basis.

Response: After consideration of the comments received regarding our proposal to require the AOs to submit surveyor conflict-of-interest declarations to CMS on an annual basis, we have decided not to finalize this proposal as proposed. We are not finalizing our proposal to require the AOs to obtain and submit the surveyor declarations to CMS annually. We will instead require the AOs to submit the surveyor conflict-of-interest declarations for CMS to review upon request and during each application review process.

Comment: One commenter stated that receiving and maintaining the declarations could be unnecessarily burdensome to CMS. This commenter requested that the surveyor declarations be handled on an exceptions basis whereby the declaration would only need to be reported to CMS if it indicated a conflict of interest. In the alternative, CMS could conduct audits of the AOs annually to ensure the declarations are obtained and maintained as required.

Response: We have also considered the burden to CMS associated with the receipt and review of these declarations and have decided to modify our proposal related to surveyor declarations as stated in the “Final Decision” section.

Final Decision: After consideration of the comments received regarding our proposal at § 488.5(a)(22) to require the AOs to submit surveyor conflict-of-interest declarations to CMS on an annual basis, we have decided not to finalize this as proposed. We will instead require the AOs to maintain the surveyor conflict-of-interest declarations, to be provided to CMS to review upon request and during each

application review process. We are also modifying the provision as proposed by removing the sentence from applicable regulations text, “This provision will become applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE].” We are making this modification for the final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date and individual provisions will no longer need to be specified in the regulatory text.

F. Proposed Restrictions on Fee-Based Consulting Services Provided by AOs to the Medicare-Certified Providers and Suppliers They Accredited (Proposed § 488.8(i))

CMS recognizes the value of consulting services provided by independent, third-party consultants who provide insight and expertise to assist facilities in achieving and maintaining compliance with the AO and Medicare health and safety standards. These interventions are beneficial and often tailored to meet a facility’s specific compliance needs. Consulting services also may assist a provider or supplier in identifying quality concerns, whether based on the Medicare requirements or standards of practice, and therefore these services may improve the safety of patient care. AO consulting activities are not prohibited by Federal law and there are no current CMS regulations prohibiting AOs from providing consulting services.

However, AOs assume a public trust role when voluntarily applying to CMS for deeming authority. This authority, once granted, conveys Medicare certification for those entities accredited by the AO and it is essential that the integrity of the AO oversight process be above question. A number of AOs with CMS-approved accreditation programs currently provide AO consulting services to the Medicare-participating healthcare facilities they accredit as well as to facilities that they do not accredit. When an AO provides consulting services to a provider or supplier it accredits, it may create a conflict of interest for several reasons.

First, AOs provide deeming surveys to providers or suppliers on behalf of CMS. AOs are required to use accreditation standards that are comparable to or exceed the Medicare standards and survey processes in the performance of deeming surveys. A potential or actual conflict of interest arises from allowing a CMS-approved AO with deeming authority the ability to charge a provider or supplier to conduct a deeming survey to identify non-compliance (for

Medicare participation) and also charge for providing AO consulting services to help the provider meet Medicare requirements.

Second, providers and suppliers often choose AO consulting specifically for the additional resources and assistance provided. Some AOs publicly advertise the ability of their consulting services to simulate what to expect from the actual AO survey. It is possible that providers and suppliers found to be non-compliant by their AO may assume that the most direct path to compliance is to hire the AO's consulting services. Such an assumption would provide AOs with consulting services an unfair advantage over other, third-party consulting services.

Finally, by charging for accreditation services (for example, deeming surveys) and also for the subsequent consulting services, for the purpose of remediating deficiencies identified by the same AO, there may be an expectation from providers and suppliers that the AO would demonstrate the effectiveness of their consulting services for such deficiencies on subsequent compliance surveys. In other words, the provider or supplier may expect to receive a favorable survey report because they have paid the AO not only for accreditation but also for consulting services which are promoted by the AOs to help the provider or supplier do well on their survey. In addition, this expectation may push AOs to ignore significant deficiencies found during survey of its consulting clients to demonstrate the efficacy of its consulting and to promote these services.

In short, an AO's business model is geared toward retention of its accredited providers and suppliers. AOs that provide both regulatory oversight through Medicare deeming surveys and also consulting services, which are geared towards assisting clients comply with the requirements required to pass the surveys, invite concerns about the integrity of their final compliance determinations.

CMS issued an AO Conflict-of-Interest RFI (83 FR 65331) in 2018 to gather feedback related to AO conflict-of-interest practices. We received 128 public comments in response to the RFI. Many commenters stated that consulting provided by an AO or its associated consulting division or company to the healthcare facilities it accredits is a conflict of interest. These commenters stated that this conflict of interest arises from granting the inherently governmental function of monitoring patient safety, by regulating healthcare providers through accreditation, to a

private entity, especially when that private entity profits from those who are regulated.

Several commenters alleged that AOs that provide fee-based consulting may have the incentive to ignore deficiencies detected during the accreditation survey, to provide a "good" survey report to demonstrate the apparent efficacy of their AO consulting services and also to keep the paying customer(s) happy. Many commenters also suggested that if an AO provides poor survey results to a healthcare facility that has paid a significant fee for accreditation, it is unlikely that the facility would continue to retain that AO as a service provider.

After careful review and analysis of the public comments received in response to the RFI, we agree that a conflict of interest arises from the contractual and financial relationship between the healthcare provider and the AO, which is a private entity that profits from the performance of regulating healthcare providers through accreditation. AOs that provide consulting services generate additional revenue beyond the fees realized for accreditation services by providing consulting services to the same facilities they accredit.

We proposed at § 488.8(i) several restrictions on fee-based consulting provided by these AOs, their consulting divisions, or separate business entities. By "fee-based consulting division," we mean a separate division within the AO that provides consulting services. This division of the AO would have a separate manager and staff. By "separate business entity," we mean a business entity, such as a company or corporation, that is separate and apart from the AO and that has been established by the AO, either under a similar or different name, for the purpose of the providing consulting services.

The proposed regulation at § 488.5(i) would still allow AOs to provide fee-based consulting services to the providers and suppliers they accredit with restrictions that address the conflict-of-interest issues associated with this service.

We proposed at § 488.8(i)(1) that, unless excepted under proposed § 488.8(i)(4), AOs and their associated consulting divisions or companies would be prohibited from providing fee-based consulting services to any healthcare provider or supplier to which the AO provides accreditation services prior to an initial accreditation survey. However, the healthcare provider or supplier may seek fee-based consulting services from an entity entirely

uninvolved in that provider's or supplier's accreditation process. This option allows these providers and suppliers support they may believe necessary to meet Medicare standards and requirements prior to serving patients while eliminating any conflict of interest for their AO.

For purposes of proposed § 488.8(i)(1), the term "initial survey" would mean the first accreditation survey of a healthcare provider or supplier performed by an AO. The term "prior to the initial accreditation survey" would mean the time period beginning on the day the provider or supplier enters into a contract with the AO to provide accreditation services and continuing until the date that the initial accreditation survey is completed. The survey completion date would include the completion of any required plans of correction by the provider or supplier. In addition, if a healthcare provider or supplier was terminated or withdrew from the AO's accreditation and later retained the services of that AO, the first survey of the returning healthcare provider or supplier performed by the AO would be considered an initial accreditation survey.

The requirement of proposed § 488.8(i)(1), which would prohibit an AO from providing fee-based consulting or coaching to a healthcare provider or supplier prior to the initial accreditation survey, would provide a more accurate assessment of the provider's or supplier's baseline operating conditions and deficiencies on the initial survey. Such a raw assessment would not be possible if the provider or supplier receives AO consulting prior to the initial accreditation survey.

In addition, such a baseline assessment of deficiencies would be useful to the AO in assessing areas needing improvement and developing a plan of correction and areas of focus for its consulting services. This restriction would also remove the financial incentive on the part of the AO to ignore deficiencies during the initial survey of providers and suppliers that paid for consulting services prior to an initial survey.

We note that this proposal only restricts an AO with deeming authority and a consulting practice from providing consulting services to its accredited providers and suppliers prior to the initial accreditation survey. It does not prohibit providers and suppliers from hiring third-party consulting services prior to their initial AO survey—in other words, this proposal does not prohibit other

consulting services from being used during this period.

We do not anticipate that this proposal would cause a negative impact on the patient care provided by the provider or supplier for several reasons. First, providers or suppliers would be able to obtain AO consulting during the first 24 months of the 36-month reaccreditation cycle which occurs after the initial survey. This education could be tailored to address the deficiencies found during the initial survey. Second, the provider and supplier could always seek consulting services and education prior to the initial survey from a third-party consultant or an AO other than the one that is doing their survey. The purpose of our proposal to prohibit AO fee-based consulting prior to the initial survey and during the 12-month period prior to each reaccreditation survey was to reduce or remove any potential or actual conflict of interest. However, if a provider or supplier were to seek consulting from a third-party consultant that has no relationship to the AO that accredits that provider or supplier, no conflict of interest would exist.

We also proposed at § 488.8(i)(2) to prohibit AOs from providing fee-based consulting services to a healthcare provider or supplier it accredits within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. For purposes of proposed § 488.8(i)(2), the term “re-accreditation survey” would mean any subsequent accreditation surveys performed by the AO after the initial survey.

The accreditation cycle for most Medicare-certified providers and suppliers is 36 months (3 years), which means that the AOs perform an accreditation survey of these providers and suppliers no less than every 36 months. The proposed language at § 488.8(i)(2) would allow AOs to provide fee-based consulting during the first 24 months (2 years) of the accreditation cycle, but not during the 12-month (1-year) period preceding the re-accreditation survey. For example, with this proposal, if the initial survey was completed on June 1, 2025, the provider's or supplier's reaccreditation survey would be due by June 2, 2028. The AO could provide consulting to the provider or supplier from June 2, 2025, to June 2, 2027. The AO would be prohibited from providing AO consulting to the provider or supplier from June 2, 2027, to June 2, 2028. An accredited provider or supplier would retain the ability to use consultants, including other AOs, not affiliated with their AO at any time, including any timeframe prior to or after an

accreditation survey for Medicare compliance.

The proposed requirement would provide the accredited provider or supplier ample time, prior to their next accreditation survey, to obtain the education they need to understand the CMS requirements and the AO's accreditation standards and survey process, to implement the AO's accreditation standards and CMS standards in their facility, and to rectify any deficiencies found during the initial survey.

The proposed requirement at § 488.8(i)(2) would address the actual or potential conflicts of interest associated with AO fee-based consulting because it creates a 1-year time period prior to the re-accreditation survey in which the AO is prohibited from providing any type of additional teaching or “coaching” that would help the provider or supplier “pass” or obtain better scores on the upcoming accreditation survey.

We further proposed at § 488.8(i)(3) that the AOs or their associated consulting divisions or companies be prohibited from providing fee-based consulting services to a healthcare provider or supplier in response to a complaint received by the AO regarding that provider or supplier. Our rationale for this requirement is that AOs are required by CMS regulation to investigate and resolve complaints received regarding their accredited providers and suppliers (that is, 42 CFR 488.5(a)(4)(ix); 42 CFR 488.5(a)(12)). This regulatory requirement includes investigating the complaint and working with the accredited provider or supplier to help them resolve any deficient practices identified in the complaint. AOs charge significant fees for their consulting services. AOs should not profit by providing consulting to a provider and supplier in response to a complaint that they are regulatorily required to investigate and resolve. This proposed regulation would prevent this from occurring.

We proposed at § 488.8(i)(4)(i) to (iv) that the restrictions upon AO fee-based consulting would not apply to the following situations: (1) AO fee-based consulting services provided during the 24-month period after the date the initial or re-accreditation survey is performed (proposed § 488.8(i)(4)(i)); (2) AO fee-based consulting services provided to address complaints received and investigated by the SA regarding an AO's accredited provider or supplier in which one or more condition-level or immediate jeopardy deficiencies are identified, provided that the fee-based consulting must occur after the SA complaint investigation and survey has

been completed and must only address those issues identified by the complaint survey (proposed § 488.8(i)(4)(ii)); (3) AO fee-based consulting services provided to healthcare providers or suppliers the AO does not accredit at the time the consulting services are furnished (proposed § 488.8(i)(4)(iii)); and (4) consulting or general education provided by the AO about their accreditation program (proposed § 488.8(i)(4)(iv)).

Proposed § 488.8(i)(4)(ii) would allow AOs to provide AO fee-based consulting services in response to complaints received by the SA regarding an AO's accredited provider or supplier. However, this consulting must be provided by the AO after completion of the SA investigation and complaint survey. We would permit AO consulting services after a complaint is received by the SA, because the SA, not the AO, would perform an investigational survey. Therefore, the affected provider or supplier should be permitted to seek consulting from its AO, in accordance with the restrictions stated, to address the issues identified in the SA complaint and complaint survey, if appropriate.

It is important to note that AO consulting should only be provided when serious deficiencies have been identified in the SA's complaint investigation report. By serious deficiencies, we mean deficiencies that would be considered condition-level by the SA and the AO. However, the AO should first work directly with the provider or supplier, as part of their accreditation services package, to resolve the issues identified in the SA's complaint investigation report and only provide separate AO consulting services if these issues cannot be resolved successfully through other methods. It has always been the duty of the AOs to address and resolve complaints received regarding its accredited providers and suppliers, whether said complaint is received by the AO or the SA. An AO receives a significant fee for the accreditation services provided. We believe that the investigation and resolution of complaints falls squarely under these paid accreditation services. We do not believe it appropriate for AOs to offer fee-based consulting/educational services in response to each and every complaint received regarding one of its accredited providers or suppliers. In other words, an AO should not realize additional profit from its paying customers, when it has already been paid to perform the task at hand.

Proposed § 488.8(i)(4)(ii) would prohibit AO fee-based consulting until after completion of the SA's

investigation and complaint survey. By “completion of the SA’s investigation,” we mean the date upon which the SA has completed all work required to investigate the complaint and has issued its findings. This restriction is necessary because if the affected provider or supplier were to receive consulting from the AO prior to the completion of the SA’s investigation and complaint survey, the affected provider or supplier potentially could alter processes, operations, or documentation, all of which could compromise the SA’s investigation of the complaint. In such a scenario, the investigation and complaint survey report would not be an accurate reflection of the issues identified in the complaint. While it may seem counter-productive for the affected provider or supplier to obtain AO consulting after completion of the SA’s investigation and complaint survey, we believe that it would be helpful to the affected provider or supplier. After completion of the SA’s complaint survey and investigation, the affected provider or supplier would receive a complaint investigation report, which would allow the AO to tailor the consulting services or other educational activities to address any deficiencies identified in said report. Also, through AO consulting services, the AO could work with the affected provider or supplier at their own pace to implement long-lasting and sustainable changes that address the deficiencies identified, as opposed to the implementation of quick temporary solutions or corrective action prior to completion of the complaint investigation. A quick temporary solution would be one that the provider or supplier implements on a short-term basis, typically only during the time that the surveyors are present. By contrast, a long-lasting and sustainable solution would be one in which the provider or supplier implemented the solution, oriented the staff to its requirements, regularly monitored for compliance with the requirements, and corrected non-compliance on a continual basis.

Proposed § 488.8(i)(4)(iii) would further allow AOs to provide fee-based consulting services to healthcare providers or suppliers the AO did not accredit at the time the consulting services were furnished. If the AO had not provided accreditation services to a provider or supplier at the time consulting services were provided, the AO would not have a preexisting financial relationship with that provider or supplier. Thus, no conflict of interest would exist.

Proposed § 488.8(i)(5) would require AOs to report information about the fee-

based consulting provided to the providers and suppliers they accredit to CMS. Proposed § 488.8(i)(6) would provide for actions against AOs that provide fee-based consulting in violation of the restrictions set forth in proposed § 488.8(i)(1) to § 488.8(i)(3). We proposed at § 488.8(i)(6)(i) that if an AO was found to be in violation of the restrictions set forth in paragraphs §§ 488.8(i)(1), (2) and (3), CMS could initiate actions against the AO. These remedies would be set forth in proposed § 488.8(i)(6)(i) and (ii) and would include placing the AO on a program review, and involuntary termination of the CMS-approved AO’s accreditation program(s).

Whether or not we would impose the remedies proposed in §§ 488.8(i)(6)(i) and (ii) would depend on the severity of the violation and the facts and circumstances surrounding the violation. Such facts might include the number of providers and suppliers that contracted for prohibited AO consulting services, and the number of times the AO violated the restrictions of § 488.8(i). We proposed at § 488.8(i)(7) that the requirements at § 488.8(i) would become applicable 1 year from the effective date of the final rule with comment period to allow for an appropriate time of transition. We believe that this would provide ample time for the AOs to prepare for and implement the proposed requirements at § 488.8(i).

We note that other CMS programs have established similar conflict-of-interest and independence provisions for organizations that have a public trust role in assessing the quality of services provided. For example, in the Medicaid program, CMS has established regulatory standards with respect to the independent judgment of any External Quality Review Organization that reviews the quality of the Medicaid managed care organization for the State (42 CFR 438.354). These regulations establish, among other requirements, that an External Quality Review Organization may not review any managed care entity for which that organization has also conducted a private accreditation review within the previous 3 years.

Our proposal to place restrictions on the provision of specific consulting services by AOs to their currently-accredited providers and suppliers is authorized by section 1865(a)(2) of the Act, which gives CMS the broad power of oversight of the activities of AOs. The provision of specific AO consulting services is one of the factors in section 1865(a)(2) of the Act that should be considered in determining whether a national accreditation body

demonstrates that all of the applicable conditions or requirements of this title are met or exceeded and that its determination is free from any conflict of interest such as that discussed in this rule.

The comments and our responses are set forth below.

Comment: We received several comments of general support for the proposal to place restrictions on consulting services provided by AOs to the Medicare-certified providers and suppliers they accredit. One commenter expressed appreciation for CMS’ recognition that AOs provide helpful direction and support via fee-based consulting to facilities seeking accreditation. Another commenter voiced their appreciation for CMS’ efforts to provide policies that aim to ensure actual or perceived conflicts of interest do not arise when AOs offer accreditation and consulting services. One commenter agreed that there is fee-based consulting abuse by specific AOs while another commenter stated that they agreed with the overall intent of the proposed provisions to curb such behavior.

Response: We thank the commenters for their input and support of the proposals.

Comment: One commenter stated that there was no proposal to add a definition of the term “consulting services” to the CMS regulations at § 488.1. This commenter further suggested that CMS define and qualify “consulting services” as it relates to deemed accreditation. Another commenter stated that they define “consulting” as providing professional or expert advice for the purpose of finding a solution to a problem. This commenter suggested that CMS use this definition for “fee-based consulting”. Several commenters requested that CMS add a definition of “consulting services” in § 488.1 or elsewhere in the final rule with comment period.

One commenter encouraged CMS to clearly define what was meant by “consulting services”, and they proffered the following definition for consideration:

“Consulting is defined as the provision of any of the following:

- On-site or remote assessments of an accredited organization’s compliance to AO’ standards and/or the Medicare Conditions of Participation—commonly known as mock surveys.

- Providing direct or indirect assistance in developing and/or implementing corrective actions plans for deficiencies identified as a result of any type of survey activity. This does not include a review of submitted

corrective action plans to an AO as a result of deficiencies identified during survey activities.

“• Providing direct or indirect assistance to an accredited organization in specific preparation activities for an AO and/or Medicare survey. This does not include providing standards interpretation or general information and resources about the survey process.”

The commenter stated that they believe that the above definition addresses the salient concerns promulgated in the proposed rule but is not so overly expansive that it prohibits an AO from working effectively with its accredited providers and suppliers.

Another commenter stated that the Merriam-Webster dictionary defines “consulting” as “providing professional or expert advice.” This commenter further states that the Merriam-Webster dictionary defines “education” as “the action or process of educating or of being educated; to provide with information.” This commenter stated the opinion that, based on these definitions, they do not view the provision of general education as a conflict of interest.

Another commenter stated that no definitions were provided to distinguish between consulting, education, or training. The words are used interchangeably throughout the document. There could be a conflict of interest if the AO provides consulting services whereby the AO provides individualized analysis of a particular organization and participates in preparing, guiding, and assisting a specific organization in creating the processes and documentation necessary to pass accreditation. There is no conflict if the AO makes available tools and education to assist organizations to come into and remain in compliance with accreditation standards, and Federal and State regulations. AOs should be permitted to provide tools and education through workshops, webinars, gap analysis, policies, and forms that are designed for a general audience.

Response: While we did not propose a definition, we did include a description of “fee-based consulting services” in the proposed rule (89 FR 12001). This is the same description of fee-based consulting defined in the “Medicare Program: Accrediting Organizations Conflict-of-Interest and Consulting Services Request for Information, that was published on December 20, 2018 (83 FR 65331); hereinafter referred to as “2018 AO Conflict-of-Interest RFI”.

After careful consideration of the many comments received on both the 2018 AO Conflict-of-Interest RFI and the proposed rule regarding fee-based consulting services versus consulting services, we are retaining the qualifying term, “fee-based,” and are adding a definition of consulting services at § 488.1 that would be incorporated into the requirements at §§ 488.8(i) and (j).

Comment: One commenter was concerned that the definition of fee-based consulting at § 488.5 includes fee-based general education. Another commenter stated that they provide free education to the providers they accredit including a range of fee-based general education certification programs for providers accredited by the AO and those not accredited by the AO.

This commenter further stated that these courses contain high-level content, are taught by the AO staff, and include testing knowledge acquisition and retention at the end of the course. The commenter stated that their intent in offering these courses is to support the CMS mission of ensuring healthcare providers who are certified by Medicare understand the intent of the regulatory text to provide high-quality safe care to beneficiaries and their families. One commenter stated that they conduct fee-based ‘training’ workshops for individuals about regulatory and quality requirements, sales, and leadership, and faculty may include part-time surveyors. The commenter questioned whether that would be considered a form of fee-based consulting or a conflict of interest. One commenter questioned how CMS would view a part-time surveyor of the AO who provides consulting services during their time when they are not actively on the clock for the AO. One commenter agrees there should be restrictions on fee-based consulting activity of AOs (or associated division/business entities) when it directly conflicts with the business of accreditation. This commenter stated that particular AOs are engaging in fee-based services for the provider and suppliers they accredit through activities such as completing mock surveys to identify an organization’s areas of non-compliance, assisting organizations with the plan of correction completion, offering for purchase products such as survey readiness and policy/procedure manuals, and advising services that help an organization pass a survey.

This commenter stated that while these services are couched as advisory or gap analysis services by the AO, they still represent a conflict of interest. One commenter was concerned that the definition of fee-based consulting at § 488.5 includes fee-based general

education. One commenter stated that while they would like to offer all their education free of charge, as a nonprofit, this would significantly impact their ability to operate. One commenter stated that they are generally supportive of this proposal but have major concerns regarding the language in the proposed rule specifically, (89 FR 12009), stating that the restrictions on fee-based consulting would not prohibit an AO from providing free education about the Medicare conditions, the AO’s accreditation standards and survey process as long as the AO does not raise its accreditation fees or do anything else that would cause the provider or supplier to incur any additional costs for the education provided by the AO’s accreditation division or consulting division or consulting company. This commenter stated that they provide a variety of support services (educational webinars, staff training resources, template documents, standards interpretation, etc.) to its accredited organizations free of charge. The services are not targeted to a specific organization or in response to any organization’s specific needs. They are simply available to all organizations to use as they wish. There is no requirement for an accredited organization to use these services, nor is the organization’s survey affected by such use or non-use. They believe this approach should not be construed as being tied to accreditation fees and thus be considered fee-based consulting services.

This commenter further stated that they provide an annual education conference that is open to both accredited and non-accredited organizations. There is a separate per person fee charged to attendees. The commenter stated that the fee barely covers the cost of the conference and there is no profit made. Their accredited providers and suppliers are not required to attend, nor does attendance (or lack thereof) impact any survey activity or their accreditation status. They state that this is essentially a community-wide education conference. They point out that if this is considered fee-based consulting services, then their accredited facilities would not be able to attend. This commenter strongly urged that the noted language be stricken from the final rule.

One commenter stated that, relative to fee-based consulting and education provided by the AOs, CMS specifies that the proposals would not prohibit the AOs from providing no-cost education, such as general education about the AO’s accreditation and survey process and mock surveys. The restrictions on

AO fee-based consulting would also not prohibit AOs from providing education about the Medicare conditions, AO standards, or survey process, to its accredited healthcare providers and suppliers, as long as this education was provided completely free of charge. The commenter observed that the provision would confuse the industry as the distinction between education and consulting was unclear. This commenter stated that providers have shared with them that a primary driver of utilization of an AO is the ability of the facility to seek information and guidance that helps them understand, interpret, and comply with the Medicare conditions and regulatory requirements.

This commenter recommended that AOs be allowed to provide this type of education on a global basis, that is, through workshops sponsored by the AO, workshops where AO staff present, conference presentations, and webinars hosted by the AO or other entities such as national or State associations.

One commenter stated that while they do not presently offer fee-based consulting services, they do offer training services and other supportive services that complement accreditation and quality improvement activities in their accredited providers. This commenter requested that we clarify our definitions of all the types of services subject to this requirement, to ensure that discretionary interpretations do not unfairly impact AOs or restrict their ability to do business. One commenter stated that allowing AOs to provide no-cost education could enhance healthcare providers' understanding of accreditation standards and processes without compromising the impartiality of the AOs. One commenter generally agreed with our views on the necessity of avoiding potential conflicts of interest that may arise from the provision of fee-based consultations by AOs to accredited providers and suppliers. However, they noted that providers benefit from the educational resources provided by AOs.

The commenters stated that should CMS finalize this requirement as proposed, providers would face uncertainty about the timing of accessing otherwise beneficial education from an AO and that CMS itself recognizes that AOs have expert insight that is valuable to providers in meeting their specific compliance needs.

Response: We are not going to opine on the legality of specific hypothetical examples of education, training, and consulting services provided by commenters at this time. However, general education provided by an AO

would not constitute a conflict of interest. Section 488.8(i)(4)(iv) allows AOs to provide general education unless it meets the definition of consulting services we are finalizing in this rule. As we have noted previously, we have also added a definition of "Fee-based consulting services" at § 488.1 that more clearly outlines the type and general timing of the specific consulting services an AO might provide to facilities that it accredits and that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. We believe that this definition will help AOs and providers determine which types of AO consulting services are restricted by this rule and when these restrictions would apply.

Comment: One commenter stated that two of the three AOs that accredit home health and hospice providers offer intensive educational courses about the AO's standards, conditions of participation and survey process. Individuals successfully completing these intensive workshops are granted a "certification". The information in these workshops is extremely helpful to individuals in learning about the Medicare conditions of participation as well as the AO standards, interpreting and applying them correctly. The types of individuals completing these workshops are those employed by facilities that are accredited or going through the accreditation process as well as those consulting in these areas or employed by larger consulting firms. CMS should consider the potential for conflicts of interest with the consultants and consulting firms with these certifications.

Response: We thank the commenter for this information.

Comment: One commenter noted that some AOs also certify products for meeting the AO's standards and/or verify products for innovation. While the AOs state on their website what certification/verification means, providers and the public may view these products as being endorsed by the AO as meeting the conditions of participation. CMS should consider requiring the AOs to specify that the products are not endorsed as meeting the conditions of participation or in any other way endorsed by CMS.

Response: This comment is outside the scope of this rule, but we thank this commenter for their suggestion.

Comment: One commenter requested that CMS clearly define "interest in or relationship with" accredited organizations, to avoid any discretionary concerns among AOs or provider entities.

Response: We proposed such definitions in the proposed rule (89 FR 12005). We believe that the definition provided in the proposed rule is adequate and are finalizing it in this rule without change.

Comment: One commenter stated that some AOs in the healthcare sector that offer consulting services to the same entities they accredit perform the roles of both inspecting and accrediting. This commenter believes that this dual role compromises the objectivity and fairness of the accreditation process.

Response: We are not clear as to what the commenter means here by the term, "inspecting", especially in relation to the term "accrediting", but we thank this commenter for their comment.

Comment: One commenter requested clarification on whether the restrictions on AO fee-based consulting restrictions would apply to Medicare-certified providers and suppliers that seek only AO accreditation without deemed status. This commenter noted that some providers and suppliers obtain non-deeming AO accreditation and use the SA for Medicare certification.

Another commenter requested that additional language be added to specify that fee-based consulting that is related to accreditation services is restricted. This commenter stated that that they offer fee-based growth strategy consulting services. The commenter stated that this program is available to accredited (deemed/non-deemed) and non-accredited provider organizations to assist them in developing an ethical marketing plan to boost admissions and revenue through strategic solutions tailored to their market, referral sources, and needs. The commenter further stated that their fee-based growth strategy consulting services are in no way linked to their accreditation activity and was assessed by the AO and cleared before implementation for conflict-of-interest issues.

Response: We believe that the provision of marketing and growth strategy and development services to facilities that the AO accredits for deeming purposes would still create a conflict of interest for the AO and would be subject to the requirements of this rule.

However, in our discussion of the proposed restrictions on fee-based consulting, we did not specifically address the scenario in which the AO provides fee-based consulting to a provider or supplier that receives accreditation from an AO for non-deeming purposes and uses the State survey agency for certification. We only considered the scenario in which the AOs provide fee-based consulting to the

providers and suppliers that they accredit for deeming purposes, as discussed in the preamble (89 FR 12006). We believe that in cases where a facility uses the SA for certification and participation in the Medicare program and only uses the AO for non-Medicare accreditation and/or consulting purposes, no conflict of interest would exist and therefore no specific requirements would be needed to address these situations.

Comment: One commenter recommended that CMS revise the proposed regulatory text at § 488.5, to qualify that only fee-based consulting that is directly linked to accreditation services and impacts survey activity be restricted.

Response: In the proposed rule, we stated that the restrictions on fee-based consulting did not apply to (1) AO fee-based consulting services provided during the 24-month period after the date the initial or re-accreditation survey is performed (proposed § 488.8(i)(4)(i)); (2) AO fee-based consulting services provided to address complaints received and investigated by the SA regarding an AO's accredited provider or supplier in which one or more condition-level or immediate jeopardy deficiencies were identified, provided that the fee-based consulting occurred after the complaint investigation and survey has been completed and only addressed those issues identified by the complaint survey (proposed § 488.8(i)(4)(ii)); (3) AO fee-based consulting services provided to healthcare providers or suppliers to which the AO does not provide accreditation services (proposed § 488.8(i)(4)(iii)); and (4) no-cost consulting or general education provided by the AO about their accreditation program (proposed § 488.8(i)(4)(iv)).

We further stated that “[w]e believe that it is important that healthcare providers and suppliers receive education that would assist them in compliance, so long as it is not provided on a for fee basis, which would introduce another financial relationship between the AO and the provider or supplier that could cause a conflict of interest.” (89 FR 12009.)

We did not address the situation either in the RFI or proposed rule about fee-based consulting that was related to non-deeming accreditation. However, we believe that in cases where a facility uses the SA for certification and participation in the Medicare program and only uses the AO for accreditation and/or consulting purposes, no conflict of interest would exist (because the facility's Medicare participation would

be based on the findings of a SA, with which the AO has no financial relationship) and therefore no specific requirements would be needed to address these situations. We have also added a definition of the specific consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period.

Comment: One commenter urged CMS to clarify that limitations on the “fee-based consultation services” would apply specifically to individual hospitals with which the AO contracts to provide the consultation services—and not to all hospitals across an entire hospital system, many of which may not contract with the AO for these services.

Response: We have added a definition of the specific consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. The definition of, and the restrictions on, fee-based consulting services in this final rule with comment period will only apply to those individual hospitals and other facilities that have contracted for AO consulting services and will not apply to all facilities within a hospital or healthcare system.

Furthermore, the restrictions on consulting will only impact those individual providers and suppliers (with individual CMS Certification Numbers (CCNs)) that might contract with the AO's consulting division or company to receive the specific consulting services defined in this final rule with comment period. The AO's consulting services are services that are separate and apart from the AO's accreditation services and a separate fee is usually charged. Use of an AO's consulting services is optional on the part of the provider or supplier accredited by that AO. The restrictions on consulting, as finalized here, will not affect any providers and suppliers that do not contract for an AO's consulting services, regardless of whether they are part of a larger overall system where other providers or suppliers in the system might be contracting with an AO for consulting services. For example, if an AO accredits Hospital A, which is part of a larger system that includes Hospitals B and C, the AO would be prohibited from also providing consulting services to Hospital A under the definition and the restrictions that we are finalizing in this rule. However, this same AO would only be prohibited from providing consulting services to Hospital B or Hospital C if the AO also accredited B or C and only in accordance with the definition and requirements that we are finalizing in

this rule. Accreditation of one hospital or facility that is part of a larger system does not disqualify an AO from providing consulting services unless the parameters established by our definition and the requirements in this rule are met for these facilities and the AO involved in both accreditation and consulting.

b. Comments on Restrictions on Providing Fee-Based Consulting in Response to Complaints

Comment: One commenter stated that AOs should be free to provide consulting expertise to accredited providers who are seeking to correct or remedy a complaint situation that is being investigated by a SA. This commenter further stated that there should be a restriction on consulting only when the AO is addressing a problem with the provider that is considered a “condition” level. The AO should be permitted to provide consulting services to address Standard or Immediate Jeopardy levels of SA complaint investigations.

Response: While an AO would be prohibited from providing specific consulting services to a provider or supplier it accredits in response to a complaint the AO receives about that provider or supplier, the AO would be permitted to provide AO consulting services in response to complaints received by the SA regarding an AO's accredited provider or supplier. However, this consulting must be provided by the AO *after* completion of the SA investigation and complaint survey.

We proposed to permit AO consulting services after a complaint is received by the SA, because the SA, not the AO, would perform an investigational survey. Therefore, the affected provider or supplier should be permitted to seek consulting from its AO, in accordance with the restrictions stated, to address the issues identified in the SA complaint and complaint survey, if appropriate. However, we believe that an AO's consulting should only be provided in response to an SA complaint when serious deficiencies with the provider/supplier have been identified as part of the SA's complaint investigation report. In the proposed rule, we described “serious deficiencies” as deficiencies that would be considered condition-level by the SA and the AO.

We say this because it has always been the regulatory duty of AOs, as part of the accreditation services they provide, to respond to and investigate any complaints regarding its accredited providers and suppliers, whether said

complaints are received by the AO or the SA.

Therefore, the AO should first work directly with the provider or supplier, as part of their accreditation services package, to resolve the issues identified in the SA's complaint investigation report and only provide the specific AO consulting services defined in this rule if these issues cannot be resolved successfully through other methods.

Comment: The proposed rule states. . . "In other words, AOs should not realize additional profit from its paying customers, when it has already been paid to perform the task at hand." All AOs do not price their services to include an unlimited supply of addressing their client complaints. Accreditation clients want a cost-effective solution and that can involve a base pricing structure for the accreditation service only and services to provide a complaint visits or related consulting to assist the provider to resolve a complaint would be billed on an as needed basis.

Response: As we stated, it has always been the duty of the AOs to respond to and investigate any complaints regarding its accredited providers and suppliers, whether said complaints are received by the AO or the SA. The AOs should perform this task regardless of how much they charged the provider or supplier for accreditation services. In other words, the investigation and resolution of complaints by the AO is an administrative service on the part of the AO that they are required to perform as a condition of approval by CMS as an AO exercising "deeming authority".

Comment: One commenter opined that the use of third-party fee-based consultants would avoid perceived conflicts because they do not make compliance determinations about the provider or supplier. Another commenter stated that, as a matter of public policy, fee-based consulting services should largely be run by third parties, not the AOs themselves.

Response: We thank the commenters for their comments.

Comment: One commenter noted that in the proposed rule CMS acknowledged that independent fee-based consulting is a valuable resource that can help providers and suppliers improve the quality and safety of the care they provide. They stated that, however, CMS has proposed to put restrictions on the use of AO fee-based consulting by healthcare providers and suppliers without adequate justification, and that it appears the agency is contradicting itself as the agency expressly acknowledges the value of such services.

Response: In the proposed rule, we recognized the value of fee-based consulting by independent, third-party consultants who provide insight or expertise to assist facilities in achieving or maintaining compliance with AO and/or Medicare's health and safety standards (89 FR 12006). The consulting services provided by AOs to the providers and suppliers it accredits can be beneficial in assisting the providers and suppliers in achieving or maintaining compliance with the AO's and Medicare's health and safety standards. However, because of the conflict of interest associated with specific consulting services, we proposed restrictions on specific AO consulting services and at certain points in the process. We believe these restrictions are minimal in comparison to a total ban on consulting. The restrictions finalized in this rule would also not prevent an AO from providing any consulting or general education to its providers and suppliers about their accreditation program.

Comment: One commenter noted that CMS states the prohibition on an AO providing fee-based consulting prior to an initial survey is to provide a "more accurate assessment of the provider's or supplier's baseline operating conditions and deficiencies on the initial survey." Yet, CMS would allow healthcare providers or suppliers to use a third-party consultant prior to the AO's initial survey. Another commenter stated that continuing to allow third-party consultants both acknowledges the role of education pertaining to compliance with Medicare requirements and contradicts the agency's belief that consulting prior to an initial survey by AOs also conducting the initial survey—even when paired with a robust firewall that fully mitigates any COI concerns—would not result in an accurate assessment of baseline operating conditions.

Response: This commenter is correct that our restrictions on consulting will allow the providers and suppliers accredited by an AO to seek fee-based consulting from third-party consultants at any time, without restrictions. The proposals we have made for restrictions on consulting are to address and mitigate, to the extent possible, the conflicts of interest associated with AO consulting. We had no need to propose any restrictions on the consulting provided by third-party consultants because no conflict of interest is associated with the provision of consulting by these parties. Even if we were inclined to prohibit or restrict the provision of fee-based consulting by third-party consultants, we do not have

the statutory or regulatory authority to do so.

Comment: One commenter stated that in the proposed rule, CMS suggested that providers found to be non-compliant by their AO might assume that the most direct path to compliance would be to hire the AO for its consulting services; such assumption would provide AO consulting services with an unfair advantage over other, third-party consulting services. These fee-based consulting services provide the extra benefit of bringing actual survey experience. Therefore, there is no rational justification for artificially distorting the market to dissuade healthcare provider and suppliers from receiving such benefit, which would ultimately benefit patients.

Response: We have added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. In this final rule with comment period, we have not prohibited AO fee-based consulting in its entirety but have merely placed some limited restrictions on this service to help mitigate the conflicts of interest associated with specific AO consulting services and the timing of those services. The purported benefit that the commenter notes is exactly related to the conflict of interest for AOs that we are addressing in this rule. Facilities may still use the services of third-party consultants as well as the consulting services provided by an AO that does not accredit the facility.

Comment: One commenter stated that while it is understandable that there could be a public perception of conflicts of interest when a subsidiary of an AO consults with the hospitals it accredits, hospitals report that the "firewall" between their accrediting AO and its consultative subsidiary is sufficient to prevent any such conflict of interest.

Response: We agree with this commenter that there is a potential conflict of interest associated with the provision of consulting to the providers and suppliers the AO accredits. However, we disagree with this commenter that a "firewall" would eliminate this conflict of interest entirely and are therefore finalizing additional restrictions and parameters for consulting services provided by AOs to the facilities they accredit for deeming purposes.

Comment: One commenter stated that they have policies in place to address conflicts of interest during surveys and accreditation decisions. This commenter stated that as long as conflict-of-interest requirements and related processes are followed, actual conflicts of interest that

could undermine the integrity of a CMS-approved accreditation program can be mitigated.

Response: We thank this commenter for sharing this information.

Comment: One commenter stated that it has robust, government-evaluated firewall policies which prohibit the sharing of information related to accreditation surveys and decisions between its accreditation and fee-based consulting divisions. This commenter further stated that its firewall policies help to ensure that accreditation surveys and decisions are free from real or perceived conflicts of interest. Another commenter stated that the U.S. Government Accountability Office (GAO) reviewed its firewall policies and found no concerns with the policies; GAO recommended that that AO continue with its current process to assess and monitor the firewall policies.

Response: We appreciate the information shared by the commenter. However, as stated, we do not believe that firewall policies alone are sufficient to eliminate conflicts of interest that CMS is addressing in this rule.

Comment: One commenter that provides fee-based consulting stated that they have shown that appropriate policies, such as strong COI policies and a robust firewall policy, have maintained the integrity of their accreditation survey process and decisions while also ensuring their accredited facilities have access to quality improvement tools.

Response: We thank the commenter for this information.

Comment: One commenter stated that it is important for CMS, the public, and patients to have faith in the accrediting decisions of AOs and in the health and safety of the health systems where they seek care. However, AOs should be able to continue providing these services if they are able to demonstrate that they maintain robust firewalls between the consulting and accrediting units of the organization and report on these consulting relationships.

Response: We agree with this commenter that it is important that the public and patients have faith in the accrediting decisions of AOs and in the health and safety of the health systems where they seek care. Our proposal for restrictions on fee-based consulting did not prohibit providers and suppliers that are accredited by AOs that provide fee-based consulting from obtaining these services. We have also added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. Therefore, the requirements of this final

rule with comment period will only restrict the provision of specific types of AO consulting services to specific time periods during the accreditation period.

Comment: One commenter opined that fee-based consulting services promote understanding of accreditation requirements by providers and suppliers and help them attain accreditation. However, they agree that a better separation between those fee-based consulting services and the accrediting/surveying services needs to exist to ensure conflicts of interest do not result in inappropriate accreditation.

Response: We thank this commenter for submitting their comment. We agree that it is necessary for the AOs that provide consulting services to have and to strictly enforce robust firewall policies and procedures to ensure that the AO's accreditation and consulting divisions remain completely separated. This is necessary to maintain the integrity of the accreditation process.

Comment: One commenter stated that CMS stated that a real or perceived conflict of interest arises when an AO provides fee-based consulting services to help a provider or supplier meet Medicare requirements while also charging the provider for conducting a deeming survey to assess compliance. This commenter also stated that CMS incorrectly assumes there are concerns with the integrity of AO compliance determinations when an AO that provides Medicare deeming surveys also has a separate and distinct arm that provides fee-based consulting services.

This commenter stated that CMS did not consider the fact that the AO has robust firewall policies between its fee-based consulting and accreditation divisions. The firewall policies ensure that there is no exchange of accreditation survey and decision information between these two entities.

Response: We did consider AO firewalls between their consulting and accreditation divisions and have determined that firewalls alone are insufficient to prevent conflicts of interest. We continue to believe that the additional conflict-of-interest requirements in this rule, including those specific to firewall policies and procedures between the survey and consulting arms of an AO, are still needed. Therefore, we have also added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period so that we can further clarify and strengthen the firewall requirements that are an integral part of what AOs must do to prevent and mitigate conflicts of interest in this area. In this

final rule with comment period, we are therefore limiting the restrictions on AO consulting services that were previously proposed and more clearly specifying what those restrictions are.

Comment: One commenter stated that, although CMS notes that providers or suppliers could still access AO fee-based consulting during the first 24 months of the 36-month reaccreditation cycle after the initial survey, providers and suppliers should not be cut off from all available resources and tools prior to accreditation or reaccreditation. This commenter further stated that the opinion that CMS' intention to restrict consulting prior to an initial survey to assess a baseline operating condition—even where there is no basis for any conflict-of-interest concern on account of a robust firewall—runs counter to the intent of the quality improvement process, which aims not to assess a facility at its lowest performance but to assess performance and to provide tools and resources to implement and sustain improvement initiatives.

Response: We have determined that firewalls alone are insufficient to prevent conflicts of interest and have therefore also added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. In this final rule with comment period, we are therefore clarifying the restrictions on AO consulting services that were previously proposed.

Comment: One commenter stated that, due to the firewall, surveyors have no idea what issues were addressed by consultants, so there is no way in which it can bias the survey. The commenter further state that, ironically, one could even state that it would be an improvement of process if the surveyors were aware of prior deficiencies to ensure that they were adequately and durably addressed.

Response: As we have previously stated, we have determined and firmly believe that firewalls alone are not sufficient to prevent conflicts of interest. The conflict of interest may not affect the details of a survey but manifest in the accreditation decision itself. We have therefore also added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. In this final rule with comment period, we are therefore clarifying the restrictions on AO consulting services that were previously proposed.

Comment: Several commenters stated that they are in favor of fee-based consulting services provided by AOs to

strengthen oversight and prevent conflict of interest. One commenter opined that, due to the complexity of the Medicare CoPs and CfCs, AOs are in a unique position to provide this education and technical assistance, and that hospitals rely on these services not only to prepare for surveys, but to identify and implement opportunities for quality improvement. Another commenter opined that hospitals must expend tremendous resources to ensure compliance with complex accreditation requirements. They benefit from the expertise of consultative services in providing education, training, publications, and technical assistance to assist in understanding standards and preparing for surveys.

Response: We agree that the consulting services provided by AOs can help the providers and suppliers accredited by the AO to understand the Medicare CoPs and CfCs. We would like to point out that providers and suppliers can also obtain these consulting services from third parties. There is no conflict of interest associated with the consulting services provided by third parties because these parties do not also provide the accreditation surveys for these providers and suppliers as the AOs do. In this final rule with comment period, we have not prohibited AO fee-based consulting in its entirety but have merely placed some limited restrictions on this service when it is provided by the provider's AO, to help mitigate the conflicts of interest associated with specific AO consulting services and the timing of those services.

We have also added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. In this final rule with comment period, we are therefore limiting the restrictions on AO consulting services that were previously proposed.

c. Comments Supporting Proposed CMS Restrictions on AO Fee-Based Consulting Services

Comment: Several commenters expressed support for our proposal to place restrictions on the fee-based consulting services provided by AOs to the healthcare providers and suppliers they accredit.

One commenter stated that the proposal to prohibit AOs from providing fee-based consulting services to their accredited facilities addresses legitimate concerns about maintaining the objectivity and credibility of the accreditation process. However, it also acknowledges the value of education and guidance by permitting no-cost

educational services and allowing third-party consulting. Another commenter stated that our proposed restrictions of fee-based consulting seek to balance the need for impartial accreditation with the ongoing need for healthcare provider organizations to prepare effectively for such assessments. One commenter stated that there may be appropriate times when fee-for-service consulting is warranted and or/needed and should be allowed and accounted for where there are firewalls to protect the integrity of the process within the guidelines of this rule. Reporting requirements and proposed penalties for non-compliance underscore the seriousness of these concerns while aiming to ensure transparency and accountability. One commenter stated that while the proposed restrictions by CMS aim to safeguard the integrity of the accreditation process and maintain public trust in AOs, they also recognize the importance of education and preparation for healthcare provider organizations.

Response: We thank the commenters for their support of our proposals for restrictions on fee-based consulting. We have also added a definition of the specific AO consulting services that would be subject to the requirements of §§ 488.8(i) and (j) in this final rule with comment period. In this final rule with comment period, we are therefore limiting the restrictions on AO consulting services that were previously proposed.

Comment: One commenter stated that they agreed with CMS that without certain restrictions (such as demonstrable management separation between the consulting and accrediting divisions and limitations on when the fee-based consulting affiliate could provide consulting services relative to the date of the survey) an AO providing both regulatory oversight (through Medicare deeming surveys) as well as consultation on passing those surveys could call into question the integrity of the accreditation process.

This commenter stated that the proposed measures will ensure accountability of AOs and their fee-based consulting services to comply with CMS rules related to conflicts of interest.

One commenter strongly encouraged CMS to ensure that AOs have zero conflicts of interest by identifying and halting any survey practices and outcomes that could generate downstream revenue to an AO from IPFs and other providers that received negative audit findings. This commenter further stated that establishing and maintaining this critical check and

balance should be a top priority for CMS. This commenter further stated that this practice should include prohibiting fee-based consulting services that AOs provide to IPFs and other providers following an accreditation determination.

Response: We thank the commenters for their support of our AO fee-based consulting proposals. In this final rule with comment period, we have not prohibited AO fee-based consulting in its entirety but have merely placed some limited restrictions on this service to help mitigate the conflicts of interest associated with specific AO consulting services and the timing of those services.

Comment: One commenter who does not provide fee-based consulting services stated that “[h]undreds of our clients each year successfully achieve accreditation without any fee-based consulting services from our organization. While we appreciate that education is an important part of the accreditation process, fee-based consulting services are not”.

Response: We thank this commenter for their comment. We believe that education is an important part of the accreditation process.

Comment: One commenter expressed support for the proposals related to fee-based consulting services, including the proposed restrictions on the provision of fee-based consulting services provided by AOs to healthcare providers and suppliers they accredit prior to the initial survey, and within 12 months prior to the next scheduled reaccreditation survey of a provider or supplier.

Response: We thank this commenter for their support of the proposals related to fee-based consulting.

Comment: One commenter stated that the proposed restrictions on fee-based consulting should be “seen as a regulatory floor by CMS, not the end of all potential areas for regulatory development moving forward.”

Response: We thank this commenter for their comment and will take their suggestion under advisement. We will be monitoring the consulting activities of the AOs after the provisions become effective to see what, if any, additional regulation on this activity is needed.

Comment: One commenter stated that they believe that the proposed restrictions on fee-based consulting could ultimately raise healthcare costs because the fees associated with purchasing fee-based consulting would be passed on to the consumer. This commenter further stated that they have been told by their clients who have worked with other AOs that those AOs

increase, and sometimes double, accreditation fees to fund the consulting hours necessary to successfully manage relationships with other AOs.

Response: We thank this commenter for their comment, but we do not believe the restrictions in this rule on fee-based consulting would increase healthcare costs since the requirements do not completely prohibit AOs from providing fee-based consulting services. The requirements in this rule also do not mandate that accredited facilities must purchase consulting services from AOs or third-party consultants. The use of fee-based consulting services in preparation for either an SA or an AO survey is a choice made by each facility.

Comment: One commenter stated that the need to purchase consulting services in the accreditation space essentially creates a “haves and have nots” scenario among accreditation clients, in which smaller entities would not be able to afford the fee-based consulting services offered by the AO. The commenter also stated that AOs that market and provide fee-based consulting services for the facilities they accredit prior to an accreditation survey for deeming purposes are potentially implying that the purchase of such services would guarantee the facility’s accreditation and deemed status. The commenter states that this puts smaller facilities with potentially limited budgets when compared to larger facilities, and especially those in medically underserved communities, into a difficult situation, one which might ultimately exacerbate issues of patient access to care in these communities.

Response: We thank this commenter for their comment. We agree that there may be smaller providers and suppliers that are not able to afford the consulting services offered by some AOs. However, we have seen no evidence that would suggest that larger providers that use fee-based consulting services consistently perform better on surveys than smaller facilities that do not use consulting services.

Comment: One commenter supported our proposal to prohibit AOs from providing fee-based consulting services prior to an initial accreditation survey within 12 months prior to reaccreditation surveys, and in response to a complaint received by the AO regarding the provider or supplier. This commenter further stated that these proposed restrictions on fee-based consulting are reasonable.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter stated that the proposed provisions related to fee-

based consulting would allow CMS to proactively ensure that conflicts of interest would not arise by increasing transparency.

Response: We thank this commenter for this comment.

Comment: One commenter agreed that there should be restrictions on the fee-based consulting activities of AOs (or associated division/business entities) when they directly conflict with the business of accreditation. This commenter stated that particular AOs provide fee-based services for provider organizations that they accredit. Examples include completing mock surveys to identify an organization’s areas of non-compliance, assisting organizations with the plan of correction completion, offering for purchase products such as survey readiness and policy/procedure manuals, and advising services that help an organization pass a survey. These services are couched as advisory or gap analysis services, but they represent conflicts of interest.

Response: We thank this commenter for their comments.

Comment: One commenter supported our proposals to place restrictions on the fee-based consulting services provided by AOs to the healthcare providers and suppliers they accredit; prohibit an accrediting organization or its associated fee-based consulting division or company from providing fee-based consulting services to any healthcare provider or supplier prior to an initial accreditation survey; prohibit AOs from providing fee-based consulting services to healthcare providers and suppliers they accredit within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier; and prohibit AOs from providing fee-based consulting services to a healthcare provider or supplier in response to a complaint received by the AO regarding that provider or supplier.

Response: We thank this commenter for their support for this proposal. We note that in this final rule with comment period we have not prohibited AO fee-based consulting in its entirety but have merely placed some limited restrictions on this service to help mitigate the conflicts of interest associated with specific AO consulting services and the timing of those services.

Comment: One commenter supported our proposed restrictions on fee-based consulting services provided by the AOs to the providers and suppliers they accredit for the following reasons:

- Limiting fee-based consulting services encourages AOs to prioritize

their primary role of objective accreditation.

- By restricting fee-based consulting services, accrediting bodies can reinforce the principle that accreditation should be a fair and objective evaluation of quality standards, fostering a culture of excellence and continuous advancement in healthcare provision.

- This approach promotes a clearer separation of duties and diminishes the likelihood of financial factors influencing accreditation decisions.

- Paid consulting undermines the significance and integrity of accreditation, potentially leading to a focus on identifying errors to generate consultation work rather than supporting quality improvement in a collaborative, collegial environment.

- When all interested parties are committed to serving the public, the outcomes will be more robust.

Response: We thank this commenter for their support of this proposal.

d. Restrictions on Fee-Based Consulting and Accreditation Fees

Comment: Creating educational materials involves costs at every stage, from research and development to production and distribution. These expenses are necessary to ensure quality and effectiveness in providing valuable learning resources. Without generating revenue to cover these costs, sustaining the production of educational materials would be challenging. A successful business model must factor in these overhead costs and set pricing strategies accordingly. Charging for educational products is essential to maintain sustainability and invest in continuous improvement.

Response: We understand that the AOs would have some expense associated with the development of educational materials. However, once developed, we believe that the AOs would be able to use these materials over and over without further expense. Also, the AO generates revenue from the fees it collects for the accreditation services provided. Educational materials related to the AOs accreditation standards and survey process should properly be part of the accreditation program; any cost for the development for same would be paid from the accreditation fees collected.

In addition, there are currently nine AOs that accredit Medicare providers and suppliers. Only four of these AOs provide fee-based consulting. The other five AOs provide the required education and materials to the providers and suppliers they accredit free of charge. It is our understanding that the four AOs that charge for education and materials

do so for profit. While we do not object to this arrangement, we note that it does not appear to be necessary to maintain an AO as a going concern.

Comment: One commenter alleged that, in addition to dictating what services an AO can provide, the proposed rule seeks to establish for what services an AO could receive payment. AOs can provide education about the Medicare conditions, AO standards, or survey process, to its accredited healthcare providers and suppliers, as long as this education is provided completely free of charge.

Response: While this commenter's allegation is rather general in nature, we believe it refers to fee-based consulting. We respectfully disagree with this commenter, for several reasons. First, we note that they have misconstrued our proposed exception to the restrictions on fee-based consulting as an attempt by CMS to dictate what services an AO can provide and establish services for which an AO can receive payment. In the proposed rule, we generally defined fee-based consulting as any type of education for which the AO charges a fee. We stated that the restrictions on fee-based consulting would not apply to any type of education for which the AO does not provide a fee or provides at no charge to the providers and suppliers it accredits. We have not dictated what type of content the AO can or cannot provide with its fee-based education or education that is provided for free. We have only proposed to place restrictions on the provision of fee-based consulting in certain circumstances.

Further, while CMS has proposed to place restrictions on fee-based consulting, we have not restricted the AOs ability to charge for the fee-based consulting that is provided within those restrictions. In the proposed rule we stated that we would expect the AOs not to raise their accreditation fees to recoup any lost profits caused by our proposed restrictions on AO fee-based consulting. To do so would be to penalize the providers and suppliers that do not contract with the AO for fee-based consulting. Also, if an AO were to raise its accreditation fees to recoup lost profits from the restrictions on fee-based consulting, this action would demonstrate to us that profit is the main motivation for the provision of its fee-based consulting services to its accredited providers and suppliers. Please see the previous discussion of the conflict-of-interest requirements at section IV.D. of this final rule with comment period for our arguments as to why these requirements are needed to ensure that profit is not the main

motivation for the services that an AO might provide to its accredited facilities.

Comment: The proposed rule concludes that the AO would not be allowed to raise the price of their accreditation services because of the provision of this education or do anything else that would cause the provider or supplier to incur any additional costs for the education provided by the AO, its consulting division or separate consulting company to the providers or suppliers it has contracted with to provide accreditation services. The impact of this cannot be overstated. Not only is CMS attempting to shape the services offered and the way they are delivered, but it is also dictating the pricing structure. This level of control impinges on operational autonomy, hindering the capacity of the AO to thrive in a competitive market and manage a not-for-profit with a viable financial margin. Navigating these stringent guidelines places significant strain on resources, diverting the focus from the AO's core mission and impeding long-term sustainability.

Response: We define fee-based consulting generally as any type of education for which the AO charges a fee. We stated that the restrictions on fee-based consulting would not apply to any type of education for which the AO does not provide a fee or provides at no charge to the providers and suppliers it accredits.

While CMS has proposed to place restrictions on fee-based consulting, our proposal would not restrict the AOs ability to charge for the fee-based consulting that is provided within those restrictions.

In the proposed rule we stated that we would expect the AOs not to raise their accreditation fees to recoup lost profits caused by our restrictions on AO fee-based consulting. To do so would be to penalize the providers and suppliers that do not contract with the AO for fee-based consulting. Also, if an AO were to raise its accreditation fees to recoup lost profits from the restrictions on fee-based consulting, this action would demonstrate to us that profit is the main motivation for the provision of its fee-based consulting services.

Comment: Creating educational materials involves costs at every stage, from research and development to production and distribution. These expenses are necessary to ensure quality and effectiveness in providing valuable learning resources. Without generating revenue to cover these costs, sustaining the production of educational materials would be challenging. A successful business model must factor in these overhead costs and set pricing strategies

accordingly. Charging for educational products is essential to maintain sustainability and invest in continuous improvement.

Response: We understand that the AOs would have some expense associated with the development of educational materials. However, once developed, we believe the AOs would be able to use these materials over and over without further expense.

Also, the AO generates revenue from the fees it collects for the accreditation services provided. Educational materials related to the AOs accreditation standards and survey process should properly be part of the accreditation program and we believe any cost for the development for same should come from the accreditation fees collected.

In addition, there are currently nine AOs that accredit Medicare providers and suppliers. Only four of these AOs provide fee-based consulting. The other five AOs provide the required education and materials to the providers and suppliers they accredit free of charge. It is our understanding that the four AOs that charge for this education and materials do so for profit.

Comment: One commenter stated that healthcare providers and suppliers should not be cut off from all available resources and tools prior to accreditation or reaccreditation. This commenter further was concerned that if there is a harmful situation, such as poor infection control practices, and deficiencies in fire safety, appropriate review of physician conduct, or other serious deficiencies, then letting those deficiencies persist until an inspection only perpetuates the risk for harm of one or more patients.

Response: We respectfully disagree with the premise of this comment. The AO not being allowed to provide fee-based consulting to a provider or supplier prior to a survey should not affect how such deficiencies are handled by the facility prior to that survey. Medicare-certified providers and suppliers must comply with all Medicare patient health and safety requirements as a condition for participation in the Medicare program, regardless of whether they are surveyed for compliance by an SA or an AO and regardless of when the next survey may occur. All participating providers and suppliers must take immediate action to address deficiencies that could result in patient harm as soon as they become aware of such deficient practices and harmful situations and should not wait for the next survey. If a facility believes that it needs consulting or educational assistance to fully address such deficiencies, the requirements of this

rule do not prohibit it from using another AO's consulting services or those of a third-party consultant.

Comment: One commenter stated that our proposed restrictions on AO-fee-based consulting restrict providers from seeking all available tools and resources and has the potential to decrease the quality of care. The commenter states that the fee-based consulting provided by third-party consultants isn't "as good" as that provided by the AOs. This commenter also contends that the use of third-party fee-based consulting has the potential to decrease the quality of patient care.

Response: We respectfully disagree with this commenter. The only way that we could restrict the access of providers and suppliers accredited by AOs that provide fee-based consulting to available tools offered by the AO would be if we prohibited fee-based consulting altogether. However, we only proposed to place limited restrictions on the fee-based consulting provided by the AOs. As finalized, the provider or supplier will have access to the AOs fee-based consulting services and other included resources, manuals and tools during the first 24-months of each 36-month accreditation period. In addition, the providers and suppliers can seek fee-based consulting from third-party consultants at any time, even prior to the initial accreditation survey.

We disagree with the claims made by the commenters about third-party fee-based consulting. There is little difference between the consulting services provided by the third-party consultant and the AOs. The fee-based consulting provided by the AOs focuses on the AO's accreditation standards, whereas third-party consulting is based on the Medicare standards, since the consultants may not have access to the AO's accreditation standards.

Comment: One commenter stated that for its fee-based consulting division to comply with the prohibition on fee-based consulting during the 12 months prior to each reaccreditation survey, the AO's consulting division would need continually updated information from the AO's accreditation division on which provider and suppliers were being accredited by the AO and the next expected survey date.

Response: The commenter is correct.

Comment: One commenter stated that for AOs to comply with the proposed prohibition on fee-based consulting to a provider in response to a complaint received by the AO regarding that provider, the consulting affiliate would need communication from the AO regarding the complaint and to determine whether what the provider is

seeking consulting is related to the complaint. The proposed CMS firewall requirements and The Joint Commission firewall policies strictly prohibit AOs from sharing complaint information with the consulting affiliate. As proposed, these requirements would lead to a less rigorous firewall than currently used by The Joint Commission.

Response: We respectfully disagree with this commenter for several reasons. First, AOs will be completely prohibited from providing fee-based consulting to a provider or supplier in response to a complaint received by the AO about that provider or supplier. Second, we have proposed such a restriction because, pursuant to our existing regulations, it is the AO's responsibility to respond to and investigate complaints involving its accredited providers and suppliers. To resolve the issues identified in the complaint, it may be necessary for the AO's accreditation division to provide non-fee-based education. We do not believe it is appropriate for the AO to use a complaint filed against one of its accredited providers or suppliers as an opportunity to unjustly profit from providing fee-based consulting. It would also be a violation of the AO's firewall policy to communicate to the AOs fee-based consulting division that a complaint has been received regarding one of the AOs accreditation clients.

Comment: One commenter stated that CMS failed to provide an explanation of why the AO's fee-based consulting services must only address those issues identified by the complaint survey when the complaint has been received and investigated by the SA regarding an AO's accredited provider or supplier in which one or more condition-level or immediate jeopardy deficiencies have been identified.

This commenter further stated that an AO's fee-based consulting should be permitted to work with healthcare organizations (HCOs) to address all quality and safety issues and not just those identified during an SA complaint survey otherwise quality and safety issues may remain unresolved.

Response: We respectfully disagree with this commenter. We discussed the rationale for this proposal in the proposed rule (89 FR 12008), where we explained that that AOs are required by CMS regulation to investigate and resolve complaints received regarding their accredited providers and suppliers (that is, 42 CFR 488.5(a)(4)(ix); 42 CFR 488.5(a)(12)). This regulatory requirement includes investigating the complaint and working with the accredited provider or supplier to help them resolve any deficient practices

identified in the complaint. AOs charge a significant fee for their fee-based consulting. AOs should not profit by providing fee-based consulting to a provider and supplier in response to a complaint that they are regulatorily required to investigate and resolve. This regulation would prevent this from occurring. We further explained in the proposed rule that AO fee-based consulting should only be provided when serious deficiencies have been identified in the SA's complaint investigation report. By serious deficiencies, we mean deficiencies that would be considered condition-level by the SA and the AO. However, the AO should first work directly with the provider or supplier, as part of their accreditation services package, to resolve the issues identified in the SA's complaint investigation report and only provide AO fee-based consulting if these issues cannot be resolved successfully, through other methods. We would expect to find that if an AO offers fee-based consulting/educational services to the provider or supplier, they do so only after trying all non-cost options available, and that the fee-based consulting/education was reasonably expected to resolve the deficiencies identified in the complaint.

Comment: One commenter supported our proposed requirement that the AOs that provide fee-based consulting services must have or implement AO fee-based consulting firewall policies and procedures that ensure complete separation between their AOs fee-based consulting and accreditation divisions. However, this commenter stated that two of the AOs that provide fee-based consulting provide home health and hospice fee-based consulting programs that have a unique collaboration and teaching ethos. This commenter stated that these fee-based consulting programs should be enhanced and supported, not restricted. They encouraged CMS not to create barriers to these trainings or restrict AOs ability to provide these educational opportunities to providers. The commenter further stated that these home health and hospice fee-based consulting programs could provide immense value to providers and suppliers by ensuring compliance with CoPs.

Response: We thank this commenter for their support for our proposed firewall policies and procedures. However, this commenter supported our proposal, so long as it was not related to or did not affect fee-based consulting programs for home health and hospice providers.

Our rule will not completely prohibit AOs from providing fee-based

consulting to the providers and suppliers it accredits. It will only prevent the AOs from providing this service during specific times including prior to initial surveys and during the last 12 months of the 36-month accreditation cycle. The AO would be able to provide fee-based consulting to the providers and suppliers it accredits during the first 24 months of the 36-month accreditation cycle. Providers and suppliers would be able to seek fee-based consulting from a third-party consultant at any time with no restrictions.

Comment: One commenter stated that the proposed restrictions on AO fee-based consulting, if finalized, would eliminate a key source of provider education and compliance and as a result, stifle consulting relationships. This would undermine the very health and safety goals CMS seeks to advance. Health systems leveraging these relationships would have to identify another AO to use or an external consulting service, which would hinder their ability to maintain continued compliance with health and safety regulations.

Response: We respectfully disagree with this commenter because providers and suppliers would be permitted to seek fee-based consulting from a third party at any time, without restrictions, so long as that AO does not provide accreditation services to the provider or supplier at the time the consulting services are furnished.

Comment: One commenter stated that the proposed restrictions on fee-based consulting, if finalized, would be disruptive to existing relationships and processes, particularly in cases where health system staff have had longstanding relationships with their AO's fee-based consulting divisions. The commenter provided an example scenario in which a health system currently receives fee-based consulting services from an AO and is due for a re-accreditation survey in the next 12 months. The health system would essentially have to terminate its consulting relationship with the AO or find another AO to use for accreditation, which could delay its ability to receive accreditation in a timely manner. In the case of termination of the consulting arrangement with the AO, the health system would have to find another suitable consultant that meets the needs of the health system.

Response: We respectfully disagree with this commenter. We believe that the 12-month restriction requirement in this final rule with comment period addresses the actual or potential conflicts of interest associated with AO

fee-based consulting because it creates a 1-year time period prior to the initial or re-accreditation survey in which the AO is prohibited from providing any type of additional teaching or "coaching" that would help the provider or supplier "pass" or obtain better scores on the upcoming accreditation survey.

We also believe that for a provider or supplier to correct deficiencies and make long-lasting cultural changes to the facility, they need to have plenty of time to do so. We further believe that when a provider or supplier waits until the last minute to correct deficiencies and come into compliance with the AO's accreditation standards, the changes made will be hastily made and will not last.

Comment: One commenter stated that the proposed prohibitions on fee-based consulting are inconsistent with the aims of existing conflict-of-interest policies and proposed requirements. In their comment, this commenter stated that CMS has "prohibited" fee-based consulting, this commenter stated that these "prohibitions" on fee-based consulting are inconsistent with the existing conflict-of-interest policies and proposed requirements. This commenter does not state whether they are referring to their own policies and procedures or those of CMS.

Response: In the proposed rule, we proposed some limited restrictions on the fee-based consulting provided by AOs. We do not believe that the restrictions as finalized will conflict with existing CMS regulations, guidance, policies and procedures. This is because CMS does not currently have any regulations, guidance, policies or procedures related to fee-based consulting provided by AOs.

To the extent our final rule with comment period conflicts with the AOs existing policies and procedures, our restrictions are being implemented pursuant to the broad oversight authority of AOs granted to CMS by section 1865 of the Act. After the provisions of the final rule with comment period and new regulations for restrictions on AO fee-based consulting become effective, the AO will be required to revise its existing policies and procedures to be consistent with the provisions of the final rule with comment period and new CMS regulations.

Comment: One commenter stated they believed that there is significant variation in the types of fee-based consulting services provided by AOs, ranging from educational support and guidance on understanding the CoPs to specific, targeted recommendations on how to address potential or actual

deficiencies. Therefore, not all types of consulting services would implicate concerns about a potential conflict of interest.

Response: We respectfully disagree with this commenter. If the fee-based consulting provided by an AO to the providers and suppliers it accredits is in any way related to the AO's accreditation process, the accreditation survey, the AO's accreditation standards and/or the CMS standards, then a conflict of interest would exist. This conflict of interest arises from the contractual and financial relationship between the AO and the provider or supplier. The AO charges a fee for the fee-based consulting that is designed to assist the provider or supplier do better on the accreditation that is also administered by the same AO.

The business connection between the provider and the AO creates a relationship that the AO could have incentive to manipulate. For example, the AO could gain from ignoring the deficiencies of certain providers; these missed deficiencies would call the AOs' neutrality into question. The AO could also have the incentive to downplay deficiencies during the survey of a consulting client to increase the apparent efficacy of its consulting services, or perhaps play up the deficiencies of non-clients to increase the apparent value of the consulting services to these prospective clients.

Comment: One commenter suggested that CMS can address many of its concerns through better oversight and reporting, as proposed in the rule, such as biannual AO reporting to CMS of fee-based consulting services. This proposal entails the AO providing information on the fee-based consulting services it offers, any providers and suppliers to which the AO provides consulting services, and detailed information on the nature and scope of these consulting services. Providing this data will equip CMS with the necessary tools to monitor conflicts of interest.

Response: We thank this commenter for their suggestion. We will take it under advisement.

Comment: One commenter stated the opinion that many of the AO oversight proposals in the proposed rule work at cross purposes with one another, lack context, violate the legislative intent of accreditation oversight, and are inconsistent. This commenter also stated that the proposed restrictions on fee-based consulting, which are aimed at reducing conflicts of interest, will limit the AOs' contact with facilities seeking or renewing deemed status and constrain the nature of communications and services AOs may offer to such

facilities. This commenter also opined that this proposal, if finalized, will prohibit the AOs that provide fee-based consulting from communicating with facilities within a year of their survey.

This commenter further stated that many AO communications are meant to facilitate improvement in facilities, at the precise moment the facilities are most receptive to input and have their attention most focused on compliance. If the healthcare system's collective goal is to improve the care provided to beneficiaries, any information that can help the facility should be welcome. Instead, these limits remove valuable information from facilities, making it harder for facilities to comply and increasing the odds that AOs perform poorly on the proposed scores. The proposed rules would create tension by prohibiting communications that could improve AO scores.

Response: In this final rule with comment period, we are restricting the AOs that provide fee-based consulting from providing fee-based consulting at the following times:

- At any time prior to the initial survey
- During the last 12 months of each 36-month accreditation period
- In response to a complaint received by the AO about an accredited provider or supplier.

However, our restrictions on fee-based consulting *do not* prevent the AOs from communicating with its accredited provider or supplier during the restricted periods, so long as the communication does not consist of the provision fee-based consulting services. In addition, providers and suppliers are free to seek fee-based consulting from a third-party consultant or another AO that does not provide accreditation to that provider or supplier at the time the consulting services are furnished. The providers and suppliers are free to seek fee-based consulting from third party consultants and other AOs at any time without restrictions.

Comment: One commenter that does not provide fee-based consulting objects to the specific time boundaries proposed in § 488.8(i) of the proposed rule. This commenter stated that these limitations would adversely and unfairly affect their ability to communicate with their customers in the ordinary course of business. The commenter further stated that their annual survey model would preclude such limitations.

This commenter requested that CMS clarify these terms and date triggers, as accreditation activities are intensely date-driven and discretionary reviews would adversely affect these timelines.

Response: We are not sure what this commenter means by limitations on communications. We proposed at § 488.8(i) to place limitations on the fee-based consulting provided by the AOs. These limitations on fee-based consulting, as finalized, will prohibit the AOs that provide fee-based consulting from providing these services prior to the initial survey and during the 12 months prior to each reaccreditation survey. This means that the AOs can provide fee-based consulting to their clients that contract for this service during the first 24 months of the 36-month accreditation cycle.

Our restrictions on fee-based consulting, as finalized, will not prevent the AO's accreditation division from communicating with their accreditation clients at any time or interfere with the AOs accreditation activities. In fact, this proposal will not affect those AOs that do not provide fee-based consulting services, or educational events found to be consistent with fee-based consulting at all.

Final Decision: After consideration of the comments received, we have decided to finalize our proposal to place restrictions on fee-based consulting with a minor change to § 488.8(i)(1) to reference the definition "fee-based consulting services" as finalized at § 488.1. We are also modifying the provision as proposed by removing the sentence, "The provisions at paragraph (i) of this section will become applicable beginning [DATE 1 YEAR FROM THE EFFECTIVE DATE OF THE FINAL]." We are making this modification for this final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date of this final rule with comment period and individual provisions will no longer need to be specified in the regulatory text.

G. Require AOs To Provide CMS With Information About the Fee-Based Consulting They Provide (Proposed § 488.8(i)(5))

We proposed at § 488.8(i)(1), § 488.8(i)(2), and § 488.8(i)(3) to place restrictions on the fee-based consulting services provided by AOs. To enforce our proposals, we proposed at § 488.8(i)(5) to require the AOs that provide fee-based consulting services to submit information to CMS, on a calendar year bi-annual basis, about the fee-based consulting services they provide.

We proposed to add a requirement at § 488.8(i)(5) that would require the AOs that accredit Medicare-certified providers and suppliers to provide CMS

with information regarding the fee-based consulting services no later than 15 days after the end of each calendar year bi-annual (6-month) period.

More specifically, this proposal would require these AOs to submit a document which contains the following information to CMS:

- Whether the AO or an associated consulting division or company established by the AO provides fee-based consulting services.
- The names and CCN numbers of all healthcare providers and suppliers to which the AO or its associated consulting division or company has provided fee-based consulting services during the previous calendar year quarter.
- The dates the AO fee-based consulting services were provided to each provider and supplier listed.
- Whether the accrediting organization has, at any time in the past provided, or is currently providing accreditation services to each healthcare provider or supplier listed in said document, and if so, the date the accreditation services were provided.
- The date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed for each healthcare provider and supplier listed in said document.
- A description of the AO fee-based consulting services provided to each healthcare provider or supplier listed in said document.

We further proposed that the two bi-annual reporting periods would consist of January 1st to June 30th and July 1st to December 31st each year. The submission deadline for the first period would be July 15th each year. The submission deadline for the second period would be January 15th each year. This would ensure that AOs are not providing fee-based consulting services to providers and suppliers prior to an initial survey, within 12 months prior to a re-accreditation survey, or in response to a complaint received regarding an accredited provider or supplier. In addition, this information would also allow CMS to see the number of providers and suppliers to which the AOs are providing fee-based consulting services.

We proposed that these provisions would become applicable 1 year from the effective date of the final rule with comment period to allow for an appropriate time of transition. We believe that this would provide the AOs with ample time to prepare for and implement this requirement.

The comments and our responses to the comments are set forth below.

Comment: One commenter requested that CMS provide the rationale for requesting biannual detailed information about which provider organizations have or are receiving fee-based consulting services from the AO and what this information would be used for by CMS.

Response: In the proposed rule, we stated that the biannual submission of the information requirement would ensure that AOs are not providing fee-based consulting services to providers and suppliers prior to an initial survey, within 12 months prior to a re-accreditation survey, or in response to a complaint received regarding an accredited provider or supplier. (89 FR 12010). However, we appreciate the comments regarding the regulatory burden and usefulness to CMS of requiring AOs to submit this information twice a year and have decided not to finalize this part of the proposed requirements in this rule. Please see the further discussion of this in the final decision section.

Comment: One commenter requested clarification on whether the information requested is for deemed status provider organizations only.

Response: The final rule with comment period requires that an AO submit the names and CCN numbers of all healthcare providers and suppliers to which the AO or its associated consulting division or company has provided fee-based consulting services during the previous 6-month period to CMS, upon request and during each application review process.

Comment: One commenter suggested that CMS consider publicly reporting the fee-based consulting information reported in a database similar to the Open Payments program.

Response: We thank this commenter for their recommendation. We will take it under advisement.

Comment: One commenter stated the opinion that the requirements at § 488.8(i)(5) pose an excessive administrative burden to the AOs who do not facilitate these types of consultative services. One commenter stated that the requirement to have AOs report bi-annually about fee-based consulting is too frequent and too cost-burdensome and recommends that this be an annual requirement.

Response: We thank the commenter for their comments regarding the administrative burden of this proposed requirement, but we believe the burden associated with the requirements at § 488.8(i)(5) is justified.

Comment: Several commenters expressed support for the proposed requirement that AOs provide CMS with

information about the fee-based consulting services they provide on a bi-annual basis. One commenter stated that the information to be reported and submission timing for these reports is necessary to ensure that AOs are upholding the integrity of their oversight role in a manner worthy of public trust.

Response: We thank these commenters for their support of the requirement that AOs provide information to CMS about the fee-based consulting services they provide.

Comment: One commenter supported a healthcare provider's or supplier's choice to work with an AO to affirm compliance with Medicare CoPs. This commenter further stated that many of its members shared positive stories of how AOs helped them better understand their deficiencies and achieve robust compliance in follow up surveys through the provision of fee-based consulting. This commenter states the belief that the additional cost of fee-based consulting is well worth the extra support to improve quality and compliance to serve beneficiaries.

However, this commenter did acknowledge and agree with CMS' concerns that oversight of these entities has led to program integrity concerns. The commenter provided an example of one accrediting body that was allegedly responsible for accrediting nearly half of the fraudulent hospices accredited in California, Nevada, Arizona, and Texas in 2022. The growth of hospice across these four States raised alarms and initiated a nation-wide program integrity effort.

Response: We recognize the value of fee-based consulting services. None of our proposed restrictions would prevent providers and suppliers from seeking fee-based consulting from the AO that accredited them during the non-prohibited times. These proposed restrictions on fee-based consulting, if finalized, would not prohibit said providers and suppliers from seeking fee-based consulting from third party consultants at any time.

Comment: One commenter supported our proposal to require the AOs to report information about the fee-based consulting services provided for the following reasons:

- Requiring additional documentation as it relates to fee-based consulting services provided by AOs to accredited facilities helps mitigate conflicts of interest, promotes a fairer and more objective accreditation system, and ultimately contributes to better quality care and patient safety.
- Detailed documentation provides a clearer picture of the nature and extent

of consulting services offered by AOs to the facilities they accredit. This allows CMS to assess potential conflicts of interest more effectively.

- Paid consulting undermines the significance and integrity of accreditation, potentially leading to a focus on identifying errors to generate consultation work rather than supporting quality improvement in a collaborative, collegial environment.

- When all interested parties are committed to serving the public, the outcomes will be more robust.

- This proposal, if finalized, will ensure that the data collected through the process will be more consistent across all AOs serving CMS.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter expressed strong opposition to the amount of detailed information on an AO's fee-based consulting services which would be required by CMS.

Response: We note this commenter's opposition to this requirement. As we stated in the proposed rule, we made this proposal to ensure that AOs are not providing fee-based consulting services to providers and suppliers prior to an initial survey, within 12 months prior to a re-accreditation survey, or in response to a complaint received regarding an accredited provider or supplier. In addition, this information would also allow CMS to see the number of providers and suppliers to which the AOs are providing fee-based consulting services.

Comment: One commenter stated that CMS' proposal is contrary to the AO firewall policies and the agency's proposed minimum requirements for a firewall because the specific details to be reported to CMS would require the AO's accreditation and fee-based consulting divisions to routinely share information regarding when fee-based consulting occurred, the type of consulting that occurred, and when an accreditation survey occurred. This commenter opined that this is exactly the type of sharing that firewall policies are intended to prohibit.

Response: We proposed to require the AOs to submit information about the fee-based consulting they provide to CMS on a bi-annual basis. More specifically, we proposed to require these AOs to submit a document (as previously described) to CMS.

We believe that the AO's fee-based consulting division should already have the required information about fee-based consulting to be reported to CMS. For example, the AO's fee-based consulting division should already know whether they have provided any

fee-based consulting services during the previous 6-month period, the dates that the AO fee-based consulting services were provided, and a description of the AO fee-based consulting services provided. In addition, the AOs fee-based consulting division would be able to obtain the information about whether the AO has, in the past provided, or is currently providing accreditation services to each healthcare provider or supplier listed in said document, the CCN numbers for the providers and suppliers receiving AO fee-based consulting, the date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed directly from each provider and supplier that receives AO fee-based consulting.

CMS defines the term “firewall” as the complete and total separation between the AO’s accreditation activities and its fee-based consulting services. However, we believe that after a provider or supplier accredited by the AO voluntarily signs up for the AO’s fee-based consulting services, it would not violate the AO’s fee-based consulting firewall policy for the AO’s accreditation division to share the limited information necessary for the AO’s fee-based consulting division to complete the biannual report for CMS. We say this for several reasons.

First, we see little harm in the AO’s accreditation division of the AO providing some of the limited information that would be necessary for the biannual report, but that cannot be provided by its clients, to the AO’s fee-based consulting division. While this may reveal to the AO’s accreditation division the identity of some of its accredited providers and suppliers that have signed up for the AO’s fee-based consulting services, we believe this would be a rare occurrence. We say this because most of an AO’s fee-based consulting clients would be able to provide the information that the AO’s fee-based consulting division does not already have.

Second, if our proposal to require the AOs to submit information to CMS about the fee-based consulting they provide is finalized, the AOs will be mandated by the CMS regulations to send the required information to CMS. Therefore, it will be necessary for the AO’s fee-based consulting division to obtain the required information from their clients if the AO’s fee-based consulting division clients are not able to provide all of the required information for the report.

Comment: One commenter stated that the proposed Federal reporting requirements for AOs that provide fee-

based consulting, if finalized, would create an unfair market advantage for third-party consultants because they would be wary of any AO fee-based consulting because of Federal reporting requirements. This commenter also believes that providers and suppliers would opt for services from a third-party consultant that did not have a Federal reporting requirement, which could significantly limit the work of AO fee-based consulting divisions that have dedicated substantial resources to maximizing patient safety and care.

Response: We respectfully disagree with this commenter. This commenter alleges that our proposal to require that the AO provide information to CMS about the fee-based consulting it provides to CMS on a biannual basis would somehow create an unfair market advantage for third-party consultants. We do not see why there would be any reason for a provider or supplier accredited by an AO to select a third-party consultant instead of the fee-based consulting services provided by their AO simply because of the reporting requirements. We believe it is likely that providers and suppliers that decide to take part in fee-based consulting would choose the fee-based consulting services provided by their AO as opposed to those provided by a third party. As we stated in the proposed rule, “. . . providers and suppliers often choose AO fee-based consulting specifically for the additional resources and assistance provided. Some AOs publicly advertise the ability of their fee-based consulting to simulate what to expect from the actual AO survey. It is possible that Providers and suppliers found to be non-compliant by their AO may assume that the most direct path to compliance is to hire the AO’s fee-based consulting services. Such an assumption would provide AOs with fee-based consulting services with an unfair advantage over other, third-party consulting services”.

Comment: One commenter stated that while CMS did not intend to do so, the AO fee-based consulting reporting requirements would result in the unintended consequence of completely restricting AOs providing AO fee-based consulting services.

Response: This commenter is correct in their assumption that CMS did not intend to completely restrict an AO’s ability to provide fee-based consulting services to the providers and suppliers it accredits. While this commenter contends that the AO fee-based consulting reporting requirements would result in the unintended consequence of completely restricting AOs providing AO fee-based consulting services, they did not provide any

specific rationale for this contention. We respectfully disagree with this commenter’s contention. We do not understand how requiring an AO’s fee-based consulting division to provide information about the fee-based consulting it provides to CMS would affect the AO’s ability to provide fee-based consulting or restrict it completely.

Comment: One commenter recommends that CMS conduct a baseline assessment of each AO’s consulting services and, based on the outcome, require submission of the requested information.

Response: We thank this commenter for their recommendation. We will take it under advisement.

Comment: One commenter recommended that CMS develop a streamlined system and processes for submission of the requested information.

Response: When this reporting requirement begins, CMs will require the AOs to send the requested information via secure email. However, we will look into other, more streamlined ways to collect this information.

Comment: One commenter suggested that if CMS finalizes the fee-based consulting proposal as proposed, that a grandfather clause be added that would: (1) make any existing contract the AOs already had for the provision of fee-based consulting services exempt from the requirements; and (2) make the requirements applicable only to all new contracts that the AOs enter into for the provision of fee-based consulting services the AOs enter into after the date the requirements become effective. This would allow the AOs to satisfy contractual obligations for fee-based consulting that they entered into prior to the effective date of the requirements.

Many fee-based consulting services contracts are for several years. Also, fee-based consulting contracts frequently include nondisclosure obligations, which must be maintained under the existing fee-based consulting contracts. The proposed effective date for the prohibitions on fee-based consulting 1 year after the rule is finalized would not be enough time to complete the AO consulting division’s contractual obligations.

Response: We thank this commenter for their suggestion. We acknowledge that some AOs may have existing contracts for fee-based services when the requirements of this final rule with comment period become effective 1 year after its publication. However, AOs must still meet all requirements in this rule, including the fee-based consulting

requirements, once the rule becomes effective, even if this requires an AO to revise the terms of any existing contract to comply with these regulations.

Comment: One commenter stated that the AO would be required to provide documentation regarding its consulting activities and customers to CMS on a biannual basis, which would force the two separate divisions (accreditation and education) to share provider information internally, which CMS has prohibited. In addition, the commenter stated that the biannual report would be seeking unobtainable information, that is, it requires the names and CMS Certification Numbers (CCNs) of all providers that receive fee-based consulting or general education from the accrediting organization. The commenter further stated that many attendees at workshops are individuals interested in understanding what accreditation is about, independent of any established provider or supplier, they may not have CCNs for a facility at the time they attend one of the AO's workshops.

Response: We respectfully disagree with the premise of the commenter that the names and CCNs of the providers and suppliers to which the AO has provided fee-based consulting services are "unobtainable." For Medicare certified facilities, this information is made publicly available by CMS and can be easily obtained by the AO using the name of the facility (see <https://data.cms.gov/search>). The requirements in this final rule with comment period are clear that the AO must submit the names and CCNs of those facilities to which it has provided fee-based consulting services as defined in this rule at § 488.1. The requirement would not apply to individuals attending AO workshops or otherwise obtaining general education from the AO about its programs; such activities do not meet the definition of "fee-based consulting services" finalized in this rule.

In response to the commenter's reference to our proposed requirement for AOs to submit this information on a biannual basis, we also note that we have withdrawn our proposal to require biannual reporting of the documentation that was proposed at § 488.8(i)(5) so that such information, and firewall policies and procedures only need be submitted upon request by CMS and at the time of application or re-application for approval of their Medicare accreditation programs.

Final Decision: After consideration of the comments received, we have decided to finalize our proposal at § 488.8(i)(5) to require the AOs collect information about the consulting

information they provide with a modification to the proposed regulations text. Based on the comments, we are not finalizing our proposal to require AOs submit these reports to CMS on a biannual basis. We will instead require the AOs to submit the consulting information for CMS to review upon request and for review during each application review process.

We are also modifying the provision as proposed by removing the sentence, "The provisions at paragraph (i) of this section will become applicable beginning [DATE 1 YEAR FROM THE EFFECTIVE DATE OF THE FINAL]." We are making this modification for this final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date of this final rule with comment period and individual provisions will no longer need to be specified in the regulatory text.

H. Actions Against AOs Found To Be Providing AO Fee-Based Consulting Services to the Healthcare Providers or Suppliers They Accredit in Violation of the Restrictions in § 488.5(i)(1) Through § 488.5(i)(3) (Proposed § 488.8(i)(6))

We proposed to implement regulations that place restrictions on the fee-based consulting services AOs provide to the healthcare providers and suppliers that they accredit. To enforce these regulations, we proposed at § 488.8(i)(6) to implement actions for the violation of the restrictions on AO fee-based consulting.

We proposed at § 488.8(i)(6)(i) that if an AO is found to be in violation of the restrictions set forth in paragraphs § 488.8(i)(1), (2) and (3), CMS may penalize the AO. These remedies were set forth in proposed § 488.8(i)(6)(i) and § 488.8(i)(6)(ii) and include placing the AO on a program review, and involuntary termination of the CMS-approved AO's accreditation program(s).

Whether or not we impose the remedies provided in § 488.8(i)(6)(i) and (ii) would depend on the severity of the violation and the facts and circumstances surrounding the violation. Such facts might include the number of providers and suppliers that contracted for prohibited AO fee-based consulting services, the number of times the AO violated the restrictions of § 488.8(i), or other facts.

The purpose of these proposed provisions was to discourage AOs from violating the proposed restrictions on the provision of fee-based consulting to the providers and suppliers they accredit.

We proposed that these provisions would become applicable 1 year from the effective date of the final rule with comment period. We believe that this would provide ample time for the AOs to prepare for the implementation of the requirements of this rule.

The comments and our responses to the comments are set forth below.

Comment: One commenter stated that they are supportive of the proposal for actions against AOs found to be in violation of the restrictions on fee-based consulting and urge its adoption.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter supported our proposal for actions against AOs that are found to be providing fee-based consulting services to the providers and suppliers it accredits in violation of the restrictions. This commenter supports this proposal for the following reasons:

- This proposal is essential for upholding public trust and ensuring the integrity of the accreditation process.
- Penalties for violations must be stringent, substantial, and enduring, given the critical nature of maintaining public confidence.
- The fundamental concept of fee-based consultancy is incompatible with the mission of accrediting bodies, as it creates a conflict of interest and fosters the perception that accreditation can be bought rather than earned through adherence to quality standards.
- Moreover, relying on fee-for-service arrangements diminishes the incentive for continuous improvement within healthcare facilities, as they may simply pay consultants to meet accreditation requirements rather than genuinely striving to enhance their practices.
- Accreditation should serve as an ongoing process driving improvement, rather than a one-time hurdle to overcome.

Response: We thank this commenter for their support of this proposal.

Final Decision: We are finalizing the requirements here as proposed.

I. Require Accrediting Organizations To Have Written Fee-Based Consulting Firewall Policies and Procedures (§ 488.8(j))

We proposed at § 488.8(j) to require any AO that provides fee-based consulting services or its associated fee-based consulting division or company to have written fee-based consulting "firewall" policies and procedures. We defined the terms "consulting division" and "associated company" in section IX.B.3. of the proposed rule. We defined the term "firewall" as the complete and total separation between the AO's

accreditation activities and its fee-based consulting services.

We proposed that these firewall policies and procedures must, at a minimum, include the following provisions: at paragraph (j)(1)(i) the AO's fee-based consulting services must be provided by a separate division of the AO or separate business entity (that is company or corporation) from the AO; at paragraph (j)(1)(ii) the AO's fee-based consulting division or separate company must maintain separate staff from that of the AO's accreditation division(s) to ensure that the fee-based consulting division staff do not perform AO's accreditation division functions and that the AO's accreditation division staff do not perform fee-based consulting division functions; and at paragraph (j)(1)(iii), the AO's accreditation staff and surveyors would be prohibited from marketing the AO's fee-based consulting services to the AO's accreditation clients.

The purpose of the provisions of proposed § 488.8(j) is to ensure that the AO maintains a complete division between their fee-based consulting program and their accreditation program. In other words, we sought to require an AO prevent any co-mingling of its fee-based consulting activities and staff with its accreditation activities and staff. We believe these requirements are necessary because several commenters to our 2018 AO Conflict-of-Interest RFI voiced concern that, even though some AOs have such firewall policies in place, the firewalls have still been breached. For example, one commenter stated that one AO's accreditation staff aggressively marketed that AO's fee-based consulting services to his healthcare facility. In addition, during a CMS validation pilot joint survey with an AO, a SA surveyor witnessed the AO's surveyors providing detailed education about the survey process to the healthcare facility staff prior to the start of the survey. This is inappropriate because surveys are to be unannounced to prevent the facility from preparing for the survey. At the beginning of a survey, a brief entrance conference is held for the purpose of introducing the survey team, providing the survey agenda to the facility staff, and telling the facility what records the surveyors will be reviewing during the survey. However, providing detailed information about the survey process and what areas the AO is going to focus on during the survey could give the facility an advantage and time to prepare for the survey. In addition, providing such education to a healthcare facility prior to a survey could assist that facility in getting a better survey report.

We do not currently have any regulations that provide oversight of the fee-based consulting services provided by AOs or their separate divisions or companies. Likewise, we do not currently have any regulations that specifically require AOs that provide fee-based consulting services to have written firewall policies or regulations that provide requirements for such policies. Regulations are needed so that CMS may ensure that an AO's fee-based consulting remains separate from an AO's accreditation activities. This division is necessary to reduce the conflict of interest associated with the provision of AO fee-based consulting services.

The comments and our responses to the comments are set forth below.

Comment: One commenter supported this proposal and urged its adoption.

Response: We thank this commenter for their support of our proposal to require AOs to have written fee-based consulting firewall policies and procedures.

Comment: One commenter stated long time support for additional requirements that would formalize AO "firewall" policies between AOs and their fee-based consulting entities.

Response: We thank this commenter for their support of our proposal to require the AOs to have written fee-based consulting firewall policies and procedures.

Comment: One commenter supports the proposal to require AOs that have written "firewall" policies & procedures that provide for complete separation ("firewall") between the AO's accreditation activities and fee-based consulting services.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter opined that "blockading the muddying of the AO accreditation role with the motivations of a fee-based consultancy is necessary to sustain the integrity of the AO regulatory oversight role."

Response: We agree with this commenter that allowing an AO to combine their accreditation and fee-based consulting activities "muddies" the integrity of the accreditation process. We further agree that the proposed requirement that AOs have and strictly enforce robust firewall policies and procedures to ensure that the AO's accreditation and fee-based consulting divisions remain completely separate is necessary to maintain the integrity of the accreditation process.

Comment: One commenter supported the proposed minimum requirements for these written policies and procedures, including the requirement

that fee-based consulting services be provided by a separate division or business entity from the AO, as being necessary to enforce compliance with the proposed restrictions on co-mingling of AO staff engaged in fee-based consulting activities with AO staff engaged in accreditation activities.

Response: We thank this commenter for their support of the proposed minimum requirement for the AO's written fee-based consulting firewall policies and procedures.

Comment: One commenter stated strong support for the proposal to require AOs that provide fee-based consulting to have written firewall policies and procedures for fee-based consulting. This commenter further opined that ensuring the integrity of the accreditation process is of the utmost importance.

Response: We thank this commenter for support of our proposal to require the AOs that provide fee-based consulting to have written firewall policies and procedures for fee-based consulting.

Comment: One commenter supported our proposal to require an AO submit a declaration from each surveyor disclosing any interests or relationships the surveyor may have in or with another survey agency or healthcare facility the AO accredits.

Response: We thank this commenter for their support of the stated proposal.

Comment: One commenter stated that AOs currently have robust firewall policies in place that contain provisions such as: (1) the entity providing consulting services is distinct from the entity providing accreditation services; and (2) the staff providing consulting services are separate from the survey and accreditation staff, ensuring that there is no conflict or interaction between the two teams.

This commenter further supported our proposed requirement for AOs to have AO fee-based consulting policies & procedures and minimum requirements for these policies and procedures. This commenter further stated that CMS' proposals on reporting would provide more transparency on these firewall policies.

Response: We thank this commenter for their support of our proposed minimum requirements for the AO fee-based consulting requirements.

Comment: One commenter supported our proposal to require the AOs that provide fee-based consulting to have written fee-based consulting firewall policies and procedures, for the following reasons:

- Firewall safety options are crucial for ensuring the integrity and impartiality of the accreditation process.

- By establishing a clear firewall between fee-based consulting services and accreditation activities, accrediting bodies can mitigate the risk of conflicts of interest and perceptions of bias.

- This separation helps maintain public trust by ensuring that accreditation decisions are based solely on the adherence to quality standards, rather than influenced by financial relationships.

- Explicit firewall safety options provide a structured framework for AOs to uphold transparency and accountability, ultimately safeguarding the credibility of the accreditation system and the facilities it accredits.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter opined that it would only be possible for fee-based consulting firewalls to prevent conflicts of interest if they were clearly defined and well supported by the AO. Another commenter opined that it was possible for firewalls to address AO conflicts of interest but stressed they would need to be clearly defined and well supported by the AO.

Response: We thank the commenters for their comments. We agree that using appropriate and robust firewalls can help reduce the conflicts of interest associated with fee-based consulting. That is why we proposed to establish a regulation at 42 CFR 488.8(j) that requires an AO to have written fee-based consulting firewall policies and procedures. We would add that the firewall policies must also provide for complete separation between the AO's accreditation and fee-based consulting divisions and activities, including separate governance, separate staff, and separate resources. Also, the fee-based consulting firewall policies and procedures must be strictly enforced by the AO.

Comment: One commenter stated that the requirement for consulting services to be provided by separate staff is too onerous particularly for small AOs, but also for AOs that provide very specialized surveys. The commenter recommended that this restriction not be implemented, but rather an informational firewall of consulting services be established. They stated that, in other words, when a surveyor provides a survey, he/she must not be aware of any consulting services which may have been provided to the client by any other surveyor or corporate department of the AO. They also stated that AO staff should be allowed the operational flexibility to co-mingle staff

to provide consulting services or AO survey services, provided that there is no knowledge by any accreditation surveyor that consulting services were provided or what the outcome or result of such services were. The AO surveyor could provide an attestation that he/she is not aware of consulting services.

Response: The separation of an AO's accreditation services and fee-based consulting services is an absolute requirement of an AO fee-based consulting firewall policy. The separation of the two divisions necessarily requires that they each maintain separate staff, governance, policies and procedures, etc.

Even the AOs that provide fee-based consulting acknowledge the need for such separation. They already have AO fee-based consulting firewall policies and procedures that provide for complete separation of their accreditation and fee-based consulting divisions and staff.

Comment: One commenter stated that the proposed rule would prohibit the AO from marketing the AO's fee-based consulting services to the AO's accreditation clients. Tools, resources, and services are provided to the public through general email distributions and publications available on the AO's website. It would not be practical to create an educational division and not alert providers to its existence.

Response: We respectfully disagree with many of the premises of the commenters. In the proposed rule, we proposed that the AOs that provide fee-based consulting services or its associated fee-based consulting division or company must have written fee-based consulting "firewall" policies and procedures. We defined the term "firewall" as the complete and total separation between the AO's accreditation activities and its fee-based consulting services. The purpose of the provisions of proposed § 488.8(j) is to ensure that the AO maintains a complete division between their fee-based consulting program and their accreditation program. In other words, we seek to require AOs prevent any comingling of fee-based consulting activities and staff with their accreditation activities and staff. Development of a joint firewall policy would not be a breach of that policy.

We believe these requirements are necessary because several commenters on our 2018 AO Conflict-of-Interest RFI, as previously discussed, were concerned that firewalls in some instances could be breached. An AO's fee-based consulting division or company could find other ways to market their services to the AO's

accreditation clients without approaching them during surveys and accreditation activities.

Final Decision: After careful consideration of the comments received, we are finalizing this provision with a technical revision to § 488.8(j)(2) to include a cross-reference to the requirement at § 488.5(a)(10) to clarify that the date specified for an AO to submit its written consulting firewall policies and procedures to CMS will be the application deadline (as well as possible other dates as specified by CMS as part of the application process).

J. Prohibit AO Owners, Surveyors, and Other Employees From Involvement With the Survey and Accreditation Process for Healthcare Facilities With Which They Have an Interest or Relationship (Proposed § 488.8(k))

We proposed to add a new requirement at § 488.8(k)(1) to prohibit AOs from allowing AO owners, surveyors, or other employees from participating in the survey and accreditation process for healthcare facilities with which they have had an interest or relationship within the previous 2 years. At proposed § 488.8(k)(1) we would require that if an AO owner, surveyor or other employee has an interest in or relationship with a healthcare facility accredited by the AO, they would be prohibited from: (1) participating in the survey of that healthcare facility (proposed § 488.8(k)(1)(i)); (2) having input into the results of the survey and accreditation for that healthcare facility (proposed § 488.8(k)(1)(ii)); (3) having involvement with the pre- or post-survey activities for that healthcare facility (proposed § 488.8(k)(1)(iii)); or (4) having contact with or access to the records for the survey and accreditation of that healthcare facility (proposed § 488.8(k)(iv)). Proposed § 488.5(a)(10)(iii) lists proposed prohibited interests in or relationships with a healthcare facility accredited by the AO, which we discussed in section IV.D. of this final rule with comment period.

We proposed at § 488.8(k)(2) to define the term "immediate family member" as any person that has a lineal familial or marital relationship with the AO owner, surveyor or other employee. Immediate family members would include a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. This definition is consistent

with the definition used for the home health and hospice conflict-of-interest requirements. This definition is required for the purposes of § 488.8(k)(1), which states that a conflict of interest can also exist when an AO owner, surveyor or other employee has an interest in or relationship with a healthcare facility the AO accredits.

Allowing an AO owner, surveyor or other employee that has an interest in or relationship with a healthcare facility the AO accredits would not only be inappropriate but could result in inaccurate survey results and/or preferential treatment of the facility.

The comments and our responses to the comments are set forth below.

Comment: Several commenters (2) supported the proposal to prohibit AO owners, surveyors, and other employees from involvement with the survey and accreditation process for healthcare facilities with which they have an interest or relationship requirements of proposed changes. This commenter stated that it would be reasonable to apply these policies to executives and other leaders in AOs.

Response: We thank these commenters for their support of this proposal.

Comment: One commenter supported our proposal to prohibit an AO owner, surveyor or other employees from having any involvement with the survey of any healthcare facilities with which the AO owner, surveyor, other employee or their immediate family members currently or within the past 2 years have had a relationship.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter supported prohibiting AO owners, surveyors, and other employees from engaging in the survey and accreditation process for organizations in which they have an interest or relationship.

Response: We thank this commenter for their support of our proposal to prohibit AO owners, surveyors, and other employees from engaging in the survey and accreditation process for organizations in which they have an interest or relationship.

Comment: One commenter supported defining the specific familial relationships listed in the proposed rule as creating a conflict of interest.

Response: We thank this commenter for support of our proposed list of applicable “immediate family members” at § 488.5(a)(10)(iii)(I) whose relationships represent a conflict of interest on the part of a family member who is an AO owner, surveyor or other AO employee.

Comment: One commenter supported our provision to prohibit an AO owner, surveyor, or other employee from engaging in the accreditation processes for an organization with which they have had past relationship or interest for 2 years.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter opined that numerous conflicts of interest could emerge without this proposed provision, and that such conflicts of interest are capable of seriously undermining the integrity of the AO accreditation process. This commenter stated the opinion that permitting a slackening of standards compromises the public trust.

Response: We thank this commenter for their comments and agree.

Comment: One commenter supported this proposal because they already have policies that prohibits their surveyors, or other employees from participating in the survey and accreditation process for healthcare facilities with which they have had an interest or relationship within the previous 3 years. This commenter noted that is an even longer period than proposed by CMS.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter supported our proposal to require AOs submit a declaration from each surveyor disclosing any interests or relationships the surveyor may have in or with another survey agency or healthcare facility that the AO accredits.

Response: We thank this commenter for support of this proposal.

Comment: One commenter supported our proposal to require AOs to take steps to prevent an owner or employee with an interest in or relationship with a healthcare facility that the AO accredits, within the previous 2 years, from having any involvement with the survey of that facility, having input into the results of the survey and accreditation for the facility, having involvement with the pre- and post-survey activities for the facility or having contact with or access to the records for the survey of the healthcare facility.

Response: We thank this commenter for support of this proposal.

Comment: One commenter supported our proposal to require AOs to collect and submit declarations from surveyors regarding any employment, business, financial, or other relationships they have with the healthcare facilities the AO accredits, aimed at enhancing transparency and trust in the accreditation process.

Response: We thank this commenter for their support of our proposal at

§ 488.5(a)(22) to require AOs to obtain and submit surveyor declarations of any interest in and relationships with healthcare providers the AO accredits to CMS on an annual basis.

Comment: This commenter opined that this requirement would lead to greater transparency in the accreditation process, building trust among interested parties by demonstrating vigilance in preventing conflicts of interest because the COI declarations process seeks to identify and mitigate any potential conflicts of interest that could bias the survey outcomes.

Response: We thank this commenter for their support of our proposal at § 488.5(a)(22) to require AOs to obtain and submit surveyor declarations of any interest in and relationships with healthcare providers the AO accredits to CMS on an annual basis.

Comment: One commenter agreed that it would be inappropriate for an AO owner, surveyor, or employee who has an affiliation or interest with a healthcare facility accredited by that AO to participate in the survey and accreditation process for that facility. This commenter urged CMS to hold SAs to the same standard.

Response: We thank this commenter for their support of this proposal. As we have stated in this final rule with comment period, and in response to the comment urging CMS to apply the same conflict-of-interest requirements to SAs, we do not believe that additional Federal conflict-of-interest requirements are necessary for SAs as they are for AOs because individual State laws, rules, and regulations regarding conflicts of interest already apply to each SA and its employees. Section 4008 of the SOM describes examples of scenarios that would be conflicts of interest for SA surveyors who have an outside relationship with a facility that is surveyed by the SA.¹⁰ Currently, section 4008 of the SOM applies only to SA surveyors and not AO surveyors.

Comment: One commenter urged CMS to prohibit AO owners, surveyors, and other employees—including their immediate family members who have an interest in or relationship with a surveyed healthcare facility from having direct or indirect input into survey results. This commenter further suggested that this prohibition apply to pre- or post-survey activities and a ban on access to all survey records.

Response: We thank this commenter for their support of the proposals we

¹⁰ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c04pdf.pdf>.

have made to prevent these types of AO conflicts of interest.

Comment: One commenter supported our proposal to prohibit AO owners, surveyors, and other employees from involvement with the survey and accreditation process for healthcare facilities with which they have an interest or relationship. This commenter stated that they support this proposal for the following reasons:

- This proposal is essential for maintaining the integrity and impartiality of the accreditation process.

- Allowing individuals with such connections to participate in accreditation activities not only creates a conflict of interest but also undermines the perception of fair and objective assessment of quality standards.

- It opens the door to potential inaccuracies in survey results and the risk of preferential treatment toward affiliated facilities if AO owners, surveyor or other employees that have an interest in or relationship with a healthcare facility accredited by the AO are permitted to have any involvement with the survey process for that facility.

- To uphold the credibility of accreditation and ensure the public's trust, it's imperative to enforce strict measures that prevent any undue influence or bias in the accreditation process.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter stated that the business model of using part-time reviewers (surveyors) could increase the likelihood of a conflict of interest and increase variation in the accreditation process.

Response: We thank this commenter for their comments. We agree that part-time surveyors may be more likely to be employed by healthcare facilities that are accredited by the AO.

Comment: One commenter stated that there are several steps an AO could take to help reduce the number of conflicts of interest for AO staff and surveyors. These steps include: (1) Hiring full-time surveyors who are sent to many geographic locations could result in fewer entanglements because they would not be hiring from the specific community where the reviews must be done; and (2) Not allowing AO employee surveyors to engage in outside consultant work.

Response: We thank this commenter for sharing this information.

Comment: One commenter stated that organizational investments in people and processes, such as providing ongoing training, interrater reliability assessments, and professional

development from within their organization, drive out avoidable variation during an accreditation.

Response: We thank this commenter for their comment. We agree that if an AO employee receives the professional development and training necessary to further their professional career, they may be less likely to seek secondary employment at a healthcare facility that can provide these benefits.

Comment: One commenter acknowledged that certain types of relationships could result in perceived or actual conflicts of interest. However, this commenter stated that health systems are large organizations and there are bound to be scenarios where AO staff or a family member would have some type of relationship with the healthcare system.

This commenter stated that the proposed definition of "immediate family member" is broad and includes not only the AO owners, surveyors or employees, but also their family members (89 FR 12063). The commenter recommended that, if CMS decided to proceed with its proposal, the agency should narrow the scope of this provision by limiting the categories of individuals who would fall under this conflict-of-interest provision, as well as the types of financial or other relationships that would result in a conflict.

Response: We used the definition of "immediate family member" set forth in the CY 2022 Home Health Prospective Payment System Rate Update (86 FR 62368). While this definition may be the same or similar to other rules for other subject matter, this does not make it inappropriate for use in the acute healthcare setting.

This issue of immediate family members arose because, at § 488.5(a)(10)(iii)(I), we proposed that AOs provide policies and procedures for the prevention and handling of potential or actual conflicts of interest that could arise from situations in which an AO owner, surveyor, or other employee has a business, employment or financial interest in or relationship with another survey agency or healthcare facility to which the AO provides accreditation services. This requirement made it necessary for us to provide examples of such situations. At proposed § 488.5(a)(10)(iii), we specifically noted that a conflict of interest would occur if the AO surveyor's immediate family (other than a non-managerial employee of a health facility accredited by the AO) engaged in any of the stated activities (89 FR 12005).

Allowing an AO owner, surveyor or other employee that has an interest in or

relationship with or that has an immediate family member (as defined by proposed § 488.5(a)(10)(iii)) employed by or has an interest in or relationship with a healthcare facility that is accredited by the AO would not only be inappropriate but could result in inaccurate survey results and/or preferential treatment of the facility. We say this because if an AO owner, surveyor or other employee has a family member employed at a healthcare facility that is accredited by the AO, that AO owner, surveyor or other employee may have a bias towards or against that facility which could have an effect on the survey results.

As we stated in the proposed rule, an AO surveyor, owner, or other employees' or their immediate family member's interest in or relationship with a healthcare facility that the AO accredits could present a conflict of interest that could affect the results of a survey in several ways. For example, an AO owner, surveyor, or other AO employee involved in the survey of a healthcare facility with which the individual has an interest or relationship could have compromised judgment, consciously or unconsciously, regarding that facility.

For example, a surveyor with an interest in or relationship with the healthcare facility being surveyed could be inclined to minimize or ignore deficiencies, possibly because he or she believes these deficiencies are not representative of the facility. A surveyor who has an interest in or relationship with the facility being surveyed could possibly influence the findings made by other members of the survey team by asking them to give the facility credit for things not observed, since he or she can "vouch" for the facility.

Comment: One commenter stated that the proposed restriction of not allowing AO owners, surveyors or other employees that have immediate family engaged in any of the stated activities, other than being a non-managerial employee of a health facility that is accredited by the AO be involved with the survey and accreditation decision making process for that facility is too restrictive.

Response: We respectfully disagree with this commenter. The scenario in which an AO owner, surveyor or other employee has an immediate family employed at a facility accredited by the AO is a clear conflict of interest because the AO surveyor could have a reason to be biased for or against the facility. Also, the family member employed at the healthcare facility could provide the surveyor with information about the facility that may not be otherwise

available to him or her during the survey process that could affect the outcome of the survey.

We believe that the benefits of prohibiting an AO owner, surveyor, or other employee from having any involvement with the survey process for a healthcare facility in which an immediate family member is employed, and thus removing a conflict-of-interest, far outweighs any inconvenience to the AO. In addition, we believe that the AOs are willing to prevent conflicts of interest.

We do not believe that having to prohibit an AO owner, surveyor, or other employee from having any involvement with the survey process for a facility at which an immediate family member is employed would be burdensome to the AOs. The AO could simply replace the conflicted surveyor with one that did not have any relationship or interest in the healthcare facility being surveyed. Moreover, we would not expect this kind of conflict-of-interest scenario to be a frequent occurrence.

Comment: One commenter stated that this proposed restriction could prohibit family members from participating in any activities with each other such as program decision-making or outcome reviews that would involve both parties. Therefore, employment in either organization itself would not necessarily reflect a conflict-of-interest.

Response: While we are not clear as to what the commenter means by “prohibit family members from participating in any activities with each other such as program decision-making or outcome reviews” [emphasis added], we disagree with this commenter if they mean that by participating with each other in program decision-making or outcome reviews, an AO owner, surveyor, or other employee has involvement with the survey and accreditation decision-making process for a healthcare facility in which an immediate family member is employed by the accredited facility and participates in the survey process for the facility, including the requisite interactions between the healthcare facility and the AO during this process. The purpose of this proposed restriction is to prevent both the facility and the AO from either consciously or unconsciously exploiting their interest in or relationship with such provider or supplier to bias the result of a survey. This restriction, as finalized, will only prohibit the AO owner, surveyor, or employee from involvement from the survey and accreditation decision-making process for that facility at which their immediate family member is

employed, and which gives rise to an interest or relationship with that facility on the part of that AO owner, surveyor, or employee. The family member employed at the facility would not be restricted from performing the duties of their employment, unless they are required to participate in the survey process. The immediate family member facility employee would only be required to recuse themselves from any involvement with the survey process.

We do not anticipate a scenario in which an AO surveyor would be working with an immediate family member who is an employee of a healthcare facility that is being accredited by the AO, unless that AO surveyor was also employed at such healthcare facility. In such a case, this AO surveyor would have a direct interest in and relationship in the healthcare facility accredited by the AO that would disqualify them from involvement with the survey and accreditation decision making processes for that facility.

It is important to note that requirements of § 488.8(k) would not prohibit AO employees from working with the appropriate employees at a healthcare facility for the purposes of the pre-survey accreditation process and fee-based consulting (with the restrictions set forth as § 488.8(i).

Comment: One commenter recommended that CMS qualify the definition of “immediate family member” at § 488.5(a)(10)(iii)(I) to limit it to an immediate family member employed by an AO who works in a position to make decisions or influence a survey outcome; only those individuals should be required to abstain from any accreditation activity. Another commenter proposed that the definition of “immediate family member” at § 488.5(a)(10)(iii) should pertain only to an immediate family member employed by an AO who works in a position to make decisions or influence a survey outcome should abstain from any accreditation activity for a provider organization that is accredited by the AO and has an immediate family member in its employment. Qualifying the circumstances for immediate family members is in line with standard Federal conflict-of-interest practice. This commenter stated that when an AO owner, surveyor, or other employee has an immediate family member that is employed at a healthcare facility that is accredited by the AO, only those AO employees that work in a position to make decisions or influence a survey outcome should abstain from any involvement in the survey and

accreditation process for that particular facility.

Response: This commenter requested that CMS limit the AO staff that would be prohibited from having involvement with the survey process to only those who work in a position to make decisions or influence a survey outcome. We do not believe that limiting this requirement to only those AO staff that work in a position to officially make decisions or influence a survey outcome would be restrictive enough to mitigate the conflict of interest associated with having a family member employed by a healthcare facility accredited by the AO. We say this because while only some of the AO staff officially make accreditation decisions, others have the potential to influence or alter these decisions.

The scenario in which an AO owner, surveyor or other employee has an immediate family employed at a facility accredited by the AO is a clear conflict of interest because the AO employee could have a reason to be biased for or against the facility, regardless of whether their job is to make accreditation decisions or not. For example, the family member of a surveyor who is employed at the healthcare facility could provide the surveyor with information about the facility that may not be otherwise available to the surveyor during the survey process that could affect the outcome of the survey. Also, an AO employee that does not make survey decisions and that has an immediate family member that works for the facility that is being surveyed could attempt to influence the survey outcome by: (1) discussing the facility with the survey team (that is, explaining the facility’s policies and procedures to the survey team); (2) actively advocating on the facility’s behalf. In addition, an AO secretary, who has a family member employed at a healthcare facility that was surveyed by the AO could potentially alter the survey report to make it better and hide deficiencies. Such activities could potentially influence the survey results and/or post-survey decision making process. Section 488.8(k) provides that any AO employee, including the AO owner, surveyors or other AO employee, who has a relationship with or interest in or has an immediate family member that is employed by a healthcare facility accredited by the AO would be prohibited from any involvement in the survey and accreditation process for that facility.

We believe that it is necessary to apply the requirements of § 488.8(k) for several reasons. As we stated in the

proposed rule, surveyors must rely on their professional judgment, in addition to Federal rules and guidelines, to determine compliance. As previously discussed, an AO surveyor, owner, or other employees' interest in or relationship with a healthcare facility that the AO accredits could present a conflict of interest that could affect the results of a survey in several ways. Even if the AO employee with the interest in or relationship with the facility being surveyed is not part of the survey team for the facility, he or she could still potentially influence the members of the survey team prior to or after the survey. For example, attempting to influence the survey decision making process, or the AO's survey follow-up activities by attempting to discuss the facility with the survey team, such as explaining the facility's policies and procedures to the survey team, or even actively advocating on the facility's behalf, potentially influencing their analysis of observed survey results. An AO surveyor, owner, or other employee that has an interest in or relationship with a healthcare facility the AO accredits might have additional motivation to improperly give that healthcare facility notice about the survey ahead of the scheduled survey date. Surveys are required to be unannounced to prevent the facility from preparing for the survey by activities such as unusual cleaning activities, painting, clearing obstructions from halls and entrances, covering up and hiding deficiencies, coaching staff, and otherwise preparing in advance for the survey. If the survey is unannounced, the healthcare facility is not able to make advance preparations so that the survey team is able to assess the facility in its usual condition and observe the typical standard of care provided.

Comment: One commenter recommended that time restrictions for individuals with interests in or relationships with healthcare facilities accredited by the AO to participate in the survey or accreditation process for those facilities be limited to the prior 1 year (not 2 years).

Response: In the proposed rule, we proposed to prohibit an AO owner, surveyor, or other employee that has an interest in or relationship with a healthcare facility that AO accredits within the past 2 years from having any involvement in the survey process for that healthcare facility. We proposed a 2-year time-period for the interest in or relationship with a healthcare facility accredited by the AO to be consistent with other rules we have finalized. We believe it is best to have the same requirements across all healthcare

settings. Therefore, we will not be following this commenter's recommendation.

Final Decision: After careful consideration of the comments received in response to this proposal, we have decided to finalize these provisions as proposed, except for § 488.2(k)(2), which we are finalizing with a minor change to conform with the language proposed at § 488.5(a)(10)(iii)(I) for the reasons explained previously.

As finalized, § 488.8(k)(1) will require AOs that have an owners, surveyors or other employees who has an interest in or relationship with a healthcare facility accredited by the AO to prohibit said owners, surveyors, and other employees from engaging in the following activities related to the healthcare facilities with which they have a relationship or interest:

- (1) Participating in the survey of that healthcare facility (§ 488.8(k)(1)(i));
- (2) Having input into the results of the survey and accreditation for that healthcare facility (§ 488.8(k)(1)(ii));
- (3) Having involvement with the pre- or postsurvey activities for that healthcare facility (§ 488.8(k)(1)(iii)); or
- (4) Having contact with or access to the records for the survey and accreditation of that healthcare facility (§ 488.8(k)(iv)).

As finalized, § 488.5(a)(10)(iii) would define such relationships with or interests in healthcare facilities accredited by the AO as including but not be limited to:

- (1) Being employed as a SA surveyor;
- (2) Being employed in a healthcare facility that is accredited by the AO;
- (3) Having an ownership interest in a healthcare facility that is accredited by the AO;
- (4) Serving as a director of or trustee for the AO;
- (5) Serving on a utilization review committee of a healthcare facility that is accredited by the AO;
- (6) Accepting any fees or payments from a healthcare facility or group of healthcare facilities that is/are accredited by the AO;
- (7) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a healthcare facility that is accredited by the AO;
- (8) Providing consulting services to a healthcare facility that the AO accredits;
- (9) Having an immediate family member engaged in any of the listed activities; or
- (10) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

As finalized, § 488.8(k)(2) conforms with the definition at

§ 488.5(a)(10)(iii)(I) and defines the term "immediate family member" as any person with which the accrediting organization owner(s), surveyors or other employees have a lineal or immediate familial or marital relationship, including a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. This definition is consistent with the definition used for the home health and hospice conflict-of-interest requirements.

K. Require the AOS that Accredited Medicare-Certified Providers and Suppliers To Use Medicare Conditions; and Strengthened Survey Process Comparability (Proposed § 488.4(a)(1) and (2))

Section 1865(a)(1) of the Act requires that if the Secretary finds that the requirements for accreditation from an accreditation organization demonstrate that a provider entity meets or exceeds all applicable conditions, the Secretary must deem such requirements to be met by the provider entity. The statutory language of "meets or exceeds" currently allows AOs to develop standards that are more stringent than those of Medicare. When an AO applies for "deeming authority," we determine whether those standards meet or exceed ours. In accordance with § 488.5(e), CMS publishes a proposed notice when CMS receives a complete application from a national accrediting organization seeking CMS' approval of an accreditation program. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS. CMS subsequently publishes a final notice, rendering its decision to either approve or disapprove a national accrediting organization's application, within 210 calendar days from the date CMS determines the AO's application was complete. The final notice outlines a summary of the findings of CMS' review and any corrective action which was required to be taken by the AO to be considered to meet or exceed our standards, or comparable survey processes. When CMS approves or reapproves an accrediting organization for deemed status, the approval may not exceed 6 years.

We are concerned that the current application review processes under § 488.5 do not go far enough. Some of

our concerns with the efficacy of the AO application review process are based on the results of the initial and renewal applications and the SA findings, as noted in this section:

- *AO Application Reviews:* Between 2017 to September 2021, we received a total of 22 AO applications for review. After review of these applications, we returned all 22 applications to the AOs because we found that the AOs' standards were not comparable to ours. The AOs' most common standards requiring revisions to meet or exceed Medicare conditions included:

governing body, physical environment, emergency preparedness, patient rights, medical/clinical records, and care planning. Additionally, AO standards regarding coordination of services; skilled professional services; infection control; staff responsibilities, and quality improvement assessment programs (QAPI) all required revisions by the AOs.

- *SA Findings:* In FY 2019, CMS conducted 119 hospital surveys (including psychiatric hospitals) and 196 non-hospital surveys totaling 315 validation surveys. In FY 2019, the SAs found serious "condition-level" instances of non-compliance 60 times in accredited hospitals (including psychiatric hospitals), and 51 instances in which the AO missed the deficiencies. In these instances, even though the AOs did not find comparable levels of non-compliance, this non-compliance was sufficient to start enforcement proceedings against the subject hospitals. These results demonstrated that the AOs may have failed to ensure their facilities were meeting Medicare's minimum standards. In total, between FY 2017 and FY 2019, CMS conducted 363 hospital (including psychiatric hospitals) validation surveys, with SAs identifying condition-level non-compliance a total of 185 times, and 158 instances in which the AOs missed comparable deficiencies. Between FY 2017 and FY 2019, CMS also conducted a total of 369 validation surveys for HHAs and Hospices, with SAs identifying condition-level non-compliance a total of 57 times and 50 instances in which the AOs missed comparable deficiencies.¹¹ This data has amplified CMS' concerns related to the comparability of survey processes as

well as the need for increased AO oversight.

Therefore, under the statutory authority granted to us under section 1865(a)(1) of the Act, we proposed revisions at § 488.4(a)(1) to require that the AOs that accredit Medicare-certified providers and suppliers use the applicable Medicare conditions as set out in CMS regulations as their minimum accreditation standards. This meant that the AOs would be required to incorporate the Medicare conditions identical to our regulations within their accreditation standards for their deeming programs. However, AOs would be allowed to use additional accreditation standards that exceeded the Medicare conditions, as permitted under section 1865(a)(1) of the Act. We would, however, require the AOs to clearly delineate their additional accreditation standards that exceed the Medicare conditions when seeking CMS approval for deeming authority.

The requirement that the AOs identify the Medicare conditions as their accreditation standards would also allow providers and suppliers to know what the minimum Medicare deeming standards are and where the AO standards exceed these standards through its accreditation program, as permitted under section 1865(a)(1) of the Act. Facilities are expected to comply with regulatory requirements of CMS and the accreditation standards of the AO; however, we have found that in certain circumstances, the facilities were more familiar with AO standards and did not fully understand that the AO standards are sometimes more stringent than the Medicare conditions. There were several instances in which our comparability review of AO standards under § 488.5 resulted in the need for AOs to correct deficiencies in their survey standards and processes, because we determined that the minimum Medicare conditions would have not been adhered to. Despite these frequent reviews, the current regulations only require AO standards to be comparable, not duplicative of the Medicare conditions, therefore increasing the likelihood of inconsistencies in interpretation.

This proposed requirement would increase the likelihood that AO standards and processes would meet or exceed our regulatory requirements and transparency for providers to understand when the AO has more stringent standards, further explained in section IV.D. of the proposed rule.

We also proposed to strengthen our process for comparability review of the AOs survey processes at proposed § 488.4(a)(2), further explained in

sections IV.E. and IV.F. of the proposed rule. More specifically, we proposed to re-designate existing paragraph (a)(1) as (a)(3) and re-designate existing paragraph (a)(2) as (a)(4) with revisions and add a new requirement at § 488.4(a)(1). This provision would require the AOs that accredit Medicare-certified providers and suppliers to use the exact text of the applicable Medicare conditions set forth in the applicable CMS regulations for each provider and supplier type as their minimum accreditation requirements. However, the AOs would be free to establish additional accreditation requirements that exceed Medicare conditions as permitted by section 1865(a)(1) of the Act. We proposed to add language at § 488.4(a)(2) that AOs use a survey process comparable to the processes set out for SAs in the SOM and approved by CMS, as outlined throughout § 488.5(a)(4). We also proposed that these requirements and changes at paragraphs (a)(1) and (2) would be applicable beginning 1 year from the effective date of the final rule with comment period.

These proposed changes to § 488.4(a)(1) and § 488.4 (a)(2) would align national health and safety standards across all AOs and strengthen the survey processes used by the AOs. We further believe that our proposal would ensure uniformity and transparency of the surveys performed by the AOs for deeming purposes and improve CMS' ability to accurately evaluate an AO's performance.

We proposed to re-designate the current § 488.4(a)(1) and (a)(2) to § 488.4(a)(3) and (a)(4). We also proposed to add requirements at paragraphs (a)(1) and (a)(2) that AOs incorporate the Medicare conditions and use survey processes comparable to those of the SA. We also refer readers to additional proposed changes made to § 488.4(a)(4) in section IV.O. of the proposed rule.

The proposal to require AOs to incorporate the Medicare conditions (as defined in § 488.1) as their minimum accreditation standards would become applicable 1 year after the effective date of the final rule with comment period.

We received several comments on the proposed provisions for use of same survey standards and the comparability of survey processes. The comments and our responses to the comments are set forth in sections III.K., III.L., and III.M. for the standards, crosswalk, and survey comparability provisions of this final rule with comment period.

We received two overarching comments related to the overall

¹¹ FY 2020 Report to Congress: Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program <https://www.cms.gov/files/document/qso-22-06-ao-clia.pdf>.

provisions for use of the same Medicare standards and survey comparability.

Comment: One commenter stated that while the commenter appreciates CMS' desire to strengthen comparability, it is unclear how CMS intends to address variability within the deeming application documentation requirements. The commenter referenced that CMS currently provides a checklist for the application documentation and that the format is at the discretion of the AO. This commenter urged CMS to propose a more efficient and organized approach to reduce redundancy and duplication, while also easing burden on CMS during the application review. The commenter recommended adoption of a standard operating procedure (SOP) that includes a standardized application template enabling AOs to respond directly to the regulatory requirements and a standardized list of required attachments for the provision of supporting evidence. The commenter requested CMS to clarify what CMS is specifically looking for when determining "comparability."

Response: We appreciate the commenter's suggestion for CMS to provide an application template for those AOs seeking deeming authority. As noted by the commenter, CMS provides AOs with a checklist for the application documentation requirements, however we have not specifically identified a format as CMS has provided flexibilities to AOs. For instance, one AO may provide all documentation in a large zip-file, while other AOs may submit separate files. CMS will review the ability for more streamlined submissions in sub regulatory and policy guidance, yet our goal is to provide a level of flexibility and innovation by AOs. We believe that requiring a crosswalk with AOs using the same language as the CoPs for their minimum health and safety standards will further streamline CMS' application review processes and as outlined in the crosswalk example of the preamble in section III.L. of this final rule with comment period, CMS has suggested a template for use. Furthermore, our assessment of comparability is aimed at assessing an AO for comparable processes against those of the SA and as outlined in the SOM as outlined in the proposed provisions. The goal is to bring greater parity to the survey processes between SAs and AOs and reduce provider confusion. As outlined in the preamble, CMS has often required AOs to submit supplemental information such as information about surveyor training and requested the inclusion of questions posed by survey

teams for evaluation of specific Medicare conditions, as the survey process policies may have not always included requirements which are expected by the SA when evaluating facilities as outlined in the SOM. For example, SA surveyors are expected to ask specific questions of the facility or during interviews with leadership depending on the specific Medicare condition. While AOs may generally have surveyor guidance suggesting a comparable review, CMS has observed firsthand during survey observations of the AOs (during their application processes), that AO surveyors omit asking facilities certain questions which CMS has deemed important to assess compliance. Therefore, the provisions pertaining to increased survey comparability aim to ensure survey processes between SAs and AOs are strengthened to ensure a consistent evaluation of both deemed and non-deemed providers and suppliers.

Comment: One commenter, while in support of both provisions related to the use of same standards and the strengthened comparability of survey processes, also encouraged CMS to pursue granting deeming authority for Skilled Nursing Facilities (SNFs). In particular, the commenter observed that AOs may currently accredit a SNF, but that CMS does not recognize deeming authority for SNFs. The commenter believes the proposed provisions will provide greater consistency among SAs and AOs but also suggest that offering AOs deeming authority with respect to SNFs would provide value to survey and certification and alleviate pressure from deeply underfunded and overextended SAs.

Response: We appreciate the commenter's support of our proposed provisions. With respect to allowing SNFs to participate in Medicare via accreditation, sections 1819(g) and 1919(g) of the Act specify that the State, rather than an AO, is responsible for certifying compliance with long-term care facility requirements. Consequently, the statute does not permit us to offer "deeming authority" for LTC facilities at this time.

Final Decision: We are finalizing the revisions to § 488.4(a) as proposed with modifications to the numbering and ordering of the regulatory provisions. The proposed regulatory provisions at §§ 488.4(a)(3) and (4) will remain where they currently are at § 488.4(a)(1) and (2), respectively, and with the regulatory text finalized as proposed. Proposed § 488.4(a)(1) and (2) will be finalized at paragraphs (a)(3) and (4), respectively. We have also made technical changes with minor re-wording of the proposed

requirements and the existing requirements to make the provisions more understandable. These changes were made in the interest of clarity and do not constitute any changes in policy, nor they do establish any new requirements in addition to those already proposed and finalized in this rule. We have included a Waiver of Notice of Proposed Rulemaking in section VIII. of this final rule with comment period.

We are also modifying the provisions as proposed at §§ 488.4(a)(1) and (a)(2) by removing the phrase, "which are applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE]". We are making this modification for this final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date and individual provisions will no longer need to be specified in the regulations text.

For a more detailed discussion of the revisions to §§ 488.5(a)(3) and (a)(4), we refer readers to sections III.L., III.M., and III.N. of this final rule with comment period related to the finalization of our provisions for the crosswalk requirements and for the use of same survey standards and strengthened comparability of survey processes.

L. Revise the Crosswalk Requirements at § 488.5(a)(3)

As a result of our proposed requirement at § 488.4(a)(1) (revised as § 488.4(a)(3) in this final rule with comment period) to require the AOs to incorporate the Medicare conditions into their accreditation standards for their deeming programs, we also proposed to modify the regulations at § 488.5 that would be affected by this requirement. Section 488.5(a)(3) requires the AOs to submit with their initial and renewal application, "[a] detailed crosswalk (in table format, as specified by CMS) that identifies, for each of the applicable Medicare conditions (as defined in § 488.1) or requirements, the exact language of the organization's comparable accreditation requirements and standards." Because section 1865(a) of the Act allows AOs to have accreditation standards for their deeming programs that meet or exceed the Medicare conditions, the content, format, and wording of AOs' accreditation standards have frequently differed significantly from that of the Medicare conditions. Therefore, we require the AOs to provide a crosswalk which identifies the applicable Medicare conditions that corresponds to each of the AO's accreditation standards. The purpose of this

crosswalk is to help us determine to which Medicare condition each AO accreditation standard corresponds.

Since we proposed at § 488.4(a)(1) to require the AOs to incorporate the Medicare conditions into their accreditation standards, it would no longer be necessary to require the AOs to submit a crosswalk that provides “comparable” standards. Instead, we proposed that AOs would need to provide a crosswalk which demonstrates that the AO has incorporated the language of the Medicare conditions, as well as to provide the AO standards which exceed the Medicare conditions (for an example, see Table 2 in section VII.B.I of the proposed rule). Similar to the existing process for submission of the AO’s crosswalk during an application, we proposed to revise § 488.5(a)(3) to require a crosswalk that demonstrates the AO’s use of CMS’ requirements and standards. AOs would provide their additional or exceeding standards under their use of the required exact language

and annotate the exceeding standards. This would further allow providers and suppliers to easily identify the minimum Medicare deeming standards and where the AO standards exceed these standards through its accreditation program.

We proposed to revise § 488.5(a)(3) to first remove the requirement that the AO provide a “comparable” standard for each of the applicable Medicare conditions or requirements and replace it with the adoption of the CMS requirements in the AO accreditation standards for any deeming program. Second, in the application that is submitted to CMS for review, the AO would have to submit a detailed crosswalk. While we would not expect the AO to use the same CMS’ CFR regulatory citations (for example, § 482.11(c) as in Tables 1 and 2) and survey tags (a letter/number identifier; for example, A–0023 as in the tables here) in place of the AO’s specific standard numbers as they are used in the AO’s internal processes and for

surveys of its accredited facilities, we would expect the AO to use the applicable CMS identifiers in the appropriate column of the crosswalk table to meet the requirements being finalized in this rule. For example, CMS’ regulatory requirement at § 482.11(c) requires hospitals to “assure that personnel are licensed or meet other applicable standards that are required by State or local laws.” In this example and aligned with our proposed provisions, the AO would be required to have an accreditation standard for its hospital deeming program which would state “The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws,” with the AO’s applicable standard number. For this example, the crosswalk would appear as follows in Table 1, with the CMS CFR citations and survey tags in the first column and the AO standard numbers in the third column.

TABLE 1—AO CROSSWALK—MEETS CMS REQUIREMENTS

CFR citation and survey tag	Medicare conditions language	AO standard number	AO standards language
§ 482.11(c) (A–0023)	The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.	XX.000	For hospitals under CMS deeming authority: The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

As seen in this example in Table 2, the AO standard number identification may vary from CMS’ CFR regulatory citation. Additionally, as previously described, CMS is not restricting AOs from exceeding the Medicare

conditions. Therefore, if an AO believes that additional accreditation standards would need to apply to their deemed facilities, an AO would submit the exceeding requirements under the particular standard. Using the same

example, the AO would submit a crosswalk similar to the example below. As seen, AO Standard Number XX.001 would be exceeding the Medicare conditions.

TABLE 2—AO CROSSWALK EXCEEDS CMS REQUIREMENTS

CFR citation and survey tag	Medicare conditions language	AO standard number	AO standards language
§ 482.11(c) (A–0023)	The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.	XX.000	For hospitals under CMS deeming authority: The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.
		XX.001	Hospitals must verify credentials of all providers including all contracted staff or individuals under arrangement. The verification must be completed prior to the official hiring of the staff.

Establishing a consistent standard across all AOs would bring transparency to the accreditation process. This would allow providers and suppliers to know what the minimum Medicare deeming conditions are and where the AO standards exceed these Medicare

conditions through its accreditation program. It would also provide greater uniformity between an AO certification survey at a facility and a State survey that may be subsequently performed at that same facility, which could include

a complaint survey or a validation survey.

Additionally, from CMS’ oversight perspective of the AO applications for deeming authority and review of the crosswalks over the last several years, we have also identified that AOs have

inadvertently omitted certain standards in their crosswalk submissions. Therefore, while the impression that requiring a crosswalk for AOs may seem unnecessary, as we would be requiring AOs to incorporate the Medicare conditions into their accreditation standards, it is imperative that CMS be able to ensure the AO has standards for each Medicare condition. The review of the exceeding standards is also critical for CMS to ensure that any additional requirements established under accreditation for deemed providers or suppliers do not conflict with the Medicare conditions.

We proposed that the provision would be applicable 1 year after the effective date of the final rule with comment period.

The comments and our responses to the comments are set forth below. We received several comments of general support for the proposal to require AOs to use the same minimum health and safety standard language as the Medicare conditions and to provide CMS with a crosswalk outlining use of the same standards and any exceeding standards.

Comment: Several commenters provided overarching support for the proposed provisions. One commenter stated the proposal would promote clear communication of AOs' standards. Another commenter suggested this would contribute to consistently improved results. One commenter also stated that this provision would streamline an already-lengthy review process as well as provide further alignment across AOs and SAs. One commenter stated this proposal would provide transparency by ensuring AOs incorporate the language of the Medicare conditions even if the AO standards exceed the Medicare conditions. This commenter also stated the provision would provide transparency to providers and suppliers by better standardizing survey practices between SAs and AOs. Another commenter stated that alignment of the language is critical to decrease unnecessary hospital burden.

Response: We appreciate the commenters' support of our proposal, and we agree this process would support overall transparency and standardization. We also appreciate and agree with the one commenter's statement that this would streamline review processes and further align AOs and SAs. We also agree that alignment of the language would decrease burden in relation to healthcare organizations understanding the minimum health and safety standards for Medicare participation.

Comment: One commenter provided general support of the provisions for use of same language of the Medicare conditions and strengthened survey process comparability. The commenter suggested that these provisions will provide alignment and consistent application of standards, which is important for protecting patients and maintaining the integrity of the survey process. The commenter appreciated CMS' intent to ensure AOs are working in a consistent and unbiased manner.

Another commenter echoed that alignment with the Medicare conditions would help improve alignment and ensure AOs conduct their work in a consistent, unbiased manner.

Response: We agree with the commenters and thank them for their general support.

Comment: One commenter stated that AOs that accredit Medicare-certified home health agencies and hospices do incorporate the Medicare conditions in their standards. This commenter agreed that adopting the same language as CMS regulations within the AOs accreditation standards is best and eliminates any ambiguity. The commenter was in support of this requirement and the crosswalk provisions. One commenter, in support of the proposed provisions, stated that the line between the Medicare conditions and additional accreditation standards can be blurry; therefore, providing clearer standards will prevent confusion among the medical staff and can potentially incentivize facilities to pursue higher standards of care. The commenter noted that this proposal would not prevent an AO or facility from being recognized for exceeding those standards. Another commenter, also in support, urged CMS to finalize the proposal and stated this would align health and safety standards across all AOs and strengthen consistency of the survey process while also improving the transparency of accreditation and reduce potential provider confusion and misinterpretation of accreditation standards. One commenter supported our proposed provision, stating that the requirement to provide a crosswalk linking the AO's accreditation standards to the corresponding Medicare conditions is a critical step in enhancing transparency, accountability, and consistency within the accreditation process. The commenter suggested that a crosswalk facilitates CMS in evaluating AOs accurately, ensuring that healthcare delivery meets quality standards effectively. Further, the commenter stated that this would provide a clear apples-to-apples comparison and facilitate thorough

understanding of accreditation standards to drive improvements.

Response: We appreciate the commenters' general overall support. We appreciate the commenters support on our proposed provision to require AOs to use the same minimum health and safety standards as the Medicare conditions. We agree that these proposals will not restrict an AO from requiring additional more stringent standards or for facilities to exceed the minimum standards. As the commenters stated, the proposal is to promote clarity and reduce confusion. We agree that the provisions of a crosswalk and use of one-to-one Medicare standards as the minimum health and safety standards provides transparency, consistency, and an understanding of the Medicare conditions for deemed facilities under an AO.

Comment: One commenter stated that leveraging Medicare participation standards as a foundation offers numerous advantages, including a trusted benchmark, streamlining processes, and maintaining a primary focus on patient safety and quality. This commenter suggested the proposal would provide a solid framework for AOs to survey to the same CMS requirements and standards as the SAs, yet also advised that it is crucial to acknowledge the necessity of supplementing the standards with facility-specific criteria to ensure comprehensive and tailored assessments that truly reflect the diverse needs and standards across healthcare sectors.

Response: We agree with the commenter, and we note that the proposed provisions do not restrict or limit AOs from continuing to impose additional health and safety requirements which exceed the Medicare minimum standards. However, the proposed provision is aimed to ensure greater clarity among Medicare-participating facilities on the Medicare requirements, and as suggested by the commenter, provides a solid framework.

Comment: One commenter advised that members of its organization have established effective working relationships with the AOs to ensure Medicare's health and safety requirements are met or exceeded. This commenter specifically stated that members of its organization are Medicare participants that must comply with specified statutory requirements of the Act and other regulatory requirements designed to protect the health and safety of patients and that some of its members demonstrate compliance with the applicable CoPs by achieving accreditation through a CMS-

approved national AO that CMS recognizes as applying standards and processes indicating regulatory compliance, rather than through a SA, in accordance with section 1865(a) of the Act. The commenter stated that the service provided by the AOs is of vital importance because the “deemed” status for accreditation earned by the hospitals satisfies the CMS requirement that a provider qualifies, or continues to qualify, for participation in the Medicare program.

Response: We appreciate the comment and agree that establishing a rapport between a facility’s staff and an AO is critical to ensure the Medicare requirements are understood for deemed programs. We further believe that by ensuring SAs and AOs use the same minimum health and safety standards will bring greater parity to the understanding of the regulatory requirements for Medicare participation.

Comment: Two commenters supported CMS’ efforts to require a crosswalk and urged CMS to make the crosswalks public to ensure providers have the complete and accurate information related to the standard requirements when choosing between using an SA or AO to meet their certification needs.

Response: We appreciate the commenters’ support and agree that transparency of the Medicare requirements and AO standards would be beneficial for the provider and supplier community. We would encourage AOs to consider transparency and public posting of their standards which would demonstrate the AOs minimum health and safety standards mirror those of the Medicare conditions and how participation with that respective AO also exceeds the minimum requirements, should the AO have exceeding standards. CMS believes exceeding standards further promote patient safety and quality of care. However, our provision is aimed at reducing potential inconsistencies while also ensuring healthcare entities are aware of the Medicare standards.

Comment: One commenter supported the proposal and noted that this proposal, in connection with the proposals on strengthening survey process comparability, would further ensure that surveys identify lapses in patient safety and opportunities for improving strategies that strengthen the delivery of care. The commenter suggested that AOs such as The Joint Commission routinely meet or exceed the regulatory standards enforced by CMS yet was in support and referenced that this could align further with the

prevention and reduction of hospital-acquired infection initiatives.

Response: We appreciate the commenters support of our proposals to require AOs use the same minimum health and safety standards of the CoPs and our proposals to further align survey processes. We agree with the commenter that this proposal will support reducing inconsistencies in the implementation of standards which has implications for lapses in patient safety, including hospital acquired infections.

Comment: One commenter stated that if accredited, an accreditation organization should be required to identify in its documentation the health and safety standards of CMS. While cost for implementation could be a concern, the proposal would guarantee that all AOs understand and support the mission and values of CMS.

Response: We thank the commenter for feedback in support of requiring AOs to have the same language of CMS for their minimum health and safety standards, to ensure facilities which are deemed by a CMS-approved AO understand the CMS requirements. We also appreciate the cost concerns raised by the commenter, however we do note that we will continue to allow for AOs to exceed our standards, whereas we believe many AOs will continue to keep some of their existing standards, demonstrating that their standards are more stringent than CMS’.

Comment: One commenter agreed with the intent of the proposal, stating that this would ensure that all accredited facilities meet a baseline level of quality and safety, align with the CMS regulations, and facilitate oversight. While the commenter agreed that the proposals are intended to enhance the quality and safety of healthcare delivery, they also present challenges for operational flexibility and innovation for AOs. Specifically, the commenter stated the requirement for use of same standards may limit the ability of AOs to innovate or tailor their standards to specific healthcare delivery contexts and the requirement to define additional standards separately when seeking CMS approval could potentially slow the process for updating or introducing new standards.

Response: We appreciate the concerns raised by the commenter. The proposed provisions surrounding the crosswalk and AOs use of the Medicare standards as the minimum health and safety standard language does not prohibit an AO from further expanding or having higher/more stringent standards. As outlined, an AO may still have additional standards. However, this provision aims to reduce the

inconsistency or challenges determining the comparability of an AO’s health and safety standards. This provision would also increase greater understanding for healthcare organizations seeking deemed status through an AO with respect to the requirements of the Medicare conditions. Further, we note that AOs are currently required to submit any changes to their standards for any deemed program to CMS for review and approval, therefore this proposal would not add complexity or slow processes for AOs implementation of more stringent standards. As part of the application review process, when CMS imposes new health and safety standards; or when an AO proposes to add or revise additional standards, CMS reviews the standards crosswalks to ensure AOs more stringent additional requirements do not conflict with the intent of the Medicare conditions. These provisions do not prohibit AOs from continuing to exceed or tailor their standards to specific healthcare delivery contexts.

Comment: One commenter, while generally supportive of the requirement, also encouraged CMS to consider how the proposed changes will affect hospitals and health systems that rely on the AO accreditation process to demonstrate their compliance with the Medicare conditions.

Response: We appreciate the commenter’s general support for our proposal and for raising concerns related to the impact to healthcare systems themselves, which rely on the AOs’ accreditation process to demonstrate their compliance with Medicare CoPs. We believe the proposal to require AOs use of the same standard language as our CoPs as their minimum health and safety standards will benefit healthcare facilities in understanding the Medicare requirements and reduce the inconsistencies between SA and AO surveys. AOs will continue to be allowed to exceed the Medicare standards; however, AOs will need to provide education for facilities and surveyors to clearly understand the intent of the Medicare requirements.

Comment: We received one comment challenging the assumption that a causal relationship exists between how an AO’s standards are written and the issues an accredited facility may encounter in demonstrating that it is in compliance with the Medicare regulations. The commenter stated that the concept of “comparability” has been the mainstay of aligning AO standards and survey processes between AOs and that of CMS. The commenter stated that the proposal to change the language to be identical would impose a

tremendous administrative burden by not only requiring the standards to be re-written, but in many cases the nomenclature used by an AO in organizing their standards would need to be revised. The commenter suggested this proposal creates a hardship for accredited providers and suppliers who are familiar with the terms of their accreditation manuals.

Response: We appreciate the commenter's concern related to the proposal to require AOs to use the same Medicare language as their minimum health and safety standard and the potential administrative burden, to include revising the AO's individual classification system (AO standard numbers) to these standards. While we appreciate the concern, we believe AOs may simply add an additional area for its individual classification system to each corresponding standard and incorporate the CoP language or adjust current language within their current standards to include the minimum CoP language, as provided in the example within the impact section of this rule. For many years, CMS has continuously needed to request changes to the AOs standards based on our review for comparability during the application processes before it could grant or renew deeming authority. Often, language in an AO manual was missing key elements of the Medicare requirement or missing the intent of the regulatory requirement. While we recognize the potential administrative burden associated, we also believe that alignment of this language will ensure healthcare facilities deemed by AOs understand the CMS minimum health and safety requirements.

Comment: One commenter questioned how CMS intends to administer this requirement when CMS does not have infection control standards for each program. The commenter stated the proposal was unclear about whether CMS would consider an AO's adaptation or implementation of the SOM and corresponding appendices as meeting this requirement. The commenter questioned if AO surveyors are provided access to these resources and educated their surveyors on the CMS guidance, will CMS consider this acceptable, or would CMS require AOs to recreate the documents for use in its programs. Finally, this commenter stated the requirements to use verbatim standards and processes appear to be viewing AOs as contractors without any differentiation or innovation, instead of independent organizations.

Response: We appreciate the commenter's request for additional clarification. The intent of the

requirement for AOs to use the language of Medicare requirements as their minimum health and safety standards is intended to reduce confusion among the provider/supplier community and ensure consistency. While CMS may not have infection control conditions for each provider type at this time, this does not restrict AOs from having additional standards where CMS has none. CMS is not requiring an AO to adopt the SOM and appendices. AOs may choose to fully adopt the Medicare standards and SOM/appendices for its deemed organizations, or the AO may use the minimum standards and exceed Medicare minimum requirements with additional standards. We refer the commenter to the survey process comparability section for additional context. Finally, the provision we are finalizing is not intended to reduce an AOs innovation, but rather to ensure consistency in the understanding of the Medicare conditions by both deemed and non-deemed organizations participating in the Medicare program.

Comment: One commenter stated that it was unclear on the proposal to require the crosswalk as the existing regulatory language at § 488.5(a)(3) already requires a detailed crosswalk. The commenter stated that in addition to this crosswalk, CMS currently also receives a copy of the AO standards, which include the CMS regulatory references for each applicable standard.

Response: We agree with the commenter that the requirement for AOs to provide a crosswalk and the copy of its standards is already required. However, we are finalizing provisions to require AOs also use the same language as our Medicare standards as their minimum health and safety standards for deemed programs. Therefore, as outlined and explained, AOs would need to submit a crosswalk which clearly identifies the one-to-one use of the Medicare standards, then further delineate any additional standards which may exceed the Medicare conditions.

Final Decision: We appreciate all commenters who have provided input on this proposed revision requiring AOs to use the same language for their minimum health and safety standards. We agree with the commenters who have stated that this alignment would bring greater understanding to facilities and reduce confusion among the provider community. After consideration of the comments, we are finalizing this proposal with minor modifications to the proposed language for clarity. AOs would be required to revise their deeming standards to use the same language as the Medicare

conditions; however, AOs will still be able to exceed the baseline language of the conditions with additional standards. AOs will be required to submit a revised crosswalk as part of the CMS-application review process using the template provided in this final rule with comment period.

However, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the regulations text stating "[DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE]". We are making this modification for the final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date and individual provisions will no longer need to be specified in the regulatory text.

M. Strengthen the Comparability of the Survey Process Between the AOs and the States

An AO must demonstrate to CMS that it has the ability to effectively evaluate a healthcare facility's compliance with the Medicare conditions using survey processes that are comparable to those survey methods, procedures, and forms required by CMS and as implemented by the SAs. A general description of SA survey processes is set out at § 488.26 and specified in the SOM.

As part of the application process as set out at § 488.5, CMS is required to complete a survey process review as part of the AO application review process. The purpose of the survey processes review is to determine whether the AO's survey processes are comparable to the CMS survey processes. The survey process comparability review is done by reviewing information in the application, such as, the AO's survey activity guides, organizational procedures for surveyors, surveyor training materials and AO survey requirements. CMS also conducts an in-person observation of an AO survey (carried out by a CMS survey observation team) as part of CMS' review of an AO's application. The purpose of the survey observation is to ensure that the AO surveyors follow the processes set out in the application and to ensure that the AO surveyors evaluate all Medicare requirements.

Sections 1865(a)(1) and 1865(a)(2) of the Act require us, when making this finding, to consider a national AO's "survey procedures" and "... its ability to provide adequate resources for conducting required surveys and

supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements. . . .” Our longstanding requirements at § 488.4(a)(3) implemented this statutory provision by requiring AOs to provide us with detailed information on their survey processes, and our regulations at § 488.5 and § 488.8 set out the procedures for comparability review. We further discussed AO survey procedures’ comparability to our SA survey processes and the SOM in the May 22, 2015 final rule published in the **Federal Register**, entitled “Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures” (80 FR 29796) (hereinafter referred to as the “2015 AO final rule”). We assess comparability by reviewing the information in the AO’s application in light of the SOM survey process requirements for SAs, which implements the survey process requirements found in parts 488 and 489 of our regulations. The role of the SOM is to provide explicit guidance on the process to assess providers’ and suppliers’ compliance with our regulatory requirements. We do however note, that the AOs are already required to submit the documentation and that most AOs provide this within their applications, therefore we do not believe this imposes any additional burden, as this has been a long-standing expectation as described in the preamble of the proposed rule (89 FR 11996) and the 2015 AO final rule (80 FR 29796), which stated that while the explicit reference to the SOM was removed, “this will not change our practice of assessing comparability in light of the SOM survey process requirements for SAs, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements”.

As previously noted, CMS received 22 AO applications between January 2017 and August 2021. Of those 22 applications, 14 were returned to the AO for revisions to the AO’s survey processes and policies, as distinguished from the finding that all 22 AO’s standards were not initially comparable with the Medicare conditions. These required survey process revisions included ensuring all surveys were unannounced in accordance with § 488.5(a)(1)(i), which we discussed in section IV.A. of the proposed rule. Other applications were returned for inconsistencies with our patient or

representative complaint processing guidance set out in Chapter 5 of the SOM. Additionally, among these 22 applications, we identified concerns within the AO survey processes during the on-site survey observations, as authorized under § 488.8(h). The following concerns were noted during the survey observations for these 22 applications:

- The survey citations and rationales for citing or not citing “Governing Body” Medicare condition violations (for example, 42 CFR 482.12) were inconsistent with CMS’ SA survey methodologies;
- The AO failed to enforce the deadlines by which facilities must come into compliance after receiving adverse survey results;
- The AO utilized timeframe(s) that were inconsistent with those of state SAs, such as deadlines for conducting follow-up activities, including follow-up surveys, for facilities that have previously demonstrated non-compliance at the condition-level; and
- The AO didn’t conduct a sufficient number of medical records reviews during a survey. (CMS expects that AO surveyors review a specific number of medical records, based on the facilities’ patient volume, to ensure that the surveyor has an accurate picture of patient care services provided within the facility).

CMS also has longstanding concerns about the performance of AOs, including the failures of AOs to conduct in-depth investigations; the lack of consistency and comparability with CMS standards; and the repeated requests for AOs to resubmit applications with conforming corrections in survey standards and processes. We also have continued concerns about the excessive frequency of disparate findings between AOs and SAs (see section IV.I. of the proposed rule) and AOs’ consistent failure to review medical records, as required by SA procedures. All of these endemic issues strengthen our resolve to ensure consistency in AO performance. Our initial and renewal application reviews are the foundation for our oversight of AOs to determine the AO’s ability to ensure facilities adhere to minimum Medicare conditions.

Because of these disparities, we proposed to strengthen our requirements under § 488.5. The proposed requirements would require AOs that accredit Medicare-certified providers and suppliers to use a survey process that is comparable to the survey processes and procedures used by CMS and the SA. We note that this has been the expectation under the existing

requirements, as a condition of obtaining and retaining deeming authority. We proposed to increase the specificity of our application and reapplication requirements for national AOs to improve documentation that would demonstrate this comparability.

We received a total of 25 comments on the proposal to strengthen survey process comparability. We note, the majority of comments responded generally to the proposed provisions under section IV.F instead of separate comments for each of § 488.5(a)(4); § 488.5(a)(4)(iii); § 488.5(a)(4)(v); § 488.5(a)(4)(vii); § 488.5(a)(4)(xi); § 488.5(a)(5); § 488.5(a)(6); § 488.5(a)(12); § 488.5(a)(13).

Comment: We received several comments generally supportive of our proposal to increase comparability of survey processes among AOs and SAs. One commenter suggested that combined with our proposal for use of the same standards, this would enable comparability of the survey process across facilities that are all required to adhere to the same standards for Medicare reimbursement. Another commenter suggested that in conjunction with our proposal for AOs to use the same minimum health and safety standards, that this would thereby strengthen and improve consistency in the survey processes of AOs and SAs and improve the transparency of accreditation surveys and reduce confusion among providers. One commenter also stated our proposals around survey comparability will achieve efficiencies and benefit all interested parties as well as the surveying entities. The commenter implied that this proposal in conjunction with our proposal to apply consistent basic training for AOs and SAs would increase accuracy and cross-agency consistency of survey findings. One commenter also provided general support and stated that these proposed provisions would help improve alignment and ensure AOs conduct their work in a consistent manner.

Response: We thank all the commenters in support of our proposed provisions to strengthen survey comparability between the AOs and SAs. We agree with the commenters and believe these provisions will work to provide greater clarity for Medicare-participating providers currently deemed by a CMS-approved AO. These proposals are intended to align survey processes for consistency, while not limiting an AO from exceeding our requirements.

Comment: We received one comment stating that providers have long reported and continue to report inconsistency in

understanding, interpretation and application of not only the Medicare conditions, but also the survey processes between SAs and AOs. The commenter supported our efforts for strengthening survey process comparability.

Response: We appreciate the commenter's support of our proposals and agree that these provisions will work to strengthen comparability and understanding of the SA and AO survey processes.

Comment: Two commenters, while generally supportive of all proposed provisions, urged CMS to consider how the proposed changes will affect hospitals and health systems that rely on the AO accreditation processes to demonstrate their compliance with the Medicare conditions. The commenters were in support of CMS proposals to ensure more consistency between AOs and the SA surveyors.

Response: We appreciate the commenters' support for our proposals to strengthen survey comparability and provide greater consistency among the AOs and SAs. We appreciate the commenters' concerns related to the impact to healthcare systems themselves, which rely on the AOs accreditation process to demonstrate their compliance with Medicare. We note, the proposals surrounding AOs strengthened survey process comparability will be a benefit for healthcare facilities in understanding the Medicare requirements and reducing the inconsistencies between surveys of deemed and non-deemed facilities.

Comment: One commenter suggested that our proposals for strengthened survey process comparability is a welcome step in promoting consistency and effectiveness. The commenter also encouraged sharing of data among SAs and AOs to improve outcomes, understand processes, and foster a culture of collaboration.

Response: We appreciate the commenter's support and agree with the need to further collaborate and share information among SAs and AOs. We believe these proposals will first provide clarity and alignment of processes to bridge the gap of inconsistencies.

Comment: One commenter provided support for the proposed provisions set forth in § 488.5(a)(4) to (13), as such provisions pertain to strengthened comparability for survey processes. The commenter specifically noted the importance of maximum documentation, transparency, and accountability within the accreditation process.

Response: We appreciate the commenter's support.

Comment: One commenter also requested that CMS consider proposals to strengthen comparability among the SAs. The commenter's experience with providers and health systems spanning across multiple States; the commenter implied that there were inconsistencies among SAs. The commenter also suggested that CMS consider proposing that all complaints related to a certified provider, including those deemed by a CMS-approved AO, should be followed up on by the SAs. The commenter suggested that AOs vary in response time and follow up, and that SAs could be relied on to respond quickly. The commenter stated that this approach would ensure a uniform complaint follow up process.

Response: We appreciate the commenter's general support for our provisions for strengthening comparability among AOs and SAs. The proposed provisions are aimed to achieve consistency among SAs and AOs. CMS expects SAs to follow the guidance set forth in the SOM and applicable program appendices. In addition, AOs are expected to have comparable complaint processes to those of the SAs, and as outlined in Chapter 5 of the SOM. We appreciate the commenter's recommendation for complaints to be conducted by the SAs for all Medicare-participating facilities; however, these recommendations are outside of the scope of this proposed rule. CMS is continuing to review our survey processes and the complaint procedures across SAs and AOs.

Comment: One commenter, in support of strengthening comparability, stated that the additional efforts CMS has proposed would further improve the survey process and ensure such surveys reliably identify lapses in patient safety and opportunities for improving strategies that strengthen the delivery of care. The commenter specifically referenced the prevention and reduction of healthcare-associated infections (HAIs) including the Centers for Disease Control and Prevention (CDC) 2022 National and State HAI Progress Report.¹² The commenter noted that the resources of the commenter's organization are translated from research based on proven science-based methods. The commenter stated that its resources are often used by facilities and the policies help to meet or exceed the quality-of-care standards set forth by CMS and AOs.

Response: We agree with the commenter that HAIs are a top priority,

and we appreciate the commenter's organization providing valuable resources to healthcare facilities to combat HAIs. The proposed provisions do not aim to limit AOs from meeting or exceeding our standards and are designed to strengthen survey processes among SAs and AOs, including the identification of infection control deficiencies within facilities. The provisions also do not restrict healthcare facilities from using resources by any healthcare industry or organization to exceed CMS' minimum health and safety standards and strive for increased patient safety as it relates to infection prevention. Again, we appreciate the support of the strengthened survey comparability proposals between AOs and SAs.

Comment: One commenter stated that its client facilities are generally supportive of the proposals, and the organization has already taken actions to align survey processes, such as survey process documentation, and creation of policies regarding the composition and number of survey teams. However, the commenter urged CMS to consider that cumulatively, these proposed provisions represent a change in requirements and will have significant cost burden, including staff burden, if implemented.

Response: We appreciate the commenter's general support of the provisions and CMS recognizes the potential burden which may be associated with some of our proposals. Regarding strengthening survey comparability among SAs and AOs, as outlined in the impact section, we believe this is not a significant burden, as the provisions primarily aim to clarify existing requirements which AOs already provide as part of the application process for deeming authority. The survey process comparability aims to ensure CMS can see critical elements of the AOs survey processes, such as the surveyor probes and questions as part of the investigation. We thank the commenter for the support and the organization's current efforts to align with these provisions.

Comment: One commenter agreed with the proposed provisions and clarifications that all AOs must use a survey process comparable to those processes set out in the SOM, yet implied that the reasoning provided in our proposed rule creates confusion as to what the actual requirement is for the definition of "comparable." The commenter stated it was unable to determine if CMS is presenting comparability as sameness, meeting, or exceeding. The commenter also

¹² <https://stacks.cdc.gov/view/cdc/148718>.

requested clarification from CMS on describing how the processes logically work together in a manner that does not provide confusion to the public and deemed facilities, and that a thorough understanding of the requirements is essential for AO compliance.

Response: We appreciate the commenter's concerns related to the meaning of comparability, in particular the proposals surrounding survey process comparability. Of note, as explained in the preamble of the proposed rule, CMS' proposed provisions for survey processes are to clarify many already existing requirements with specific focus on areas of the application review processes where CMS has found deficient practices in the AOs' survey processes. The proposed provisions related to the survey process would not require the same language as the survey processes found in the SOM, nor would the proposals restrict AOs from exceeding certain survey processes. In this final rule with comment period we are clarifying existing requirements, such as requiring an AO to provide survey protocols (such as interview questions), which are transparent to the public as outlined in the SOM yet have not always been present within an AOs initial application or reapplication for deeming authority. SAs are guided to specific survey questions when performing reviews of the CoPs, however CMS has found that AO applications over the years and survey processes for evaluation of the CoPs do not always include interview probes for surveyors. Additionally, in our review of AO survey processes over the years, we also identified instances where AOs were conducting off-site complaint investigations, which are not permitted for acute and continuing care providers per the guidance in Chapter 5 of the SOM; therefore, these investigations were not comparable to the processes of the SA. CMS believes by strengthening the language, greater comparability between SAs and AOs will be achieved. Sameness would imply requiring the same exact language and process, which is not our intent under our comparability requirement. Our intent is to ensure that AOs will continue to have flexibilities in survey approaches, while providing clarity as to what information will be required in our review of AOs applying for deeming authority to ensure that AOs are meeting or exceeding the intent behind evaluating deemed facilities against the Medicare requirements. Survey process may still be exceeded by an AO, such as requiring more than CMS requires for review of

medical records or evaluation of AO-specific standards which exceed our minimum health and safety requirements.

Comment: One commenter, while appreciating our intent to strengthen comparability, also noted CMS provides a current checklist for application documentation for submission to CMS for initial and continued approval of the AOs deeming program. The commenter stated that it is left to the individual AO to determine how to package the information and suggests CMS consider a more efficient and organized approach to reduce redundancy, while also easing the burden on CMS. The commenter suggested CMS consider development and adoption of a standardized operating procedure, to include application templates, enabling AOs to respond directly to requirements.

Response: We appreciate the commenter's suggestion for CMS to provide an application template for those AOs seeking deeming authority. As noted by the commenter, CMS provides AOs with a checklist for the application documentation requirements outlining the requirements at § 488.5, however we have not specifically identified a format as CMS has provided flexibilities to AOs. For instance, one AO may provide all documentation in a large zip-file, while other AOs may submit documentation in separate files corresponding to each required element in § 488.5. We will review the application process to determine if there are opportunities for more streamlined submissions, and if appropriate, present any changes in subregulatory and policy guidance.

Comment: CMS received one comment raising concern. The commenter stated that current inconsistencies among SAs from State to State suggest that CMS should focus on establishing consistency among SAs prior to moving to AOs. The commenter also raised concerns that CMS may not be sufficiently coordinating the investigative efforts among AOs and SAs and recommended removal of duplicative complaint survey activity among the two surveying entities.

Response: We appreciate the commenter's recommendations and CMS remains committed to achieving consistency among the SAs.

Final Decision: We appreciate the commenters who supported our proposal to strengthen the comparability of survey processes among SAs and AOs. We also recognize that some of the commenter's raised concerns on establishing consistency among the SAs as well. Based on our review of the comments received, we are finalizing

this proposal without changes. We note, AOs will be provided with additional guidance by CMS when submitting their applications for initial or continued CMS-approval of their deeming programs.

N. Revise the AO Application Documentation Requirements Related to the Survey Processes (§ 488.5(a)(4); § 488.5(a)(4)(iii); § 488.5(a)(4)(v); § 488.5(a)(4)(vii); § 488.5(a)(4)(xi); § 488.5(a)(5); § 488.5(a)(6); § 488.5(a)(12); § 488.5(a)(13))

To achieve our goal to require the AOs to use a survey process that is comparable to that used by CMS and the SAs (and in alignment with our proposal at § 488.4(a)(2) regarding comparable survey processes), we proposed the following revisions and additions to the existing AO application regulation requirements.

1. Revisions to § 488.5(a)(4) (Description of Survey Process)

At § 488.5(a)(4), we proposed to add language which includes what we believe to be the core fundamental activities of the survey process, such as pre survey preparation; offsite preparation; entrance interview and activities; information gathering and investigation, analysis of information; exit conference; post-survey activities; and statement of deficiencies-related activities. These are processes used by the SA which are needed to ensure that a Medicare-participating provider or supplier receives an unbiased, independent survey.

We have observed, both in our on-site observation of AOs during the existing process set out at § 488.8(h), as well as during the Validation Redesign Program (VRP) pilot conducted 2018 through 2019, that AOs often provided daily briefings to and had frequent discussions with the management of the surveyed facility whose purpose was not clearly described in the AO's applications. We noted that these meetings with facility management impeded or did not allow for sufficient time for the survey team to complete core survey activities, such as direct observations or interviews, in turn failing to complete a thorough review of the organization's compliance. Time spent to have casual briefings or meetings with facility management could have rather been spent to evaluate the facility's compliance with the Medicare requirements.

Therefore, the proposal to add the core activities, as well as the revisions outlined in this section, would further strengthen comparability between SAs and AOs, while continuing to allow for

flexibilities in the survey processes used by AOs. However, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the regulations text stating “[DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE]”. We are making this modification for this final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date and individual provisions will no longer need to be specified in the regulatory text.

The comments and our responses are set forth in section III.M. of this final rule with comment period.

2. Revisions to § 488.5(a)(4)(iii) (Documentation of Surveyor Forms and Guidance)

Section 488.5(a)(4)(iii) currently requires that AOs applying for deeming authority provide, among other documentation, copies of the organization’s survey forms, guidelines and instructions to surveyors. We proposed to be more specific about the level of detail we require from the survey instructions and guidance the AO provides to us when seeking our approval. Specifically, we proposed to require detailed information regarding how the AO surveys for facility compliance with the following core activities or standards within the Medicare conditions, such as: Governing Body; Patient Rights; Emergency Preparedness; Quality Assessment and Performance Improvement; Medical Staff; Nursing Services; Medical Records Services; and Infection Control. These core activities and standards are part of every State survey and based on Medicare conditions. With respect to each of these survey subject areas, we would require the applying AO to provide documentation on the instructions it provides for surveying these Medicare conditions, including survey probes, interview questions, and methods for their own review of facility documentation pertaining to these Medicare conditions.

It has become evident through our validation and comparability reviews of AOs that the documentation we currently request from them no longer suffices to adequately determine whether the AO surveyors are investigating these Medicare conditions sufficiently to ensure the health and safety of Medicare beneficiaries and other patients. AOs have failed to survey adequately for facility

compliance with their respective documentation requirements, including specific standards or survey processes. We also proposed that AOs submit their patient and staff interview questions. By having access to these questionnaires, we would be able to determine whether there are gaps in the survey processes which are leading to the disparity findings, as we have seen in our validation surveys.

Comment: One commenter was unclear about the proposal and the identified “core activities” and inquired whether the detailed information will only be required for the aforementioned areas (for example, governing body, emergency preparedness, etc.).

Response: We appreciate the commenter’s concerns relating to clarity of this proposed provision. As noted previously, some AO applications have lacked information on surveyor interview questions, protocols, or probes, as outlined in the SOM. The intent of this proposed provision was for AOs to provide surveyor guidance and interview questions comparable to those of the SOM for all Medicare conditions. While AOs have flexibilities in the format, and we are not requiring the same exact questions or surveyor probes, information provided should ensure assessment of the facility’s compliance with requirements is consistent with our expectations of the States, ranging from entrance activities, to opening conferences, to interview and documentation reviews and exit conferences with the facilities. We will provide AOs with additional guidance during their initial or continued applications for CMS-approval of their deemed programs.

Final Decision: As outlined in section III.K. of this final rule with comment period, we are finalizing this provision without any changes.

O. Revisions to § 488.5(a)(4)(v) (Survey Review Process)

At § 488.5(a)(4)(v), we proposed to add additional areas clarifying and strengthening the requirement that AOs provide a description of their document review processes in their approval applications. We proposed to add that AOs must describe processes and surveyor procedures related to the review of medical records, medical staff credentialing procedures; personnel files (including staff competency); and the number of patient observations, patient interviews and staff and facility interviews.

We have noticed that many AOs fail to review adequate numbers of records for the provider/supplier type involved. In the review of the 22 AO applications

received between 2017 and September 2021, a total of nine AOs were identified to have not reviewed the adequate number or records. Additionally, we have observed that some AO survey practices, such as interviewing patients in non-confidential settings, and deficient complaint investigations, undermine the integrity and accuracy of AO surveys. We are concerned that staff or patients may not be honest and candid if another facility staff member or supervisor is present during interviews. The expectations are that interviews are conducted privately with staff. For example, in Appendix A of the SOM, we explicitly require surveyors to “Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee.” Privacy in interviews with staff is important and encourages the likelihood of honest feedback about an organization. Additionally, we also identified a few instances (three of 22 applications) during our survey observations of AOs onsite, in which the AO did not observe actual performance of medication administration, wound care, or other services provided by the accredited facility, and most observations within the hospital setting were surgical time-outs (part of the Universal Protocol and performed in the operating room, immediately before the planned procedure is initiated). In one instance, the AO failed to ask the facility for any patient/representative complaint information, which indicates that the AO failed to conduct any investigation as to how the facility manages complaints and grievances. These specific examples raise concerns that the AO survey process does not sufficiently ensure safe practices for patients.

Furthermore, as noted in our discussion of proposed § 488.5(a)(4)(iii), we have also identified multiple instances in which the AOs have conducted limited review of facilities’ staff credentialing and competency testing activities. For instance, in one survey observation, we observed that the AO reviewed the personnel files of only one licensed practical nurse (LPN) and one phlebotomist, and did not review any personnel files for RNs, pharmacists, or dietitians, as outlined in Appendix A of the SOM, which we consider to be critical staff for this provider setting. In another survey, the AO determined that nursing staff were not documenting chains of custody of narcotic medications but failed to review the facility’s pharmaceutical policies and procedures and conducted

no interviews of pharmacy staff. In such circumstances where a category of documentation was missing from the facility's record, we would mandate that the AO or SA conduct further investigations to determine the reason for the lapse.

The comments and our responses to the comments are set forth in IV.E. of this final rule with comment period.

P. Revision to § 488.5(a)(4)(vii) (Correction of Identified Non-Compliance)

At § 488.5(a)(4)(vii), we proposed to add additional language to the existing requirement that the AO must provide us with descriptions of their procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards. We believe this requirement is not specific enough for enforcement; we have regularly had to request revisions of documents submitted by AOs during our review of applications and re-applications over the years. We proposed to clarify this language by adding the requirement that AOs must also include documentation related to dates established by the AO and how those accreditation dates are determined by the AO when deficiencies may be found during initial and reaccreditation surveys, as well as the AOs process for accreditation decisions based on survey findings. We also proposed to require the AOs to provide as part of this standard, their investigative and organizational process which the AO uses to make determinations on accreditation or the removal of accreditation and recommendation to the Survey Operations Group (based out of the various CMS Survey and Enforcement Division Locations) to remove deemed status of the non-compliant facility. We also proposed additional changes at § 488.5(a)(4)(viii) and refer readers to section IV.G., "Proposal to Require AOs to Provide CMS with Survey Findings", of the proposed rule.

The comments and our responses to the comments are set forth in section IV.E. of this final rule with comment period.

Q. Revisions to § 488.5(a)(4)(xi) (AO Training and Education Programs)

At § 488.5(a)(4)(xi), we proposed to add a new requirement to require AOs to provide CMS with documentation summarizing their staff training programs, whether web-based or via methods such as Power Point presentations or hard-copy materials, which would provide an overview of

how they train surveyors to follow their survey processes, and, where applicable, highlight differences from CMS survey processes. Currently, CMS receives limited training materials that the AO provides to its surveyors; therefore, when conducting survey observations as under our authority at § 488.8(h), it is often challenging to understand differences in survey processes. We may receive an AO's printed materials for training and/or downloaded versions of electronic surveyor training platforms; however, these materials vary. These materials indicate that some AOs collect employees' oral evidence for a survey, as opposed to a more document-focused review done by the SAs. AOs' applications do not always provide us with the entire scope of surveyor education the AO provides to its surveyors, therefore limiting the scope of our review of comparability. The current regulation at § 488.5(a)(8) only requires the AO to give us "[a] description of the content and frequency of the organization's in-service training it provides to survey personnel." CMS frequently asks AOs to submit additional training and education materials during the application review processes. Reviewing the AOs' staff training programs and documentation as outlined in the proposal will provide CMS with greater enforcement capabilities and allow CMS to better assess the AOs' consistency in training against those of required by the SAs. Additionally, because we review AO applications for comparability to CMS survey processes, this additional information would be invaluable to CMS' increased understanding of the AOs' survey processes prior to conducting a survey or during the validation or proposed direct observation process, as discussed in sections II.D. and IV.K.3. of the proposed rule.

The comments and our responses to the comments are set forth in section IV.E. of this final rule with comment period.

R. Revisions to § 488.5(a)(5) (Composition of Survey Team)

At § 488.5(a)(5), we proposed to add requirements which describe the AOs' minimum criteria for determining the size and composition of survey teams for the facilities they accredit. We proposed to require the AO to provide us with documentation describing the criteria or process by which the AOs determines the makeup of their survey teams, based on: (1) the size of the facility to be surveyed, based on average daily census; (2) the complexity of

services offered, including outpatient services; (3) the type of survey to be conducted; (4) whether the facility has special care units or off-site clinics or locations; (5) whether the facility has a historical pattern of serious deficiencies or complaints; and, (6) whether new surveyors are to accompany a team as part of their training.

Our on-site survey observation of AO surveyors has found some concerning practices. For example, some AOs use time limits on the length of their investigations, which can limit the depth and accuracy of the investigation. One AO only permitted themselves a 2-day period in which to conduct a survey of a CAH, whereas the policy of the SA is based on the scope of services provided by the provider, type of survey to be conducted, complexity of services offered and whether the facility has off-site locations. The AO's policies did not allow for flexibility to have the survey exceed 2 days, which may not be enough to allow for all departments to be surveyed, or in the event of an immediate jeopardy or condition-level non-compliance finding, for a closer investigation to be conducted. While fortunately no condition-level non-compliance was identified in that instance, the strict AO policy on timeframe of survey conflicts with our intent for AOs to thoroughly complete the investigative process and did not allow for flexibility in survey length. It appears based on this example that at least one AO may not be giving consideration to the size and number of outpatient departments or provider-based locations per facility and the need to investigate immediate jeopardy or condition-level non-compliance when deciding on time limits for surveys. Additionally, some AOs have not always ensured surveys are conducted on all off-site locations that are still certified under the main campus or facility CCN as is required for SAs in accordance with Appendix A of the SOM—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, Survey Protocol, Task 3 ("Information Gathering/Investigation").¹³ Clarifying these minimum expectations would help AOs meet Medicare conditions and create more consistency between the approaches used by AOs and the SAs.

Comment: The commenter requested clarification. The commenter stated, specifically for CAHs, surveys are usually assigned to a single clinical surveyor for 2 to 3 days yet suggested our proposed provisions would limit

¹³ https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

survey composition to only registered nurses (RNs).

Response: We appreciate the commenter's concern. We proposed to require AOs to be able to provide clear criteria by which the AOs determine the makeup of their survey teams. CMS made note that during observations, some surveyors assigned to a survey were rushed to complete survey activities due to the AOs current policies which may not have accounted for outpatient locations. Additionally, while no fault to an AO, we have observed new staff including leadership in many facilities which have not experienced a survey, where time onsite may be delayed. Our proposal was not to limit or restrict the composition, but rather to ensure that the survey team or surveyor is adequately prepared, can complete the investigative process of a survey, and has flexibility in survey length. CMS is not prohibiting AOs from using physicians as part of the survey teams when surveying CAHs or other providers for compliance. However, we do note that Appendix A and Appendix W of the SOM requires that when a survey calls for one clinical surveyor which must be a registered nurse (RN), that use of a physician in lieu of an RN would not be comparable, as the evaluation of nursing services is specific to an RN role. We would expect that AO surveyor team composition rules meet our minimum requirements and are comparable to those of the SA.

Final Decision: As set forth in section IV.E. of this final rule with comment period, we are finalizing this proposal without revision, with the exception of the modification as outlined below. AOs will be expected to have comparable survey team composition as outlined within our SOM Appendices.

However, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the applicable regulations text stating that a particular provision(s) will become applicable 1 year after the effective date of the final rule with comment period, or any similar language to that effect. We are making this modification for the final rule with comment period since we have decided that all provisions of the rule will become effective 1 (one) year after the publication date and individual provisions will no longer need to be specified in the regulations text.

S. Revisions to § 488.5(a)(6) (Adequate Number of Surveyors for Size of Facility)

At § 488.5(a)(6), we proposed to add language to the existing requirement

that requires the AO to provide documentation demonstrating the overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the overall survey staff to match growth in the number of accredited facilities while maintaining regular re-accreditation intervals for existing accredited facilities. We proposed to add language demonstrating that the AO has enough surveyors to ensure that it can complete all survey activities within the time allotted.

Through our direct observations as part of the application process, we identified several instances in which the scope of document reviews was limited and the content of medical records was not thoroughly reviewed, because it seems the AO surveyors did not have enough time to review records. This may be a systemic issue across AOs.

The comments and our responses to the comments are set forth in section IV.E. of this final rule with comment period.

T. Revisions to § 488.5(a)(12) (Complaint Survey Documentation Requirements)

At § 488.5(a)(12), we proposed to add additional elements critical to the AOs' effective investigation of complaints about their client facilities. Specifically, we proposed that the AO in its application documents for CMS approval of its deeming authority would also have to include: (1) a description of its process for triaging and categorizing complaints about the surveyed facility; (2) timeframes for responding to complaints and a method to track and trend complaints (for example, frequency of similar complaints, complaint type, etc.) received with respect to the AOs accredited facilities; (3) procedures and persons responsible for the review of plans of corrections; and procedures for follow up if the plans of corrections are not adequate; (4) AO requirements for plans of corrections for standard level deficiencies; (5) follow up survey procedures and monitoring of condition-level findings; (6) procedures for addressing immediate jeopardy deficiencies; and (7) sharing of previous deficiency findings or complaints with survey teams. The existing regulatory requirement for the AO to provide procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals is insufficient. Of our 19 AO initial and renewal applications received over the last several years, CMS has requested additional AO documentation for this

particular standard to adequately assess the comparability of survey processes. Strengthening the language will bring greater clarity as to the expectations for documents to the AO submitting an initial or renewal application.

Comment: One commenter stated that AOs currently already provide documentation related to complaints. The commenter suggested that the proposed rule for this section was unclear as it discussed complaints and also discussed overall survey process policies. The commenter questioned if the intent is to provide CMS with these policies only if they are related to complaint investigations.

Response: We appreciate the commenter's request for additional clarification. Section E. of the proposed rule specifically aims to address overall survey comparability among the SAs and AOs. When discussing survey processes this includes complaint investigations and an assessment of AOs to ensure that AOs have a comparable process to Chapter 5 of the SOM. We agree with the commenter that AOs currently provide the information outlined in § 488.5(a)(12) for CMS-review during the application processes. However, we have added additional context and guidance to the rule to be more specific. We believe that by providing this level of specificity within the regulation ensures new organizations seeking to become a CMS-approved AO will be knowledgeable of what CMS is requiring from them to assess comparability. We further believe this will also ensure that CMS receives this documentation with all applications, potentially reducing the number of times CMS must request further information from an AO during the 210-day application review process.

Final Decision: As outlined in section IV.E. of this final rule with comment period, we are finalizing this provision without any changes.

U. Revisions to Accreditation Decision-Making Policies and Reporting § 488.5(a)(13)

At § 488.5(a)(13), we proposed to re-designate existing paragraph (ii) to (iii) and add two new paragraphs at (ii) and (iv). The section currently requires an AO applying or re-applying for deeming authority to provide CMS with a description of its processes for accreditation status decision making. The proposed revision would require the AO to document its specific policies and procedures for reporting accreditation decisions to CMS, including timeframes for notification. Additionally, we proposed to require the AO to submit specific

documentation describing how it will inform us when one of the facilities they accredit withdraws from accreditation. This communication is necessary since it alerts us that such facility will need to be surveyed by the SA next time. By requesting this additional information related to accreditation decisions made by the AOs, as well as reviewing documentation on how the AO notifies their facilities and CMS and our SAs of a facility withdrawing from the AO, CMS will strengthen the existing requirements and create a more consistent, uniform review of the AO survey process for comparability. We also believe we will be able to review the AOs' processes for reporting and identify under what circumstances an AO maintains accreditation of a facility versus the potential CMS decision to drop deeming authority by requiring this information. We have found in several instances that even after our determination of serious health and safety deficiencies in accredited facilities, and CMS' removal of the AO's deeming authority, a facility still remains nominally accredited, which may mislead the public into assuming that the facility has no health and safety concerns. When CMS provides deeming authority to an AO, the expectation is that its standards meet or exceed Medicare conditions and that surveys are comparable to those of the SAs, which may not be the case for an AO accreditation. Facilities may voluntarily end their deeming and accreditation from an AO or be involuntarily removed from deeming authority. When this occurs under the deeming process, the facility is placed under the SA's jurisdiction, meaning the SA will survey and monitor the facility for compliance with Federal requirements. Through the establishment of a more rigorous and comprehensive survey process review during the required application and renewal process, our concerns regarding insufficient compliance would be addressed. The proposed additional and revised requirements would ensure a more uniform assessment and improve our evaluation of AO performance to ensure that surveys conducted by AOs are comprehensive and fully examine all Medicare conditions. We also believe that adding these detailed documentation requirements in regulation would establish a consistent standard across all AOs and would bring uniformity and transparency to the accreditation process.

We proposed that the provisions clarifying the existing requirements to require AOs that accredit Medicare-certified providers and suppliers to

provide us with more detailed descriptions of their survey processes and procedures would become applicable 1 year from the effective date of this final rule with comment period.

The comments and our responses to the comments are set forth in section IV.E. of this final rule with comment period.

V. Require AOs To Provide CMS With Survey Findings (§ 488.5(a)(4)(viii)(A))

General AO survey findings are entered into a CMS database known as the Accrediting Organization System for Storing User Recorded Experiences (ASSURE). This database collects general information about the accreditation survey, such as, date, survey findings and severity of problems indicated by the findings. It generally does not include actual survey reports. Currently AOs provide a limited set of data for surveys within the ASSURE database. We use this information in addressing administrative program elements, and in assessing AO performance. To date, we have not consistently required the AOs to submit copies of their survey reports and related information.

We proposed to modify § 488.5(a)(4)(viii) to require that AOs provide all survey reports to CMS, which would not be disclosed except under the limited circumstances permissible under subsection 1865(b) of the Act. AOs would be required to submit a statement that the organization agrees to provide CMS with a copy of all survey reports, including but not limited to, initial, re-survey, and complaint survey reports, and/or any other information related to survey activities as CMS may require (including corrective action plans) as part of its initial and renewal applications, or upon CMS request. The proposed revision to § 488.5(a)(4)(viii)(A) would expand the requirement from the current requirement that AOs provide survey reports from applicants seeking initial participation in Medicare (with other surveys only upon request). Under our proposal, we would have access to any survey reports, including initial, reaccreditation, complaint surveys, and corrective action plans that CMS may require. These reports, like those of survey agencies, would assist CMS in program analysis including tracking citations issued to accredited facilities to determine whether there is a concern with an AO's performance. Similarly, these reports would assist in reviewing disparate findings in which the SA may have cited a deficiency within an

accredited facility that the AO failed to recognize.

Current §§ 488.5(a)(4)(viii) and 488.5(a)(11)(ii) allow CMS to receive copies of the AOs' survey reports. However, CMS is prohibited by section 1865(b) of the Act as well as § 488.7(b) from disclosing these surveys, with the exception that CMS may disclose such a survey and related information to the extent that they are from home health agencies, or hospice programs, or pertain to an enforcement action taken by CMS. Furthermore, the stem statement of § 488.7 requires that a Medicare participating provider or supplier, in accordance with § 488.4, must authorize its respective AO to release to CMS a copy of its most current accreditation survey including corrective action plans and any information related to the survey that CMS may require." Section 488.7(b) further provides that CMS may publicly disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

CMS has the authority under section 1875(b) of the Act as well as regulations at § 488.8(a)(1) to evaluate the performance of the AOs through review of the organizations' survey activity. Through consistent access to AO survey findings CMS would enhance our ability to analyze survey findings and processes, identify emerging quality of care issues and patterns in AO survey findings, and, ultimately, improve care for our beneficiaries.

As the proposal for revision to § 488.5(a)(4)(viii) is being made in connection with our proposal to require the AOs that accredit Medicare-certified providers and suppliers to use the proposed revised comparable survey processes and procedures, we propose that the revisions to § 488.5(a)(4)(viii) become applicable 1 year from the effective date of this final rule with comment period.

We received two comments which are set forth below.

Comment: One commenter raised concerns that AOs already submit survey reports to CMS and any other report is available on request of CMS, as part of the application process. The commenter also raised concern related to ability for CMS to intake, review, house and access all survey reports from the AOs.

Response: We appreciate the commenter's note that AOs already submit survey reports for their deeming surveys when requested by the CMS. Since CMS is actively working on

technical implementation details, as notated in the final decision, we are not finalizing the proposal to require AOs to submit all survey reports to CMS. CMS will continue to expect, as outlined in our current regulations, that AOs submit survey reports to us upon request.

Comment: One commenter requested clarification on the intended use of the detailed reports and whether the information was necessary to be provided for all surveys.

Response: The intent of the proposed provision for AOs to submit all survey reports was to ensure CMS access to review AO survey findings at any time. Since CMS is actively working on technical implementation details, as described in the final decision, we are not finalizing the proposal to require AOs to submit all survey reports to CMS. CMS will continue to expect, as outlined in our current regulations, that AOs submit survey reports to us upon request.

Final Decision: As set out in our responses to the commenter's concerns, we are not finalizing the proposal to require AOs to submit all survey reports to CMS. CMS will continue to expect, as outlined in our current regulations, that AOs submit survey reports to us upon request.

W. Require That AO Surveyors Must Take the CMS Online Surveyor Basic Training (§ 488.5(a)(8))

Prior to 2006, CMS offered basic surveyor training courses in a traditional in-person classroom setting. Over time, we began providing online basic surveyor training courses for each provider and supplier type (ambulatory surgical centers (ASCs), hospitals, home health agencies (HHAs), etc.), as well as training specific to writing skills for surveyor documentation.

Basic training online courses are designed to provide surveyors with the basic knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare conditions. The online courses also help develop and refine surveying skills, foster an understanding of the survey process, and enhance surveyors' overall ability to conduct and document surveys. Courses are self-paced web-based training. Users may access the online courses at any time and have ongoing access to the course. This affords surveyors the opportunity to refresh knowledge regarding Medicare conditions and processes whenever necessary. The numbers of learners trained in online courses have been steadily increasing since their inception.

Currently, the trainings are publicly available through the CMS Quality, Safety & Education Portal (QSEP) website at <https://qsep.cms.gov>. These trainings are free of charge for AO surveyors and the public at large.

SA surveyors are required to take CMS program-specific trainings along with SA-led orientation, field survey observations, and mentoring as part of a comprehensive training and education program to assure an adequately trained, effective surveyor workforce.

SAs may perform validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, and HHAs) accredited by the AOs. Validation surveys compare the survey findings of the AO to those of the SA to see if there are any disparities. The disparities found between an AO's surveys and an SA's surveys is used in a performance measure called the "disparity rate" and is tracked by CMS as an indication of the quality of the surveys performed by the AO as described in the proposed rule. The disparity findings between AO surveyors and SA surveyors may, in part, be attributed to differences in surveyor training and education, which varies from AO to AO, and may be inconsistent with the CMS-provided SA surveyor training discussed earlier in the proposed rule.¹⁴ We further believe that uniform surveyor training would increase the consistency between the results of the surveys performed by SAs and AOs and have a positive impact on the historically high disparity rates. The Fiscal Year 2020 "Report to Congress: Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program,"¹⁵ showed variation in overall disparity rates, by provider type, as well as by the AO. For example, for the disparity rate from FY 2018 to FY 2019, hospitals, HHAs and ASCs had the only decreases in disparity rates of all the program types, with a 5 percentage point, 11 percentage point and 7 percentage point decrease respectively. The disparity rates for psychiatric hospitals increased by 7 percentage points from FY 2018 to FY 2019. The disparity rates for CAHs and hospices increased by 5 percentage points and 3 percentage points respectively from FY 2018 to FY 2019. On November 9, 2021, we published a final rule in the **Federal Register**, entitled, "Medicare and Medicaid Programs; CY 2022 Home

Health Prospective Payment System Rate Update" (86 FR 62240). In that final rule, we finalized implementing regulations, codified at § 488.1115(a), to require AO surveyors to have successfully completed the relevant CMS-sponsored basic hospice surveyor training prior to conducting any hospice program surveys in accordance with Division CC, section 407 of the Consolidated Appropriations Act of 2021 (CAA 2021) (89 FR 62367 to 62370).

In addition to these hospice program surveyor training requirements, we proposed to amend the provision at § 488.5(a)(8) by adding new paragraphs (a)(8)(i) to (a)(8)(iv), which would impose a new training requirement on those surveyors working for AOs that accredit Medicare-certified provider and suppliers (89 FR 12019). We noted that we had previously made a similar proposal in the calendar year (CY) 2019 Home Health Prospective Payment System Rate Update proposed rule (83 FR 32470, July 12, 2018). However, we did not finalize this proposal, due to commenters' concerns with course enrollment access and the amount of time we estimated it would require for an AO surveyor to complete the course.

CMS stated it believes the concerns raised by interested parties during the previous proposed rule comment period had been addressed by narrowing the scope of the required training and providing additional details regarding implementation. Therefore, we again made this proposal to address the consistency of surveyor knowledge and interpretation, since we proposed to require the AOs to use Medicare conditions and survey processes. We describe the courses required as well as the estimated time for each in section VII. of the proposed rule. We proposed at § 488.5(a)(8) a description of the content and frequency of the organization's in-service training it provides to survey personnel, and we would also require AOs to submit their training materials to CMS as part of the application process. We additionally proposed at § 488.5(a)(8)(i) to require that all AO surveyors complete two CMS mandatory courses which instruct surveyors, for all facility types, how to document their findings in the standardized survey materials. We stated we would also require AO surveyors to complete all relevant CMS online program-specific basic surveyor training, which we have already established for State and Federal surveyors. For example, AO hospital surveyors would be required to take the following CMS online courses: (1) Principles of Documentation for Non-

¹⁴ <https://qsep.cms.gov>.

¹⁵ The most recent Report to Congress may be accessed at <https://www.cms.gov/files/document/qso-22-06-ao-clia.pdf>.

Long-Term Care; (2) Basic Writing Skills for Surveyor Staff; and (3) Hospital Basic Training. A hospice surveyor would take the Principles of Documentation for Non-Long-Term Care; Basic Writing Skills for Surveyor Staff; and Hospice Basic Training courses. If an AO surveyor participates in both hospital and hospice surveys, they would take the two documentation courses and the two basic training courses. These courses would be the minimum mandatory requirements for AO surveyors. In addition, we stated we would also require that all AO surveyors would be required to take any updates to the CMS online surveyor courses when necessary. Any training above and beyond the minimum CMS online surveyor courses would be at the AO's discretion.

We proposed at § 488.5(a)(8)(ii), that AO surveyors hired after the date of implementation of this provision would be required to complete the required CMS online surveyor training courses prior to serving on a survey team (except as a trainee). We stated we believed a time requirement is necessary to ensure that the AO surveyors take the CMS online surveyor training in a timely manner and is consistent with the existing hospice program surveyor training requirements at 42 CFR 488.1115(a).

We proposed at § 488.5(a)(8)(iii) that AOs would also be required to document that the CMS online surveyor training courses were completed and the date of completion in the surveyor's staff personnel records. The purpose of this requirement would be to allow the AO and CMS to have records that document that the requirements had been met by each surveyor. We stated we would review these training records during our initial and renewal application review processes. We further proposed at § 488.5(a)(8)(iii) to require that the AOs maintain this documentation of course completion by each surveyor for no less than one accreditation cycle, so we could verify that AO surveyors had completed the online courses as part of the AO's next renewal application process. One accreditation cycle would be defined as the period of time during which the AOs' CMS approval is in effect, starting from the date of application approval and continuing until the date of approval of the next renewal application.

We explained this proposed requirement would align with and expand upon recent regulations that require hospice program AO surveyors to successfully complete the CMS online Basic Hospice Surveyor Training

prior to performing any hospice program surveys.

In addition, we proposed at § 488.5(a)(8)(iv) that the provisions proposed at §§ 488.5(a)(8)(i) through (a)(8)(iv) would be applicable beginning 1 year after the effective date of this final rule with comment period.

The comments and our responses to the comments are set forth below.

Comment: We received five comments specifically related to AO surveyors taking the CMS online basic training and documentation courses. Comments were generally accepting of the proposal but noted that AOs already provide comparable programmatic training to their surveyors. A few were strongly supportive of the requirement for AO surveyors to take the same online surveyor basic training as the SA surveyors to promote consistency in surveyor knowledge and interpretation in the survey process.

Response: We appreciate the support and agree that for consistency purposes, AO surveyors and SA surveyors should be required to take the same online surveyor basic training courses.

Comment: A commenter requested clarification on the proposed regulatory language that the AO will maintain this documentation for no less than one accreditation cycle. They questioned the use of "accreditation cycle" and requested clarity on whether CMS wanted AOs to maintain their completed training indefinitely or only for a 3-year period which is the timeframe for facility accreditation cycles.

Response: We appreciate the opportunity to clarify this language and provide a clearer expectation for maintaining surveyor training records. As noted in Section H. of the proposed rule preamble, one accreditation cycle would be defined as the period of time during which the AOs' CMS approval is in effect, starting from the date of application approval and continuing until the date of approval of the next renewal application. As part of the deeming application review process, the CMS team reviews a sample of the AO surveyor files to ensure they meet the basic requirements for surveying, which includes but is not limited to any required licensure, education, and training. We would expect to see documented completion of the required CMS online training courses within the surveyor files. Therefore, we proposed the language of retaining that information for one accreditation cycle meaning one application cycle. However, the commenter raised a good point about needing clarity in the actual timeframes. In order for CMS to ensure

oversight of these requirements and to be consistent with the proposed times for completing the training, we would need to see when the initial surveyor training was completed as well as any subsequent completions due to CMS required updates.

Final Decision: After consideration of the public comments received, we are finalizing the requirement for AOs to complete two mandatory CMS online documentation courses and the relevant program-specific CMS online basic surveyor training course. However, we are modifying the language at 488.5(a)(8)(iii) for maintaining documentation "for no less than one accreditation cycle" to "of the initial completion and any subsequent completions." We believe this revision is consistent with the original intent of the proposal.

However, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the applicable regulations text stating that a particular provision(s) will become applicable 1 year after the effective date of the final rule with comment period, or any similar language to that effect. For this final rule with comment period, we are making a modification that all provisions of the rule will become effective 1 (one) year after the publication of this rule.

X. Establish Criteria for "National in Scope" (§ 488.1)

On April 5, 2013, we published a proposed rule in the **Federal Register** entitled, "Medicare and Medicaid Programs; Survey, Certification, and Enforcement Procedures" (78 FR 20564), hereinafter referred to as the "2013 AO oversight proposed rule", which proposed modifications to the CMS AO oversight regulations. In the 2013 AO oversight proposed rule, we stated that we proposed to revise § 488.5 and explained that the demonstration of "national in scope" by an AO must be specific to each accrediting program for which new or renewed CMS approval is sought (78 FR 20567). We also proposed to define "national accreditation organization" in § 488.1 and explained that CMS requires an AO program seeking initial approval to "already be fully implemented and operational nationally" (78 FR 20566). In the 2015 AO final rule (80 FR 29796), we explained that we would not require an AO to reach facility minimums or meet specific geographic distribution requirements to be deemed national in scope (80 FR 29802). We did this because we believed AOs should be able

to demonstrate the ability to scale over time.

We have never specified objective criteria for “national in scope” in regulations. And, as the number of AOs (and the number of applications from AOs) grow, it is in the best interest of CMS and the AOs to establish specific criteria to define “national in scope.” Establishing a specific definition and criteria for what CMS would consider to constitute widely located geographically across the United States (U.S.) would ensure that CMS is objective and consistent during the AO application review process when deciding whether an AO’s accreditation program is, in fact, national in scope. This would further ensure that new AOs, submitting applications for deeming authority, are represented across the nation and not clustered within one area of the country. Furthermore, this also provides an opportunity for facilities to choose any AO with a CMS-recognized accreditation program for its provider/supplier type, versus only having one AO to choose.

Therefore, we proposed to add a definition for “National in scope,” to the CMS regulations at § 488.1 to establish criteria for determining when an AO’s accreditation program meets the requirement. We proposed that the definition, “National in scope” would mean that the providers and suppliers accredited by an AO under a specific accreditation program, must be widely located geographically across the U.S. The proposed requirement for “national in scope” would have two components. First, the AO would be required to have accredited at least five providers or suppliers under the accreditation program in question. Second, the five providers or suppliers accredited by the AO under that accreditation program would have to be geographically located in at least five out of the six geographic regions.

The addition of the proposed definition of “National in scope” requires that we also define the term “geographic regions of the U.S.”, because this is a component of the definition of “National in scope”. Therefore, we proposed to add a definition for “Geographic regions” at § 488.1.

The proposed six geographic regions consist of six groups of States that cover the northeast, southeast, mid-west, central, south, and western areas of the United States which provide six possible areas in which an AO could accredit a provider or supplier to meet the second part of the “national in scope” test. In contrast, the use of a simple north, south, east and west

geographical division of the U.S. would only provide four possible regions in which an AO have accredited providers and suppliers.

We explained in the proposed rule that we believe that use of these six geographic regions as the geographical test for “national in scope” would provide a standard by which CMS could measure whether an AO has accredited the required number of healthcare providers or suppliers in varying geographical areas of the U.S. We further believe the requirement that an AO have one provider or supplier in at least five of the six geographic regions would demonstrate the AO’s ability to scale up and develop a national presence over time and align with CMS’ current consortiums or regions.¹⁶ AOs would need to be able to demonstrate this standard in their initial applications for deeming authority, as well as continue to meet this definition, which would be evaluated within their renewal applications.

We also explained that we believe that this proposed definition of “Geographic regions” would ensure that we are impartial and consistent during the application review process. We also believe that this proposed definition would provide the AOs with objective criteria for the definition of “national in scope” that they can strive to meet prior to submitting an application, especially for possible new accrediting programs.

We note that § 488.1 currently defines “national accrediting organization” as “an organization that accredits provider entities (as that term is defined in section 1865(a)(4) of the Act) under a specific program and whose accredited providers and suppliers are widely located geographically across the U.S.” Because we proposed to add a specific definition for “National in scope” to § 488.1, that requires a two-part test, we explained it would also be necessary to update the definition of “National accrediting organization” to add the requirement that the AO must be national in scope.

This would ensure that new AOs submitting applications for Medicare approval of their accreditation programs, would be required to show that they have the ability to provide accreditation services to providers and suppliers across the nation and not just those clustered within one area of the country. Making it a requirement that AOs be capable of providing accreditation services throughout the

U.S. provides the opportunity to healthcare providers and suppliers in all regions of the U.S. to obtain deeming accreditation from the AO of their choice.

Therefore, we proposed to revise the existing definition of “National accrediting organization” at § 488.1. The proposed new definition of “National accrediting organization” would read as follows “*National accrediting organization* means an accrediting organization that is national in scope and accredits provider or suppliers, under a specific accreditation program.”

The comments and our responses to the comments are set forth below.

Comment: We received three comments in strong support of the definition of “national in scope.” One commenter stated the clarification around national in scope determinations, along with defining the regions is helpful for new programs. One commenter stated their support and urged CMS to finalize its adoption, and the other commenter stated this change was a much-needed clarification of the application process.

Response: We appreciate the commenters’ support for defining “national in scope.” We agree that this clarification is helpful for new programs as well as new organizations wishing to apply for Medicare deeming authority.

Comment: We received one comment disagreeing with the definition as the commenter suggested the defined regions are inconsistent with CMS’ current regions. Additionally, the commenter noted that these provisions may create unintended competitive barriers to entry within the accreditation market. This commenter provided examples where an AO may have providers or suppliers in a Northeast State, a South and Western State, but no providers available in the Southeast or Central regions due to accreditation markets and demographic conditions. The commenter suggested that AOs would not be able to meet eligibility requirements since they would only have four regions rather than the required five. The commenter further implied that the language defined in section 1865(a)(4) of the Act, which states national accrediting organization to mean an organization that accredits provider entities, under a specific program and whose accredited provider entities under each program are widely located geographically across the U.S. is sufficient.

Response: While we appreciate these concerns, in 2020, CMS underwent a reorganization of the CMS Regional Offices, now known as the CMS Locations. The proposed regions

¹⁶ CMS Organizational Chart, Page 17, Survey Operations Group https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Downloads/CMS_Organizational_Chart.pdf.

outlined within the provisions align with the coverage of CMS' current six geographic locations of the Northeast, Atlanta, Chicago, Dallas, Denver and Seattle Locations. Furthermore, the requirement for five of the six geographic locations demonstrates that an organization is national as intended by the existing regulations and section 1865(a)(4) of the Act. For instance, an CMS-approved existing AO or a new organization wishing to apply for deeming authority would only be required to have one survey or provider seeking deemed status in five of the six locations, (1) Northeast: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont; (2) Southeast: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee; (3) Midwest: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin; (4) Central: Iowa, Kansas, Missouri, and Nebraska; Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming; (5) South: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas; (6) Western: American Samoa, Arizona, California, Hawaii, Commonwealth of the Northern Mariana Islands, Guam, Alaska, Idaho, Nevada, Oregon, Washington. This means the organization would only need to demonstrate national presence in five States out of 50 States. We do not believe this would cause undue burden.

Comment: We received one comment raising concerns on the implications of transplant deeming programs. The commenter stated that in the case of transplant programs, there are approximately 260 programs nationwide and that the proposal would limit the number of programs available to demonstrate AO compliance. The commenter recommended that CMS consider limiting the proposal for transplant to three of the six regions to meet CMS' proposed definition of "national in scope".

Response: We appreciate the commenter's concerns related to transplant programs and the definition of "national in scope". We note, to date CMS has not established or approved a transplant deeming program. We will take the commenter's concerns into consideration.

Comment: We received one comment suggesting that CMS' proposed definition should not restrict the exploration of new methodologies and

innovative approaches to accreditation. The commenter stated that instead of focusing solely on geographic coverage, accreditation standards should be rooted in scientifically developed criteria endorsed by nationally recognized bodies. The commenter believes this would ensure evolution with advancement in healthcare practices.

Response: We appreciate the commenter's concerns. The intent for defining the geographic regions is to provide a method for assessing and ensuring organizations with deeming authority, or seeking deeming authority are of national presence as intended by the existing regulations. The proposed definition would not limit innovation or new methodologies but rather ensure consistency and one set process across all AOs.

Final Decision: After consideration of the comments received, we are finalizing the definition and criteria as set out in the proposed rule without change.

Y. Revise the Definition of "Rate of Disparity" and To Use the Process and Outcome Disparity Rates and Performance Measures (§ 488.1)

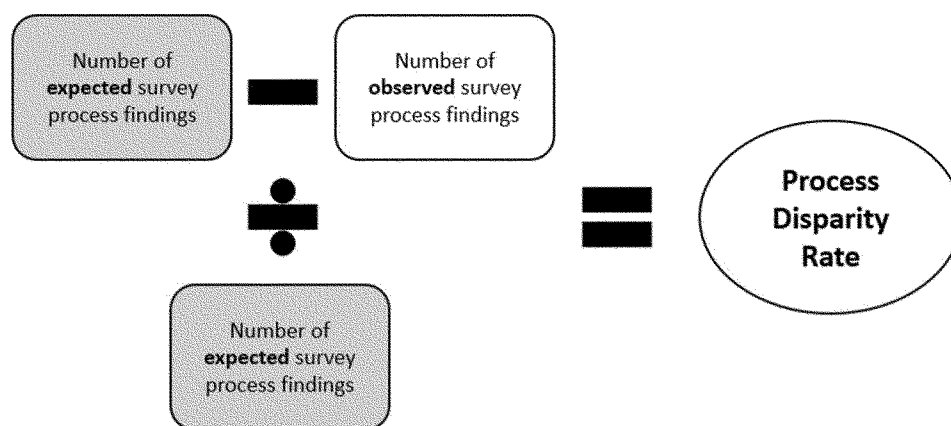
In section IV.L. of the proposed rule, we proposed to revise the validation program by using two different types of validation surveys, which are: (1) the 60-day "look-back" validation survey and, (2) a direct observation survey approach, to evaluate the performance of the AOs. Validation surveys are full surveys performed for a representative sample of accredited facilities. Look-back validation surveys are completed by the SA within 60 days of an AO's full accreditation survey for the same facility. In some cases, representative sample "mid-cycle validation surveys" may be conducted whether or not there has been a preceding AO survey. The analysis of the validation survey findings is reported as a "disparity rate". As previously discussed in section II.C. of the proposed rule, this rate of disparity is currently defined at § 488.1 as the percentage of all sample validation surveys for which a SA finds noncompliance with one or more Medicare conditions and where no comparable condition-level deficiency was cited by the AO and it is reasonable to conclude that the deficiencies were present at the time of the AO's most recent survey of that provider or supplier. The goal of the validation process is to determine whether the findings of the two surveys are comparable.

In calculating the current rate of disparity, the numerator is the number of surveys in which the AO missed at least one condition-level deficiency found by the SA and the denominator is the number of surveys in the validation sample. The result is the percentage of validation surveys where the AO missed finding a significant deficiency identified by the SA. If the AO missed at least one serious deficiency in a third of the validation surveys, the disparity rate would be 33 percent. A lower disparity rate indicates better AO performance.

The existing definition of "rate of disparity" is not applicable to the direct observation validation survey (DOVS) because it focuses on the survey process as opposed to the outcome of the survey. Therefore, we proposed to revise the current definition of "rate of disparity" located at § 488.1 and replace this definition with two new definitions, which are "outcome disparity rate" and "process disparity rate".

The outcome disparity rate would be applicable to the look-back validation survey, which is the current method of validation. We proposed that the new definition of "outcome disparity rate" would generally remain as the existing definition of "rate of disparity" at § 488.1 but would be revised and retitled as "outcome disparity rate" to distinguish it from the "process disparity rate".

When calculating the process disparity rate, the numerator for one provider or supplier for which the DOVS is done would be the number of observed survey process findings and the denominator would be the number of expected survey process findings for all DOVS. The observed survey process findings are the actual number of Medicare conditions that were observed being surveyed for by the AO. The expected survey process findings are the total number of Medicare conditions that the AO should have examined during the survey observation. The result would be reported as a percentage. A high percentage indicates greater disparity between the expected AO performance on DOVS and the actual AO performance on the DOVS. For example, a DOVS with 75 observed process findings out of 100 expected process findings would yield a process disparity rate of 25 percent $(((100-75) \div 100) * 100)$, indicating a 25 percent difference between what is observed and what is expected (See Figure 1).



The proposed process disparity rate would be applicable to the DOVS and would be defined as the difference between the observed survey process findings and the expected survey process findings.

The overall process disparity rate for a particular AO would be calculated by taking the average of the process disparity rate for each DOVS performed for an accreditation program of an AO. Preliminary results obtained from the VRP pilot during the period of June

2018 to July 2019 are shown in Figure 2. While we will analyze and explain the pilot data when more is available, we share preliminary data here as a sample of how the process disparity rate will be calculated.

Provider Type	Number of Direct Observation Validation Surveys	Average Process Disparity Rate
Ambulatory Surgery Center	8	19%
Home Health Agency	3	1%
Hospital	11	10%
Psych Hospital	3	7%
Hospice	1	N/A

NOTE: Caution should be used in drawing broader inferences from the data in Figure 2 of this final rule with comment period because the sample size is very small.

Final Decision: We received no comments specific to this provision. We are finalizing the removal of the definition of “Rate of disparity” and adding the definition of “Process disparity rate,” as we proposed. However, we are not finalizing the addition of the proposed definition of “Outcome disparity rate” because this term only applies to the look-back validation surveys, which we are also not finalizing in this rule.

Additionally, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the regulations text stating that a particular provision(s) will become applicable beginning on a specific date, or any similar language to that effect. We are making a

modification that all provisions of the rule will become effective 1 (one) year after the publication of this final rule with comment period.

Z. Require AOs To Submit a Publicly Reportable Plan of Correction for Unacceptable Performance Measure Scores (§§ 488.8(a)(2) and (4))

In section IV.J. of the proposed rule, we proposed to revise the definition of “disparity rate” to include process and outcome disparity rates. We noted that the proposed definition of outcome disparity rate generally remains the same as the currently defined definition of disparity rate. We further noted that we have been measuring the outcome disparity rate as a performance measure for years. To monitor an AO’s ongoing performance as provided by section 1875(b) of the Act and § 488.8, we

proposed in paragraph (a)(2) of § 488.8 to expand the types of validation activities included in the performance review. We also proposed in paragraph (a)(4) to require AOs to submit a plan of correction that would be publicly reported, when the AO’s performance on survey activities identify disparity concerns either through the outcome disparity rates or process disparity rates.

We proposed to revise § 488.8(a)(2) to broaden activities that CMS would evaluate in our ongoing review of AOs. Specifically, we would monitor the results of our outcome disparity rate, the look-back validation surveys, complaint surveys, and the process disparity rate as determined by DOVS. In addition, we proposed to revise § 488.8(a)(4) to require that when an AO’s outcome disparity or process disparity performance measure scores, as

determined from look-back and DOVS, reveal that the AO's accreditation survey activities do not meet an acceptable performance threshold established by CMS, the AO would be required to submit an acceptable plan of correction to CMS which identified corrective action the AO proposed to take to correct their performance.

We proposed at § 488.8(a)(4)(i), to require that the plan of correction be submitted to CMS for review within 10 business days of the AO being notified by CMS of not meeting the acceptable performance threshold. We also proposed that to be acceptable, the AO's plan of correction would have to: (1) document specific actions being taken by the AO to address improving performance (proposed § 488.8(a)(4)(i)(A)); (2) document the timeframe for implementation of the plan (proposed § 488.8(a)(4)(i)(B)); (3) plan for ongoing monitoring of the plan of correction toward achieving an acceptable level of performance (proposed § 488.8(a)(4)(i)(C)); and (4) identify the individual responsible for implementation and monitoring of the

acceptable plan of correction (§ 488.8(a)(4)(i)(D)).

CMS would subsequently communicate with the AO on the acceptability of the plan of correction and would provide oversight of implementation. We proposed at § 488.8(a)(4)(ii) that upon review and approval of the submitted plan of correction, CMS would provide ongoing evaluation of the progress of plan implementation.

Finally, we proposed at § 488.8(a)(4)(iii) that the AO's plan of correction be made subject to public reporting by CMS. Once approved, the plan of correction would be publicly available for review. This means that the acceptable plan of correction would be displayed publicly by CMS once approved. This plan of correction would be utilized to increase an AO's accountability for maintaining performance standards.

The purpose of this oversight is to improve AO survey activity outcome and processes with the presumption that improvements toward acceptable performance would improve the health

and safety of patients receiving services in Medicare-participating facilities. This is an effort to strengthen AO oversight by requiring AOs to address issues and take corrective action to improve to an acceptable level of performance. Previously, this was handled verbally or through written correspondence between the AO and CMS staff without a specific plan of correction.

The proposed publicly reportable plan of correction would be based on both an analysis of data to identify the outcome and process disparity performance measure(s) for which the AO did not meet acceptable performance as well as significant instances of disparity. An analysis matrix would outline both outcome performance and process performance areas of successful achievement and those areas for which achievement was less than acceptable as demonstrated by the outcome and process disparity rate data. An example of what a plan of correction matrix might look like is indicated in Figure 3.

Figure 3

Overall Condition Citation Performance

OUTCOME + PROCESS +	OUTCOME + PROCESS -
• QAPI • Nursing Services ** • Discharge Planning • Patient's Rights • Infection Control • Medical record requirement for psychiatric hospitals *	• ASC – Patient's Rights • ASC – Governing Body and Management* • Physical Environment • ASC – Environment * • ASC – Infection Control** • Medical record services *
OUTCOME - PROCESS +	OUTCOME - PROCESS -
• Organ, tissue and eye procurement • Emergency Services** • Medical Staff** • Emergency Preparedness** • Radiologic Services** • Utilization Review**	• ASC – Pharmaceutical Services * • ASC – Emergency Preparedness** • ASC- QAPI * • Food and Dietetic Services ** • Respiratory Care Services **

* Includes condition citations matched from validation surveys only.

** Includes condition-level citations matched from complaint surveys only.

The matrix in Figure 3 is representative of FY 2018 data collected during the DOVS, look-back validation surveys, and complaint surveys (which investigate specific allegations) conducted by the SA at AO facilities. If deficiencies were cited first by the AO and validated by the SA during a look-

back or complaint survey this is considered an outcomes match. If the AO survey process under direct observation by the SA did not raise concerns, this indicates a positive outcome and positive process, which are represented in the top left box. The top right and bottom left boxes indicate

where improvements need to be made in either the process or outcome of the respective Medicare requirement, while the bottom right box shows where improvements in both measures should be made.

The AO would be able to use this matrix to identify if the less than

acceptable performance is either outcome-focused, process-focused, or both. The proposed plan of correction would be required to be submitted to CMS within 10 business days following CMS' notification to the AO of less than acceptable performance, and would have to address the areas of improvement and the specific actions to be taken by the AO to improve those areas on a sustainable basis.

The comments and our responses to the comments are set forth below. We received a total of four public comments on this provision.

Comment: One commenter was supportive of this proposal and urged its adoption.

Response: We appreciate the commenter's support of this provision.

Comment: One commenter was pleased that CMS continues to demonstrate its commitment to improving the quality of care across the healthcare continuum.

Response: We appreciate the commenter's support for this provision as we continue our commitment to improving the quality and safety of care for patients.

Comment: One commenter supported the requirement for AOs to submit a publicly reported plan of correction for unacceptable performance measure scores. The commenter believes this will ensure quality control across AOs and ensure unacceptable performance is addressed.

Response: We appreciate the commenter's support for this provision as we believe the transparency of AO oversight can improve the quality of AO performance.

Comment: One commenter strongly opposed this provision to make plans of correction public believing it sets up the AO community to liability in the current litigious environment and may have a negative impact on providers/

suppliers choosing AOs. The commenter noted that accreditation is voluntary and noted that providers/suppliers may use accreditation for initial surveys and then return to State jurisdiction after they receive their CCN. They believe this puts an additional burden on State agencies and will cause additional delays in State agency survey activity for these providers/suppliers.

Response: We recognize the concerns of the commenter and the potential impact on business practices, but we have an obligation to be transparent in our oversight of AO performance. Public reporting provides transparency and allows providers the opportunity to make an informed decision about the performance of an AO when deciding the AO that best meets their needs.

Final Decision: We are finalizing this section and modifying the proposed language of the requirements to remove the terms, "outcome disparity rate" and "look-back validation survey" from paragraphs (a)(2) and (a)(4) of this section.

AA. Revisions to the AO Survey Validation Program (§ 488.9)

Prior to discussing our finalized provisions, the following provides (1) background on validation surveys, (2) background on look-back validation surveys, and (3) background on additional approaches to conduct validation surveys, before (4) introducing CMS' proposed changes.

1. Background on Validation Surveys

Section 1864(c) of the Act permits the SAs to perform validation surveys of provider and supplier types participating in Medicare via accreditation under section 1865(a) of the Act; the SA surveys validate the AOs' accreditation processes. The accreditation validation program is one component of CMS' oversight of AOs

with approved Medicare accreditation programs, and consists of two types of validation surveys:

- Complaint surveys—focused surveys based on complaints from patients, family, facility staff, or other governmental entities, which, if substantiated, could indicate serious non-compliance with one or more Medicare conditions; and
- Validation surveys—full surveys, which are routinely performed for a representative sample of deemed facilities as part of the annual CMS–AO representative sample validation survey program. These surveys are completed by the SA within 60 days of an AO full accreditation survey for the same facility.

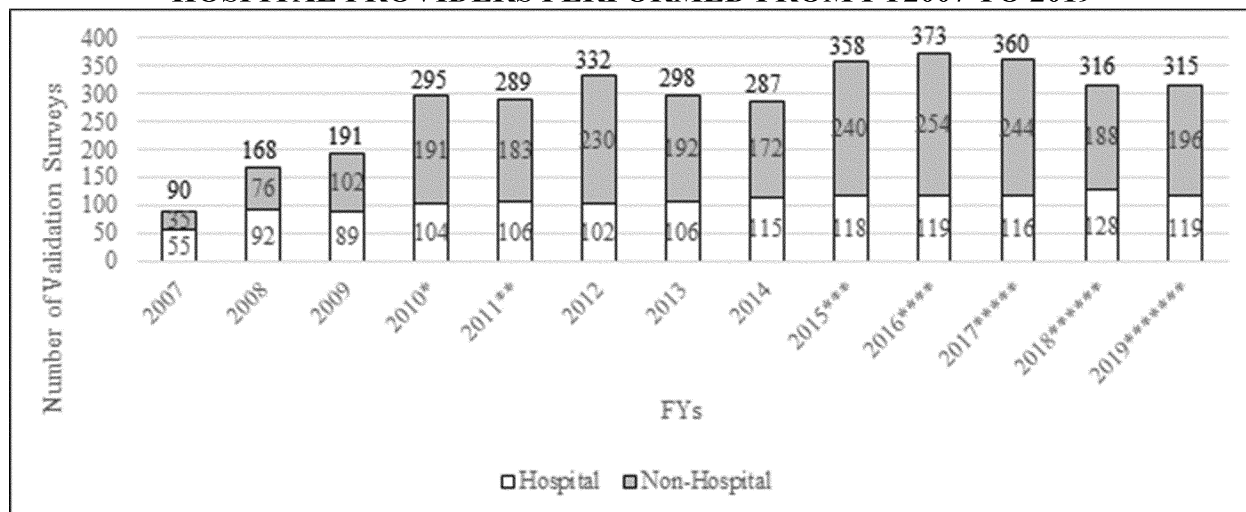
Prior to 2007, section 1875 of the Act required CMS to report to Congress annually only on The Joint Commission's (TJC's) hospital accreditation program.¹⁷ In FY 2007, we expanded this oversight and began conducting representative sample validation surveys for selected non-hospital facility types (CAHs, HHAs and ASCs), in addition to those already being performed for accredited hospitals. In FY 2010, hospice look-back validation surveys were added, and in FY 2011, psychiatric hospital validation surveys were added. In FY 2019, we conducted a total of 315 representative sample look-back validation surveys for six facility types across the AOs.¹⁸ This total was comprised of 119 hospital surveys (including 20 psychiatric hospitals) and 196 non-hospital validation surveys. (See Figure 4.)

Figure 4

¹⁷ Section 125(b)(4) of Public Law 110–275 (2008), which was subsequently revised to apply to all AOs.

¹⁸ Outpatient physical therapy and rural health clinics were not part of the validation sample.

NUMBER OF SAMPLE VALIDATION SURVEYS FOR HOSPITAL AND NON-HOSPITAL PROVIDERS PERFORMED FROM FY2007 TO 2019



[68]

*In FY 2010: The non-hospital total of 191 includes 72 mid-cycle ASC validation surveys.

**In FY 2011: The hospital total of 106 includes 33 mid-cycle LTCH validation surveys.

***In FY 2015: The hospital total of 118 includes 16 psychiatric hospital validation surveys.

****In FY 2016: The hospital total of 119 includes 21 psychiatric hospital validation surveys.

*****In FY 2017: The hospital total of 116 includes 21 psychiatric hospital validation surveys.

*****In FY 2018: The hospital total of 128 includes 21 psychiatric hospital validation surveys.

*****In FY 2019: The hospital total of 119 includes 20 psychiatric hospital validation surveys.

Since 2007, CMS has worked to strengthen its oversight of AOs and increase the number of validation surveys. The recent history of completed validation surveys is as follows:

- 2015: 118 hospital and 240 non-hospital surveys totaling 358 surveys.
- 2016: 119 hospital and 254 non-hospital surveys totaling 373 surveys.
- 2017: 116 hospital and 244 non-hospital surveys totaling 360 surveys.
- 2018: 128 hospital and 188 non-hospital surveys totaling 316 surveys.
- 2019: 119 hospital and 196 non-hospital surveys totaling 315 surveys.

These numbers represent a 250 percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 315 in FY 2019. During the same time period, the number of non-hospital validation surveys conducted increased by 460 percent, from 35 surveys in FY 2007 to 196 surveys in FY 2019. The number of hospital (including psychiatric hospital) validation surveys conducted increased by 116 percent, from 55 surveys in FY 2007 to 119 surveys (99 hospital validation surveys plus 20 psychiatric hospital validation surveys) in FY 2019.

2. Background on Look-Back Validation Surveys

The purpose of look-back validation surveys of deemed providers or

suppliers is to assess the AO's ability to assess compliance with Medicare conditions. These surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare accreditation program full survey. The SA performs these surveys without any knowledge of the findings of the AO's accreditation survey. CMS determines the number of look-back validation surveys to perform for each AO based on the total number of facilities the AO accredits for Medicare participation, as well as the overall budgeted validation survey targets, by State and facility type.

The proportion of look-back surveys completed for deemed facilities is calculated by dividing the number of look-back validation surveys conducted by the total number of deemed facilities. The proportion of deemed facilities that received a look-back validation survey in FY 2019 is as follows:

- *Hospitals*: Three percent of deemed hospitals received a validation survey in FY 2019 (99 validation surveys conducted out of 3,332 deemed facilities).
- *Psychiatric Hospitals*: Four percent of deemed psychiatric hospitals received a validation survey in FY 2019 (20 validation surveys conducted out of 466 deemed facilities).

- *CAHs*: Three percent of deemed CAHs received a validation survey in FY 2019 (13 validation surveys conducted out of 449 deemed facilities).

- *HHAs*: Two percent of deemed HHAs received a validation survey in FY 2019 (84 validation surveys conducted out of 4,034 deemed facilities).

- *Hospices*: One percent of deemed hospices received a validation survey in FY 2019 (32 validation surveys conducted out of 2,458 deemed facilities).

- *ASCs*: Four percent of deemed ASCs received a validation survey in FY 2019 (67 validation surveys conducted out of 1,803 deemed facilities).

3. Background on Additional Approaches To Conducting Validation Surveys

Over the years, we have looked for ways to improve the validation survey process and the disparity rate methodology. As discussed earlier in this final rule with comment period, the disparity rate for various provider types ranged between 8 percent for HHAs and 46 percent for CAHs.

To address concerns about high disparity rates, CMS has been testing a Validation Redesign Program (VRP) pilot since 2018. In the VRP pilot, instead of the separate look-back validation survey, a direct observation

of the AO's survey is performed. During the DOVS, the SA surveyors are present when the AO surveyors perform an accreditation survey, so that they can directly observe and evaluate the ability of the AO surveyors to assess compliance with the Medicare conditions. The purpose of this direct observation is to evaluate, in real time, the AO's performance on the survey process. The real time observation of the survey allows the SA surveyors to make suggested improvements and address any concerns with AOs immediately.

From June 2018 through August 2019, CMS conducted a total of 30 VRP pilot surveys in 17 States in the acute care hospital program (11), ASC program (10), psychiatric hospital program (3), HHA program (5) and hospice program (1). This proposed direct observation validation process has yielded additional information about the extent to which the AO's process meets or exceeds the survey process used by the SA surveyors. Our findings from our VRP pilot surveys included the following:

- Certain AOs have rigid survey schedules that proved to be burdensome to the SA observers while onsite due to difficulty of SAs in coordinating their own scheduled and mandated survey work of non-accredited facilities in their State with these AO survey schedules.
- AOs may have strict timeframes for each section of the survey to which they adhere, regardless of the findings or need to further investigate an issue within a facility.
- Not all AOs survey offsite locations consistently for all portions of the survey.
- Certain AO survey methodology favored a "yes/no" or "have/don't have" format versus a more in-depth investigative approach followed by the SAs and detailed in the SOM; the survey approach used by some AOs in certain aspects of the survey could significantly affect the survey outcomes, for example missing subtle but systemic issues at facilities that could adversely impact patient care and safety if not identified during the survey.
- Verbal assertion may have been considered adequate evidence of a facility's compliance, without verification via observations and/or document review.

4. Revisions to the Existing AO Survey Validation Program (Proposed Revisions to § 488.9)

We proposed to revise the validation program by using two different types of validation surveys, which are: (1) the look-back validation survey and (2) a DOVS approach, to evaluate the

performance of the AOs. We proposed that direct observation surveys can be performed by the SA or CMS surveyors.

Specifically, we proposed at § 488.9(b) to revise the types of validation surveys. We proposed to continue using the look-back validation survey, through use of a sample of facilities in each program type, which would take place within 60 days following the AO surveys. These 60-day validation surveys are referred to as look-back validation surveys.

We proposed at § 488.9(b)(2) to also require validation using the DOVS, which focuses on real-time observation and evaluation of the AO's survey process. At § 488.9(c), we proposed rules for look-back validation surveys. At § 488.9(d), we proposed the rules for selection for look-back validation surveys. More specifically, proposed § 488.9(d)(1) would provide that "a provider or supplier selected for a look-back validation survey must cooperate with the SA that performs the look-back validation survey." We proposed at § 488.9(d)(2) that "if a provider or supplier selected for a look-back validation survey fails to cooperate with the SA, it will no longer be deemed to meet the Medicare conditions or requirements, will be subject to a review in accordance with paragraph (a) of this section, and may be subject to termination of its provider agreement under § 489.53 of this chapter".

At § 488.9(e), we proposed rules for the DOVS. These rules would include the following: (1) All DOVS would be unannounced to the AO and the facility being surveyed (proposed § 488.9(e)(1)); (2) The SA or CMS surveyors would generally be assigned to the AO surveyors on a 1:1 basis, matching the experience of the accreditation surveyor where possible, and using the CMS approved standards and processes to determine compliance with the Medicare conditions (proposed § 488.9(e)(2)); (3) the SA or CMS surveyors would observe the AO survey in accordance with CMS established policies and procedures and would report the findings directly to CMS (proposed § 488.9(e)(3)); and (4) where the SA or CMS surveyors disagree with the findings of the AO surveyors, and these differences could not be reconciled, CMS would render a final decision that would not be appealable under part 498 (proposed § 488.9(e)(4)).

At proposed § 488.9(f), we proposed circumstances in which an accredited provider or supplier would be deemed to have not met the applicable Medicare conditions or requirements, such as if: (1) the provider or supplier refused to authorize its AO to release a copy of

their current accreditation survey to CMS (proposed § 488.9(f)(1)); (2) the provider or supplier refused to allow a validation survey (for either look-back or DOVS) (proposed § 488.9(f)(2)); or (3) CMS found that the provider or supplier did not meet the applicable Medicare conditions (also known as CoPs, CfCs, or requirements) (proposed § 488.9(f)(3)).

At § 488.9(g), we proposed the consequences for non-compliance. At § 488.9(g)(1), we proposed that if a CMS validation look-back or DOVS resulted in a finding that the provider or supplier was out of compliance with one or more Medicare conditions, deemed status would be removed by CMS and the provider or supplier would be subject to ongoing review by the SA or CMS (in accordance with § 488.10(d)) until the provider or supplier demonstrates compliance. At proposed § 488.9(g)(2), we proposed that CMS could take actions for the deficiencies identified in the in accordance with § 488.24, or could first direct the SA or CMS surveyors to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24. At proposed § 488.9(g)(3), we proposed that if CMS determined that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider may be subject to termination of the provider agreement and any other applicable intermediate sanctions and remedies.

At proposed § 488.9(h), we proposed considerations for the re-instatement of the deemed status of a provider or supplier. An accredited provider or supplier would be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if any of the requirements are met, as applicable:

- It withdraws any prior refusal to authorize its AO to release a copy of the provider's or supplier's current accreditation survey (proposed § 488.9(h)(1)).
- It withdraws any prior refusal to allow a look-back or DOVS, if applicable (proposed § 488.9(h)(2)).
- CMS finds that the provider or supplier meets all applicable Medicare CoPs, CfCs, or requirements (proposed § 488.9(h)(3)).

At proposed § 488.9(i), we proposed that the existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, would not affect or limit CMS in conducting any subsequent validation survey.

Our proposal to revise the validation process by adding DOVS and our other proposed revisions to § 488.9 would be applicable 60 days after the effective date of the final rule with comment period.

We also proposed that the DOVS may be performed by not only the SAs but also by CMS surveyors. This would allow for flexibility and expediency in the performance of these validation surveys.

Our proposed revisions to the AO validation process at § 488.9 would not apply to laboratories, as they are subject to the provisions under part 493.

We received ten comments specifically on the proposed revisions to the validation program. The comments and our responses to the comments are set forth below.

Comment: Comments were generally supportive of the proposed addition of the DOVS process. Specifically, commenters stated that direct observation surveys provide a more accurate, meaningful, and timely picture of AO performance and are less burdensome for facilities than the traditional look-back validation surveys.

Response: We thank the commenters for their support.

In 2018–2019, CMS piloted a streamlined way to instead use direct observation during the AO reaccreditation surveys to evaluate an AO's ability to assess compliance with the Medicare conditions. With the end of the COVID–19 PHE on May 11, 2023, CMS resumed routine oversight activities that promote ongoing quality of care and patient safety. As announced via Admin-info Memo 23–14 (available at <https://www.cms.gov/files/document/admin-info-23-14-nltc.pdf>), the DOVS pilot resumed in October 2023, utilizing a national contractor working on behalf of CMS to directly observe and evaluate an AO's ability to assess the Medicare conditions during surveys. Both DOVS pilots have provided CMS with an additional level of oversight and, overall, more consistent evaluation of AO performance. We acknowledge the look-back surveys do not provide a one-to-one comparison of the AO's survey process performance. We believe the DOVS process provides a more accurate and real-time picture of an AO's survey performance in ensuring compliance with the Medicare health and safety requirements.

Comment: The majority of commenters encouraged CMS to phase out or completely abandon the existing 60-day look-back validation survey due to the burden on facilities, lack of CMS surveyors to complete survey workload, as well as the inaccuracy of assessing

AO performance. Commenters stated they understand the validation process to be an assessment of AO process and performance rather than comparison of a provider's compliance with Medicare regulations at different points in time. They believe the look-back surveys capture information from different points in time and do not take into account any changes made by the facility immediately after the AO survey that could influence the overall disparity rate between the AO survey and subsequent SA survey. Commenters also expressed concern that continuing to utilize the look-back validation survey option fosters unreliable results of AO survey performance as it is impossible to evaluate their process when the SA validation survey occurs at separate times.

Response: CMS is responsible for oversight of the national AOs' Medicare accreditation programs, and for ensuring that providers and suppliers under CMS-approved deeming programs meet the minimum quality and patient safety standards required by the Medicare conditions. Section 1864(c) of the Act permits validation surveys of provider and supplier types deemed for Medicare participation under Section 1865(a) of the Act as a means of validating the AOs' accreditation processes. Historically, we have measured the effectiveness of AOs by choosing a sample of facilities, performing State-conducted "look back" surveys within 60 days following AO surveys, and comparing results of the State surveys with the AO surveys. We acknowledge the commenters' concerns with the look-back validation survey process.

By withdrawing our proposed look-back validation survey method and proceeding only with the DOVS, we believe that this will reduce provider burden by not requiring an additional validation survey and thus reduce the number of times that healthcare providers have to undergo two full surveys within a 60-day period. We further believe this approach enhances the validation program and will be welcomed by both the AOs and the providers and suppliers.

Additionally, while the DOVS pilot program was successfully piloted over the last few years and AO feedback has been very positive, it has not been without its own set of challenges. The most challenging aspect of conducting a simultaneous survey for evaluating AO performance is scheduling. CMS receives AO pending survey schedules a month ahead and then chooses a representative sample of facilities from each AO for DOVS. During the DOVS pilot, surveys were always

unannounced to the facilities but were announced to the AO being observed to facilitate the 1:1 matching for experience of the accreditation surveyor where possible and to determine timing of survey start and location so that the two teams could enter the facility together. Entering the facility together is important to minimize burden and confusion to the facility being surveyed. We must ensure facilities understand they are not undergoing a double survey, but that DOVS observers are there to evaluate the AO performance. On many occasions survey start dates were changed or canceled completely due to many factors including, but not limited to, surveyor illness or emergency, weather-related travel cancellations, or mistakes in provided survey schedules. Often, these changes occurred within 24–48 hours of the survey's scheduled start date causing the national contractor working on behalf of CMS to shuffle a survey team and revise travel arrangements. Sometimes these last-minute changes incurred travel costs to the government due to airline and hotel change fees. Throughout the 2023–2024 pilot, CMS attempted to mitigate these challenges but has not yet resolved this issue to clear a path for sending DOVS observer teams completely unannounced to meet the AO's staff onsite at the AO client's facility. Additionally, review of the pilot alleviated our original concern that AOs send their best and strongest surveyor teams when they know they are being observed. We did not find this to be the case during the pilot surveys and have observed a low incidence of repeat surveyor and survey teams during our observed DOVS surveys. Therefore, we believe that validation surveys must remain unannounced to the facility and the applicable AO. However, due to the ongoing logistical concerns detailed here regarding coordination between AO surveyor teams and the CMS DOVS teams for individual surveys, we may have to exercise a degree of discretion in enforcing this requirement for AOs, after this rule is effective and implemented and once the DOVS program resumes.

Comment: One commenter raised concern over the proposal at § 488.9(g) that a facility could lose its deemed status if a condition-level deficiency was discovered during a validation survey. They stated that this proposal suggests that a deemed status accreditation survey conducted by the AO does not hold the same value as a CMS survey and, therefore, seems to undermine the agency's intent to align standards and survey processes.

Response: We thank the commenter for raising this concern and appreciate the opportunity to clarify the proposal at § 488.9(g). We have always retained the right to remove deemed status (that is, to no longer recognize a facility's accreditation as a finding of compliance) from a Medicare-participating facility for noncompliance with one or more Medicare conditions or requirements, in accordance with section 1865(c) of the Act. This most often occurs during a substantial allegation complaint survey that is conducted by the SA in an accredited facility. Although we do intend to align standards and survey processes to the extent possible, an accreditation organization does not act as an agent of CMS, unlike State survey agencies who perform their duties according to CMS' terms under contract. We do not directly employ accrediting organizations but recognize the equivalence of their determinations by granting such organizations "deeming authority" upon review of their processes and standards. Therefore, our withdrawal of a facility's "deemed status" is the one of the few tools we have to ensure that an accreditation organization's standards and processes continue to "meet or exceed" our own.

Comment: One commenter encouraged CMS to maintain a transparent process when making any future changes to the validation process policies and procedures. They requested that CMS involve AOs and other interested parties throughout the revision process and to utilize the feedback received during the pilot program to ensure the efficacy of validation surveys.

Response: We appreciate the feedback from those AOs who have directly experienced the pilot DOVS process over the last few years as it has helped guide our decision-making process. We are committed to providing meaningful oversight in an efficient manner. We remain committed to providing transparency with any changes to the validation process as evidenced by our public release of the DOVS pilot program Standard Operating Procedure via Admin-info Memo 23-14 (available at <https://www.cms.gov/files/document/admin-info-23-14-nltc.pdf>). We will continue to engage with AOs and other interested parties to ensure an efficient and effective validation program.

Comment: One AO commented on their experience with the DOVS process and, while they agreed that the existing validation process needed revisions, they shared concerns with the DOVS process going forward. In particular, this AO was concerned that DOVS observers

evaluated their performance based on personal/professional preference for particular survey methods without the supporting basis of a CMS requirement. The commenter does not believe that a CMS surveyor's personal/professional preference for a survey method should be the basis for a deficiency rating on AO performance. This commenter did acknowledge the DOVS reconsideration process as a way to address these situations if they arise but believes this is an additional burden on an AO to ask CMS for a reconsideration of the DOVS scoring.

Response: Again, we appreciate the feedback from those AOs who have directly experienced the DOVS pilot process. We agree that personal opinion and preference should not influence observations or ratings of AO performance. The intent of DOVS is to evaluate an AO's survey process in assessing facilities for compliance with Medicare conditions. During our pilot, we have continuously engaged with AOs, clarified expectations, and ensured that evaluations conducted by DOVS observers are consistent with comparable survey processes of the SAs. As the commenter mentioned, CMS has a reconsideration process for AOs to request secondary review of the DOVS findings to determine correct interpretation of the Medicare conditions by both the AO and DOVS observers and we will continue to evaluate this process.

Comment: Lastly, we received one comment stating that our proposal as drafted would subject Indian Health Service (IHS) facilities to State surveys and State surveyor oversight without their consent and that § 488.9 provides that "validation surveys" are conducted by State survey agencies without providing an exception for IHS providers.

Response: CMS is clarifying that the CMS Survey & Operations Group, CMS Locations, remains responsible for the certification of all IHS and tribal facilities and this rule does not change the existing processes for how IHS and tribal facilities are surveyed.

Final Decision: We have reviewed all the comments received on the proposed revisions to the validation program and we have also taken into account the experiences and AO feedback from our DOVS pilot over the last few years. We agree with commenters that the DOVS program has been successful and less burdensome for facilities. First, we have considered the concerns related to the look-back validation program and, based on the public comments received, are making revisions to the proposals at § 488.9 by withdrawing all of our

proposed references to look-back surveys as a process for AO validation performance in this final rule with comment period. We are also withdrawing our proposed requirements specific to look-back validation surveys and methods and have reorganized § 488.9 accordingly in this final rule with comment period. We are withdrawing these proposed provisions since they only pertain to the findings of the look-back validation surveys, specifically outcomes of surveys and the disparities between SAs and AOs regarding the citing of non-compliance with the conditions and requirements.

We are also revising § 488.9(f) in this final rule with comment period (proposed as § 488.9(h)) by adding the clarifying clause, "in addition to substantive re-approval of the facility", so that the provision will now read, "An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section, if, *in addition to substantive re-approval of the facility*, the following requirements are met, as applicable" [emphasis added]. We have revised this provision to clarify that a facility, in addition to meeting the requirement, must also undergo a successful survey on substantive grounds in order to have its deemed status reinstated.

Additionally, we are renumbering proposed § 488.9(g)(2) in this final rule with comment period as § 488.9(e) to read: "*Consequences for a finding of non-compliance.* CMS may take actions for any deficiencies identified in the DOVS in accordance with § 488.24, or may first direct the State survey agency to, or CMS may, conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24."

We are finalizing the changes to § 488.9 with the modifications previously discussed. Based on our review and analysis of both the VRP and DOVS pilots, we recognize that direct onsite observation of AOs using the DOV survey method is the most effective process for measuring AO performance. AOs, SAs, facilities, and other interested parties have all expressed agreement that DOV surveys reduce burden compared to look-back surveys and are a more accurate depiction of AO survey performance. Therefore, we are removing all references to the 60-day "look-back" surveys in the regulations and retaining only DOV surveys for the validation program.

Additionally, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the applicable regulations text stating that a particular provision(s) will become applicable 1 year after the effective date of this final rule with comment period, or any similar language to that effect. For this final rule with comment period, we are making a modification that all provisions of the rule will become effective 1 (one) year after the publication of this rule.

BB. Revise the Psychiatric Hospital Survey Process

Under section 1861(f) of the Act, psychiatric hospitals are a defined provider type. This statutory provision requires psychiatric hospitals to comply with most hospital Medicare conditions, known as CoPs, but includes a few provisions applicable exclusively to them. In 1986, special Medicare conditions for psychiatric hospitals were published and included, as part of the hospital Medicare conditions, as provisions of 42 CFR part 482. At that time, psychiatric hospital surveys were performed by either SA personnel or Healthcare Financing Administration¹⁹ (HCFA) mental health surveyors (board-certified psychiatrists, master's prepared psychiatric nurses, master's prepared psychiatric social workers, doctorally prepared clinical psychologists, and doctorally prepared clinical psychopharmacologists) who were under contract with HCFA. This extensive experience requirement was beyond what is required for other types of hospital services. This requirement limited the numbers of SAs with qualified surveyors. Therefore, a CMS contractor with specially trained and/or experienced psychiatric surveyors assisted the SAs in performing such surveys. This has resulted in a bifurcated survey process, as most psychiatric hospitals were subjected to two survey teams for each accreditation survey: the hospital survey team and the psychiatric component survey team.

However, in the FY 2014 Quality, Safety & Oversight Group Mission and Priority Document, the restrictive requirement for extensive education and/or experience for psychiatric surveyors was removed. CMS developed online psychiatric surveyor training, provided on-site psychiatric surveyor training through contractors and offered

partnership training for surveyors who did not have extensive psychiatric education or experience. This training became the standard and expectation for qualification to survey to the psychiatric Medicare conditions.

The special Medicare conditions applying to psychiatric hospitals are set forth in § 482.60 through § 482.62. The special provisions at § 482.60 require the following: (a) that the hospital be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons; (b) meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57; (c) maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and (d) meet the staffing requirements specified in § 482.62. As noted earlier, participating psychiatric hospitals must also meet the applicable Medicare conditions for acute-care hospitals.

In March 2020, we eliminated the contract for separate psychiatric hospital surveyors and provided comprehensive online training for all SAs. This training focused on the specific psychiatric hospital Medicare conditions so that the SA surveyors would be fully trained to conduct all aspects of a complete psychiatric hospital inspection. At this time, we also combined the interpretive guidance at Appendix AA for psychiatric hospital surveys into the Appendix A for hospital surveys to provide a single location for all of the Medicare conditions during a full psychiatric survey.

At this time, TJC, DNV Healthcare, and the Center for Improvement in Healthcare Quality are the only AOs that have CMS-approved psychiatric hospital accreditation programs. They conduct one complete survey of the entire psychiatric hospital, to include inspection of the regular hospital Medicare conditions and the psychiatric hospital Medicare conditions. Any AO is eligible to submit an application for consideration for accreditation to survey psychiatric hospitals for deeming purposes.

In the proposed rule, we announced our intention to integrate the acute care hospital and psychiatric hospital survey processes for SAs to ensure that there is a systematic and integrated look at psychiatric hospital safety and quality (89 FR 12028–12029). Therefore, AOs that currently survey only hospitals would need to expand their hospital

accreditation programs to include the Medicare special provisions applying to psychiatric hospitals (§ 482.60 through § 482.62) to survey for psychiatric hospitals as well.

We believe that consolidating psychiatric and acute care hospital Medicare condition oversight will improve the overall quality of the care by ensuring that systemic issues are more easily identified. With a single survey team conducting the survey for the entire facility, inconsistencies, trends, and subtle discrepancies can be connected more easily and provide a more comprehensive overview of underlying systemic issues. We believe that this comprehensive approach to survey both the psychiatric and acute care hospital will enhance patient health and safety by ensuring the system as a whole is evaluated to meet the applicable Medicare requirements. Moreover, a single survey team decreases the team's physical imprint on the facility which minimizes any facility disruption resulting from the survey. When revisits are required related to deficiencies in the psychiatric Medicare conditions, only one survey team will return for re-inspection, which will reduce coordination time and resources as well as impact on individual facilities. Finally, we have determined that combining the survey process for psychiatric hospital Medicare conditions into the hospital program would improve the cost efficiency of CMS' survey and certification activities and simplify the survey process for SAs and AOs alike.

For SAs, we would consolidate the deficiency report from psychiatric hospital survey activity into one Form CMS–2567, reporting on compliance with both the hospital Medicare conditions as well as the psychiatric services Medicare conditions. The survey process for inpatient psychiatric units located in acute care hospitals would not change, and this change would not require any revisions to our regulations.

To ensure that surveys of psychiatric hospitals and units located in hospitals are performed properly by the SA surveyors, they have been provided online training on the psychiatric hospital Medicare conditions. CMS developed this online training and released it in March 2020. It is now available to all SA and AO surveyors at <https://qsep.cms.gov/>.

We proposed to expand the acute care hospital accreditation program for AOs to include current psychiatric hospital accreditation standards. As per § 488.8(b), CMS assesses the equivalency of the AOs programs to the

¹⁹ Healthcare Financing Administration was the former name for CMS, which was changed on June 14, 2001.

CMS-approved program requirements, and, as such, this proposal to combine acute care and psychiatric hospital surveys necessarily required that we also proposed to revise the hospital accreditation program application process for AOs that have an approved hospital program, so as to include psychiatric hospital accreditation in their hospital programs. Those AOs that currently have an approved hospital program would be required to resubmit their standards, survey processes, and surveyor training (which may include the specific CMS surveyor training required by this rule for AO surveyors) to include review of the psychiatric Medicare conditions for psychiatric hospitals for CMS approval. This means that an AO that is seeking approval of a hospital accreditation program would be required to file one application that includes how they will assess for the two special Medicare conditions for psychiatric hospitals within their hospital accreditation program, whether or not they are currently accrediting psychiatric hospitals or have plans to do so in the future.

As part of this proposal, we also required that the AOs that already have an existing CMS-approved hospital program expand their existing hospital programs to include survey activities of psychiatric services in psychiatric hospitals. Those AOs who currently have an approved hospital program would be required to resubmit their standards, survey process and surveyor training for CMS approval in accordance with § 488.8(b) by no later than 30-calendar days from CMS notice to the hospital AOs using the existing process described in § 488.5(a)(19)(i). That process also permits CMS to give due consideration to a request for extension.

We hoped that this would encourage additional AOs to participate in deeming psychiatric hospitals. Overall, the intent of these proposals was to ensure that psychiatric services were evaluated in the context of the larger hospital program evaluation so that systemic quality issues were not missed. A single, comprehensive and focused survey team will be able to identify and connect individual issues and trends which may be occurring under two separate programs. Combining the two programs provides a more global view of the facility's potential deficiencies and is more likely to ensure the overall safety and quality of care delivered. For example, if there were significant issues with staff supervision of patients, one team of surveyors would be investigating areas which now cross the two sets of requirements and survey teams including patient-specific care

planning, staff training, patient rights, and potentially governing body. Integrating the survey activities for hospital and psychiatric standards would also provide an avenue for additional AOs to participate in deeming psychiatric hospitals, which would produce more competition and provide facilities with more options for surveying authorities.

The comments and our responses to the comments are set forth below.

Comment: Two commenters were in support of this proposal. There were no opposing comments.

Response: We thank the commenters for their support.

Final Decision: We are finalizing this section as proposed and will issue additional guidance to the AOs, once this rule becomes effective.

CC. Limitation on Terminated Deemed Providers/Suppliers Seeking Re-Entry Into Medicare/Medicaid (§ 489.57, § 488.4(b) and § 488.5(a)(21))

Involuntary termination of the Medicare provider agreement is the ultimate sanction for non-compliance with Medicare's basic health and safety requirements. On average, less than ten involuntary terminations occur each year for deemed providers and suppliers accredited by those AO programs that have a CMS-approved accreditation program. From January 2015 through September 2023, a total of fifty-eight accredited providers and suppliers, including ASCs, ESRD facilities, HHAs, Hospices, Hospitals, RHCs, and OPTs, were involuntarily terminated from the Medicare program for unresolved health and safety concerns. These providers currently have the option of seeking re-approval to participate in Medicare/Medicaid through accreditation by an AO with a CMS-approved program. We remain concerned that providers who have been involuntarily terminated from the Medicare program may continue to remain accredited by an AO and hold their continued accreditation out to the public as a marker of high-quality care. Most consumers, due to branding and advertising by the accredited community, associate quality of care with accreditation, rather than CMS certification of compliance with Medicare requirements. Therefore, involuntarily terminated providers who retain their AO accreditation status convey that they continue to meet high quality of care standards, despite their termination from Medicare. This situation could weaken public trust in accreditation as a marker of patient quality and safety. Since, for an AO that applies for CMS approval of its accreditation program, AO standards are

required to meet or exceed those of Medicare, we proposed at § 488.5(a)(21) that termination by Medicare would represent prima facie evidence that the facility similarly failed to meet accreditation standards.

These concerns were highlighted in media reports that noted that psychiatric hospitals terminated from Medicare for harm to patients nonetheless retained their accreditation despite serious health and safety concerns.^{20 21} An article published in the Wall Street Journal (WSJ) on September 8, 2017²² discussed patient-safety problems at three hospitals accredited by one of the AOs that also provides consulting services. These safety issues were so severe that CMS terminated two of the hospitals from the Medicare program. In each of these cases, the AO made no changes in the hospital's accreditation status and allowed it to continue promoting itself as fully accredited, despite being out of compliance with, and therefore no longer deemed to meet, the Medicare safety requirements.

The WSJ article reinforced concerns CMS had previously identified regarding the very small number of facilities that we terminated for failing to meet our basic health and safety regulations, but which nonetheless retained their AO accreditation. Continued accreditation of these outlier facilities, which have received the ultimate sanction CMS may impose based on their ongoing failure to meet basic health and safety requirements, raises serious concerns about the survey integrity and public trust attached to AO accreditation. Therefore, we proposed to explicitly prohibit AOs from allowing terminated facilities to retain their accreditation, to reduce confusion for patients and families about the continued health and safety of terminated entities.

To address the issue of terminated providers or suppliers remaining accredited by an AO, we proposed to add a new regulatory requirement at § 488.4(b) (currently reserved). More specifically, proposed § 488.4(b)(1) would provide that if CMS terminated the participation agreement of a Medicare-certified provider or supplier, under our authority at section 1865(c) of

²⁰ S. Armour, Psychiatric Hospitals With Safety Violations Still Get Accreditation, *Wall Street Journal*, December 26, 2018.

²¹ D. Gilbert Behind Joint Commission's 'Gold Seal of Approval,' a history of missed safety violations at psychiatric hospitals, *Seattle Times*, October 9, 2019.

²² S. Armour, Hospital Watchdog Gives Seal of Approval, Even After Problems Emerge, *Wall Street Journal*, September 8, 2017.

the Act, we would no longer recognize or accept the accreditation provided by an AO to that provider or supplier as demonstrating that the Medicare requirements have been met by the terminated provider or supplier.

In support of the proposed requirements at § 488.4(b), we also proposed to add a new requirement at § 488.5(a)(21) that would require AOs to provide, with their initial and subsequent renewal applications, a statement certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been terminated from the Medicare/Medicaid program, the AO agreed to terminate or revoke its accreditation of the terminated provider or supplier within 5 business days from receipt of said written notice.

The accreditation provided to providers and suppliers by AOs through an applicable CMS-approved AO program permits Medicare participation (in lieu of certification by the SA) only if CMS also approves the AO's recommendation of deemed status for the accredited provider or supplier. Therefore, if a Medicare-certified provider or supplier chooses to obtain accreditation from an AO, and then their Medicare participation is involuntarily terminated after failing to meet the Medicare conditions, we would no longer recognize the validity of the AO's accreditation with respect to that provider/supplier under our oversight authority at section 1865 of the Act. We do not believe that it is appropriate for a terminated provider's or supplier's AO accreditation to remain effective for CMS deeming purposes after we have terminated this provider or supplier for significant deficiencies that the AO may not have cited, discovered, or fully recognized. A terminated provider or supplier may attempt to use the AO's accreditation as a quality marker, when in fact their practices are severely deficient, unsafe, and non-compliant with the CMS conditions.

Under section 1865 of the Act, we may involuntarily terminate CMS approval of an AO's overall deeming authority if they miss egregious deficiencies in one of their accredited provider's or supplier's practices. However, we would prefer to withdraw our recognition of the individual provider's or supplier's deemed status instead and separately work with the AO to determine why such deficiencies went undiscovered.

Proposed § 488.4(b)(2) would provide that, if CMS terminates the participation agreement of a Medicare-certified provider or supplier, the terminated

provider or supplier would be required to meet the requirements set forth at § 489.57 before a new agreement for Medicare participation could be approved. We also proposed a new paragraph at § 489.20(z) that reinstatement of a terminated provider or certified supplier agreement would be subject to the proposed revisions to § 489.57.

The introductory text to proposed § 489.57 states that when a provider agreement has been terminated by CMS under § 489.53, or by the OIG under § 489.54, a new agreement with that provider cannot be accepted unless CMS or the OIG, as appropriate, finds that said provider or supplier meets the requirements set forth in § 489.57(a) and (b). We proposed to redesignate § 489.57(a) and (b) as § 489.57(a)(1) and § 489.57(a)(2) without any change to the text. Redesignated § 489.57(a)(1) requires a provider or supplier that has been terminated from the Medicare program to demonstrate that the reason for termination of the previous Medicare provider agreement has been removed and provide reasonable assurance that it will not recur. Redesignated § 489.57(a)(2) requires the terminated provider or supplier to fulfill, or make satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

We also proposed to add a new paragraph (b) at § 489.57. Proposed § 489.57(b) would provide that before a new agreement for Medicare participation of the terminated provider or supplier is approved, such terminated provider or supplier would have to meet the requirements of proposed § 489.57(b)(1) through (b)(3).

Proposed § 489.57(b)(1) would require that the terminated provider or supplier be under the exclusive oversight of the SA for a reasonable assurance period of a length of time to be determined by CMS, for the purposes of the initial survey, certification and demonstration of compliance with the Medicare conditions. Proposed § 489.57(b)(2) would require that the terminated provider or supplier remain under the exclusive oversight of the SA until the SA or CMS has certified the provider's/supplier's full compliance with all applicable Medicare conditions and their application for participation in the Medicare/Medicaid program had been approved. Finally, proposed § 489.57(b)(3) would provide that, during the time period in which a terminated provider or supplier is not certified to participate in the Medicare program, while the prospective provider or supplier was under the oversight of

the State survey agency, and while the new agreement for Medicare participation is pending, CMS would not accept or recognize accreditation from a CMS-approved accrediting organization for deeming purposes until the applicable Medicare requirements had been met or exceeded, as described in § 488.4 of this chapter. Our intent for proposing the new requirements at § 489.57(b) is to ensure that the SA would have the initial survey and certification oversight authority over terminated providers and suppliers seeking re-entry into the program and about which we had significant health and safety concerns. The terminated provider or supplier would remain under the oversight of the SA for a reasonable assurance (RA) period of a duration to be determined by CMS. During the RA period, the terminated provider or supplier would be required to provide reasonable assurance to the SA and CMS that the deficiencies that caused the termination have been rectified and that they are not likely to recur. This means that a terminated provider or supplier would have to use the SA, as opposed to an accrediting organization, to perform their initial participation survey and assessment of compliance before a new agreement for Medicare participation were approved. If, after completion of the reasonable assurance period, the SA found that the provider or supplier met all of the applicable Medicare conditions, it would certify said provider's or supplier's compliance and notify CMS of its findings. CMS would consider the SA's survey findings (certification) in deciding whether to approve or deny the provider's or supplier's new initial certification request for participation in the Medicare program. However, if the SA were to find deficiencies and determine that the provider or supplier did not meet the CMS conditions, the SA could take several courses of action, depending on the severity of the deficiencies. The SA could require the provider or supplier to submit a plan of correction and give the provider or supplier time to correct the deficiencies. The SA would then perform a subsequent survey to see if the deficiencies have been removed and compliance with all requirements has been achieved. If the deficiencies found during the initial SA survey were significant or egregious, the SA would reject the plan of correction and would notify CMS of its findings and recommendation, and then CMS could deny the provider's or supplier's request for new participation in the Medicare program.

The SA cannot recommend certification of a previously terminated provider or supplier that has significant condition or immediate jeopardy level deficiencies, unless these deficiencies are properly and promptly addressed and removed by the provider or supplier. Therefore, the proposed new requirements at § 489.57(b) would provide reasonable assurance to CMS that the significant health and safety concerns that warranted termination of the provider's or supplier's Medicare agreement have been corrected and compliance with all applicable requirements and conditions has been achieved before a new agreement for participation in the Medicare program is approved. We believe that SA oversight during a reasonable assurance period (of a length to be determined by CMS), and SA survey and certification that the terminated provider or supplier now meets the Medicare conditions is a safer alternative to accepting AO survey and deeming of that terminated provider or supplier. This is because in the majority of cases of terminated providers and suppliers, the SA discovered the egregious deficiencies that caused terminations during a validation or complaint survey that took place within 60 days of an AO reaccreditation survey. The AOs that accredited the terminated providers and suppliers had not detected or cited these deficiencies during their surveys.

Section 1865(b) of the Act prohibits disclosure of surveys performed by AOs (with the exception of HHAs, hospice programs, and surveys that relate to an enforcement action taken by the Secretary). However, the proposed new requirements at § 489.57(b) would allow the findings from the compliance surveys performed by the SAs to be made publicly available under our regulations at 42 CFR 401.133(a) and our statutory authority at section 1864(a) of the Act, which states: "within 90 days following the completion of each survey of any healthcare facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary must make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients' representatives), the pertinent findings of each such survey relating to the compliance of each such healthcare facility, ambulatory surgical center, rural health clinic, comprehensive

outpatient rehabilitation facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this title and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such healthcare facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization".

Thus, the proposed new requirements at § 489.57(b) would allow for greater transparency regarding the current compliance of terminated healthcare providers and suppliers seeking re-entry into the program.

The requirements at § 488.4(a)(1) and (2) (redesignated as paragraphs § 488.4(a)(3) and (4) in this rule, with minor clarifying changes in the regulatory language) further delineate CMS' authority in accepting or recognizing accreditation from a CMS-approved accrediting organization for deeming purposes. In accordance with § 488.4(a)(1) and (2) (redesignated § 488.4(a)(3) and (4) in this final rule with comment period), when a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the accrediting organization's CMS-approved accreditation program, *the accrediting organization may recommend that CMS grant deemed status* to the provider or supplier and *CMS may deem* the provider or supplier to be in compliance with the applicable Medicare conditions or requirements. [Emphasis added] Because CMS has concerns about a provider that was terminated under an AO's oversight to be deemed by that same AO upon re-entry to the Medicare program, CMS may have concerns about approving an AO's recommendation to deem that provider for a period of time after re-entry.

The comments and our responses to the comments are set forth below. We have presented these comments and responses in a topical fashion for clarity.

Comment: One commenter stated that Indian health facilities are almost exclusively surveyed by CMS surveyors instead of State survey agencies, given their direct government-to-government relationship with the U.S. The commenter stated that Indian health facilities' right to a direct CMS survey and exemption from State health facility licensing was expressly recognized by the Medicare Claims Processing Manual, (CMS Pub, 100-04), Chapter 19, Section 40.2; and codified in the Indian Healthcare Improvement Act, Public

Law 94-437, sections 221 and 408 (25 U.S.C. 1621(t) and 1647).

This commenter stated that § 489.57 would place all terminated providers under "exclusive oversight of the State survey agency", again without stating an exception for Indian health facilities. This commenter also urged that both § 488.9 and § 489.57 be amended to expressly provide that the survey and oversight functions for terminated Indian health facilities be carried out directly by CMS surveyors unless the facility expressly requests otherwise.

Response: While tribally owned and operated facilities may opt to seek deemed status and accreditation from an AO, State survey agencies performing surveys for CMS act as our agents. CMS is clarifying that surveys will continue to be performed *by or under the* direction of CMS.

Comment: One commenter believes that a strict process and procedure for investigation should be followed before terminating a provider.

Response: CMS does not terminate a provider or supplier from the Medicare/Medicaid program unless they have been found to have multiple, serious condition-level deficiencies they have failed to correct after being given opportunities to do so.

CMS does have a procedure for investigating and handling providers and suppliers that have been found to have such serious condition level deficiencies which is set forth in Chapter 2, Sections 2005A4 and 2005B of the SOM. This procedure includes investigation and attempts at correction prior to termination from the Medicare program for healthcare facilities that have been found to have serious deficiencies and non-compliance with the Medicare standards. There are additional termination processes for individual provider types such as hospitals.

Comment: One commenter supports the proposed requirements, which they described as CMS withdrawing its approval of the accreditation programs of a provider or supplier that is involuntarily terminated by CMS from participation in the Medicare program.

Response: We thank this commenter for their support of this proposal. However, this commenter seems to misunderstand the terms of this proposal. The commenter stated that CMS would withdraw approval for the *accreditation programs* of any provider or supplier that is involuntarily terminated from the Medicare/Medicaid program. We have actually proposed that CMS would not recognize the *AO accreditation* for any provider or

supplier that is terminated from the Medicare program.

Comment: One commenter supports the proposed requirement that a terminated provider or supplier must meet all of Medicare/Medicaid standards before a new agreement with that provider or supplier to re-enter participation in the Medicare/Medicaid program will be approved.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter stated for the proposed requirement that a terminated provider or supplier must be under the exclusive oversight of a State Agency or a CMS Regional Office throughout the time they are seeking to remedy past deficiencies and enter a new agreement for Medicare participation can be approved.

Response: We thank this commenter for their support of this proposal.

Comment: One commenter believes that it is imperative that all of the suggested changes, if implemented, are randomly and regularly audited to ensure AO compliance.

Response: We thank this commenter for their comment.

Comment: One commenter stated significant concerns about our proposal at § 488.5(a)(21) regarding this proposed prohibition and opposes the linkage of provider agreement termination and deemed status through an AO. This commenter stated they believe there is inconsistency and disconnection in this proposed requirement.

This commenter noted that CMS has proposed to require an AO agree to terminate or revoke its accreditation of any of its accredited providers or suppliers that have been terminated from the Medicare program within 5 business days from receipt of a written notice from Medicare notifying them of the termination. This commenter was concerned about providers and suppliers that may voluntarily terminate their Medicare provider agreement and believes that this proposal would imply that such providers or suppliers have failed to meet the CoPs, when that was not the reason for losing deemed status. The commenter voiced concern for the financial impact of losing deemed status as well as reputational impact to such providers and suppliers.

Response: This proposal applies only to providers and suppliers that have been involuntarily terminated from the Medicare program for serious deficiencies.

Comment: One commenter requested clarification on how the “reasonable assurance period” is defined.

Response: Proposed § 489.57(b)(1) would require that the terminated

provider or supplier be under the exclusive oversight of the SA for the purposes of the initial certification survey, initial certification and demonstration of compliance with the Medicare conditions. Proposed § 489.57(b)(2) would require that the terminated provider or supplier remain under the exclusive oversight of the SA until the SA had certified the provider’s/supplier’s full compliance with all applicable Medicare conditions and their application for participation in the Medicare/Medicaid program had been approved. Finally, proposed § 489.57(b)(3) would provide that CMS would not recognize accreditation from a CMS-approved accrediting organization for deeming purposes while the terminated provider or supplier was under the oversight of the SA and its new agreement for Medicare participation was pending. In addition, section 1865(c) of the Act provided that, after termination, the facility “*for such period as may be prescribed in regulations* [may] be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to subsection (a)(1).” (Emphasis added). This means that the reasonable assurance period is set by CMS and would last until the SA had certified the provider’s/supplier’s full compliance with all applicable Medicare conditions and their application for participation in the Medicare/Medicaid program had been approved.

Comment: One commenter requested clarification on whether the requirement to terminate or revoke accreditation within 5 business days after written notice from Medicare and not re-accredit until CMS has re-approved the provider or supplier applies to both voluntary and involuntary terminations. This commenter stated that they use the term “*voluntary terminations*” for what they consider withdrawals from Medicare and use the term “*involuntary terminations*” for what they consider terminations.

Response: The proposed requirement at § 488.5(a)(21) would require AOs to terminate or revoke its accreditation of a provider or supplier terminated by CMS within 5 business days from receipt of said written notice of CMS’ termination notice to the AO, and not re-accredit the provider until CMS has approved the provider or supplier for participation in Medicare. It would apply only to deemed providers and suppliers that are involuntarily terminated from participation in the Medicare program by CMS for condition-level noncompliance concerns.

Comment: One commenter requested clarification on the meaning of the term “*receipt*” in the following “within 5 business days from receipt” proposed regulation text for § 488.5(a)(21). The commenter questioned whether “*receipt*” means the date the termination notification letter is sent by CMS, or if it refers to the date the AO opens/reads the email from CMS. The commenter stated that if the receipt date is 5 business days from when CMS sends the notice, it would be difficult for the AO to meet the deadline. The commenter further recommended that CMS increase this deadline to 10 business days.

Response: In this final rule with comment period we are clarifying that we are referring to the AO’s receipt of said written notice. We believe that the proposed timeframe of five (5) business days (versus five (5) calendar days) provides sufficient time for an AO to notify a terminated provider or supplier of its accreditation termination or revocation by the AO. We interpret the term “*receipt*” to be the date the AO receives the written termination notice from CMS and clarify that we consider the date of receipt for the AO to be 5 business days after the notice is mailed by CMS or immediately upon transmission to the AO via email by CMS.

Comment: One commenter stated that it will not be possible for an AO to effectively implement and maintain compliance with these requirements unless effective communication is received from CMS, its locations, and Medicare Administrative Contractors (MACs). This is because levels of communication vary among CMS locations and MACs. The commenter stated that if the AOs are not advised by either the facility or CMS in advance of administrative work after provider/supplier submission of an application or post-survey, there could be significant associated burden for the AOs.

Response: We thank this commenter for their comment and making their concerns known. We will take them under advisement. However, we believe that the only communication required by this proposal would be the communication from CMS to the AO providing notice that one of the AO’s accredited providers or suppliers has been terminated from the Medicare program. The AO would be required to terminate its accreditation of this provider of supplier within 5 business days of receipt of this notification.

We further believe that the AO would not need to receive notifications from CMS or the MACs after it revokes or terminates its AO accreditation of the

Medicare-terminated provider or supplier. We say this because after revoking or terminating the accreditation for the Medicare-terminated provider or supplier, proposed § 488.5(a)(21) would prohibit the AOs from providing accreditation to these terminated providers and suppliers while they remain terminated from the Medicare program. It would not be the duty of CMS to notify the AOs when a previously terminated provider or supplier is approved for participation in the Medicare program.

Comment: One commenter requested additional clarity related to how these notifications would work, related to both notification of termination and notification of reinstated eligibility for deemed status through an AO.

Response: At this time CMS is still considering how the notification to an AO that its accredited provider or supplier has been terminated from the Medicare program will work. However, we will develop the guidance and process for this notification requirement prior to its implementation.

Comment: One commenter expressed concern that SAs may not have sufficient resources to meet the additional oversight requirements to ensure that significant health and safety deficiencies have been corrected.

Response: There are only a few providers and suppliers accredited by AOs for deeming purposes that are terminated from the Medicare program each year (that is, on average, less than 10). As the number of terminations is low, we believe the SAs will have the ability to perform oversight for these terminated providers and suppliers.

Comment: One commenter requested that we extend the effective date of the proposed requirement at § 488.5(a)(21). This commenter stated that if this proposal is finalized as proposed, they would need time to update their processes, obtain delegated authority from their Board for the prompt processing of such terminations, determine how terminations would be implemented within the AO's IT systems, and estimate cost implications and allocate the necessary funding.

Response: We agree that the AOs will need time to implement the requirements into their systems and processes. Unless otherwise specified, final rules become effective 60 days after publication. However, we are specifying that the requirements of proposed § 488.5(a)(21) would not become effective until 1 year after the publication date of this final rule with comment period.

Comment: Multiple commenters supported our proposal to place

limitations on terminated providers/suppliers that are seeking re-entry into the Medicare/Medicaid programs.

One commenter stated that they would fully support the proposed processes for re-entry of a terminated deemed provider and supplier into the Medicare program, if the stated reasoning and process remains unchanged. One commenter stated that they “agree with the provision that a Medicare-accredited organization must terminate the contract with Medicare-certified providers and suppliers. This creates more accountability and compliance for Medicare-accredited healthcare facilities”. Another commenter supports the proposed requirement that AOs terminate or suspend the accreditation of providers and suppliers that are involuntarily terminated from the Medicare program within 5 days from being notified of the termination.

One commenter stated that they are generally supportive of the proposals CMS has put forth to strengthen comparability across AOs and between AOs and SAs, as well as the proposed documentation requirements as part of the application process. This commenter stated that they have already taken actions to align with CMS expectations proposed to be codified by the proposed rule.

One commenter supported the proposal that a provider or supplier terminated by Medicare for serious quality and safety deficiencies would also lose its AO accreditation status and remain under the oversight of a State agency, rather than the AO, for a “reasonable assurance period” until they correct the deficiencies which caused their termination by Medicare.

Response: We thank the commenters for their support of our proposal to place limitations on terminated deemed providers/suppliers seeking re-entry into the Medicare/Medicaid programs.

Final Decision: After careful consideration of the comments received, we have decided to finalize the revisions to § 489.57 with a minor technical correction to revise § 489.57(b)(3) in this final rule with comment period. Redesignated § 489.57(a)(1), as finalized, requires a provider or supplier that has been terminated from the Medicare program to demonstrate that the reason for termination of the previous Medicare provider agreement has been removed and provide reasonable assurance that it will not recur. Redesignated § 489.57(a)(2) requires the terminated provider or supplier to fulfill, or make satisfactory arrangements to fulfill, all of the statutory and regulatory

responsibilities of its previous agreement.

Revised § 489.57(b)(1), as finalized, requires that the terminated provider or supplier be under the exclusive oversight of the SA for the purposes of the initial certification survey, initial certification and demonstration of compliance with the Medicare conditions. Revised § 489.57(b)(2), as finalized, requires that the terminated provider or supplier remain under the exclusive oversight of the SA until the SA had certified the provider's/supplier's full compliance with all applicable Medicare conditions and their application for participation in the Medicare/Medicaid program had been approved. Revised § 489.57(b)(3), as finalized, provides that CMS will not accept or recognize accreditation from a CMS-approved accrediting organization for deeming purposes while the terminated provider or supplier is under the oversight of the SA and its new agreement for Medicare participation is pending. As originally proposed, § 489.57(b)(3) would provide that, “[D]uring the time period in which a terminated provider or supplier is not certified to participate in the Medicare program, while the prospective provider or supplier is under the oversight of the State survey agency, and while the new agreement for Medicare participation is pending, CMS will not accept or recognize *deeming accreditation* from a CMS-approved accrediting organization until the applicable Medicare requirements have been met or exceeded, as described in § 488.4 of this chapter.” *[Emphasis added]*

In reviewing the public comments received and preparing our responses to those comments, we recognized that the term used in the proposed rule, “deeming accreditation,” is not the correct term to use with regard to the accreditation provided by an AO to a provider or supplier under a CMS-approved AO program and CMS' subsequent decision to accept that accreditation as evidence to deem the provider or supplier as having met or exceeded the applicable Medicare requirements. “Deeming accreditation” incorrectly implies that a CMS-approved AO program and the AO automatically confer “deemed status” (and the subsequent certification to participate in the Medicare program) when the AO “accredits” the provider or supplier. This term, “deeming accreditation”, is therefore inaccurate because CMS is always the final authority in determining whether such accreditation can be used for “deeming purposes” (that is, having met or exceeded the applicable Medicare

requirements and eligible to be certified for participation the Medicare program). In other words, accreditation of a provider or supplier by an AO for deeming purposes is a recommendation by the AO that CMS may recognize or accept the accreditation as evidence that the provider or supplier has met or exceeded the applicable Medicare requirements. Through this process, CMS either accepts or rejects the AO recommendation to deem the provider or supplier as having met or exceeded the applicable Medicare requirements.

Therefore, in this final rule with comment period we are making a clarifying revision to § 489.57(b)(3) so that it will now read as:

“During the time period in which a terminated provider or supplier is not certified to participate in the Medicare program, while the prospective provider or supplier is under the oversight of the State survey agency, and while the new agreement for Medicare participation is pending, *CMS will not accept or recognize accreditation from a CMS-approved accrediting organization for deeming purposes* until the applicable Medicare requirements have been met or exceeded, as described in § 488.4 of this chapter.” *[Emphasis added]*

We are finalizing as proposed the new paragraph added at § 489.20(z), which states that reinstatement of a terminated provider or certified supplier agreement is subject to the proposed revision to § 489.57.

We are also finalizing as proposed § 488.4(b)(1) and (2), which provide that if CMS terminates the participation agreement of a Medicare-certified provider or supplier, under our authority at section 1865(c) of the Act, we will no longer recognize or accept the accreditation provided by an AO as evidence that the Medicare requirements have been met or exceeded for that terminated provider or supplier, and that the terminated provider or supplier must meet all requirements set forth at 42 CFR 489.57 before a new agreement with that provider or supplier for Medicare participation will be approved.

Finally, we are finalizing § 488.5(a)(21), as proposed, which would require AOs to provide, with their initial and subsequent renewal applications, a statement certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been terminated from the Medicare/Medicaid program, the AO agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5 business days from receipt of said written notice from CMS.

However, as we have stated elsewhere in this final rule with comment period, and for the reasons we have provided, we have modified the proposed provisions by removing any sentence or phrase from the applicable regulations text stating that a particular provision(s) will become applicable 1 year after the effective date of this final rule with comment period, or any similar language to that effect. For this final rule with comment period, we are making a modification that all provisions of the rule will become effective 1 (one) year after the publication of this rule.

DD. Finalizing Technical Correction for End-Stage Renal Disease (ESRD) Facilities and Kidney Transplant Programs (§ 488.4(a)(4))

Section 1865(a)(1) of the Act had historically excluded dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50403 of the Bipartisan Budget Act of 2018 amended section 1865(a) of the Act to include renal dialysis facilities as provider entities allowed to participate in Medicare through a CMS-approved accreditation program. Section 50403 also removed a reference to section 1881(b) of the Act, which had prevented kidney transplant programs from being accredited via CMS-approved accreditation programs. However, CMS' existing regulations at § 488.4(a)(2) continue to exclude kidney transplant programs from participation in Medicare through accreditation, in direct conflict with the Bipartisan Budget Act of 2018 amendment. We therefore proposed to remove the exclusion specifically in our accreditation regulations, currently codified under § 488.4(a)(2) and redesignated in this final rule with comment period as § 488.4(a)(4), to align with the statutory changes implemented the Bipartisan Budget Act of 2018.

Final Decision: We received no comments related to this technical correction and are hereby finalizing this correction within the regulatory provisions.

IV. Information Regarding Timeframes and Expectation for the Submission of AO Applications

We requested public comments on the timeframes and expectation for the submission of applications submitted by AOs, because our existing AO oversight regulations do not restrict how many times an AO may submit an initial application to CMS for review. Based on our initial review of an application for completeness, which verifies the AO has submitted all required elements

under § 488.5, we often find the application to be incomplete and must return it to the AO for additional clarifications, missing items or revisions. CMS also receives applications that require multiple pass-backs due to the applicant's failure to provide complete information about issues, such as their financial viability, survey processes which appeared not to be operationalized, or similar concerns. Our existing regulations do not limit the number of times an AO may submit an application for review by CMS. It is possible that incomplete applications could be submitted an unlimited number of times.

Therefore, we solicited public comments on the following possible future limitations to the submission of applications by the AOs that accredit Medicare-certified providers and suppliers:

- An AO may only re-submit an application for CMS re-review two additional times after CMS initially deems the application to be “incomplete”.
- If the AO's application is found by CMS to be incomplete after the third submission, the AO must wait a minimum of 2 years before resubmitting the entire application for CMS consideration.

We received two comments related to our request for information.

Comment: One commenter stated that while the commenter's organization recognizes the resource demand for reviews of an application by CMS, the commenter disagreed with placing limitations on the number of reviews. The commenter suggested this is particularly concerning with an organization applying for the first time. Alternatively, the commenter suggested that limitations be placed on the number of times an organization may change their point of contact for consistent communications. Further, the commenter stated that should CMS seek to impose a term of limitation, the commenter's organization recommends an additional four rounds (five total submissions) and the timeframe for reapplication to be decreased to 1 year.

Response: We appreciate the commenter's suggestion and raised concerns. We do note that we believe this commenter may have not fully understood the proposal requesting information. The intent of the proposal is primarily geared toward new organizations wishing to apply for deeming authority, not those of our existing CMS-approved AOs. Over recent years, several organizations have applied for initial CMS-approval to become recognized for deeming

authority but have failed to meet the requirements § 488.5. Some of the organizations failed to demonstrate their ability to have comparable survey processes to those of the SAs, including not reflecting the requirements outlined in our SOM program-specific appendices. Some other areas which led to CMS determine that initial reviews were incomplete were that the applicant organizations did not document accreditation decision making processes, sufficient staff, or financial support to be able to grow the organization to be a national organization; or did not provide evidence of having sufficient data systems. CMS expects organizations who wish to become an AO to be prepared to meet the requirements for submission of an application as outlined in the regulations. Further, we note one application may be in excess of 2,000 pages and in the event of four applications in 1 year a review of over 8,000 pages to determine an organization still does not meet the intent to be recognized for deeming authority greatly strains our limited resources.

Comment: One commenter did not support our proposal to limit the number of AO applications. The commenter stated it is crucial to recognize that addressing issues comprehensively may require time, especially considering the complexity of healthcare. The commenter suggested we take a flexible approach where multiple opportunities for corrective action are provided. The commenter believes that there should be more room for individualization and that CMS should take into account unique circumstances, leading to more effective and equitable outcomes in the accreditation process.

Response: We appreciate the concerns; however, we believe the commenter may have not understood the proposal. The intent to limit the number of applications is not directly correlated with healthcare facilities but with AOs themselves. AOs must initially apply for CMS-deeming authority and reapply at least every 6 years. Once received, CMS does the following: (1) conducts a thorough review of the application for evidence organization's ability to meet or exceed the Medicare standards; (2) assesses comparability of survey processes; (3) reviews survey files, complaint files, surveyor training and educational materials; and (4) performs an onsite

evaluation of the AOs surveying a deemed facility. This process is required to be completed within 210-days of receipt of an organization's complete application. One application may range from 2,000 to 5,000 pages of policies and guidance alone. In general, this provision is unlikely to impact existing CMS-approved AOs, as the nine approved AOs are familiar with CMS evaluation and application process. The intent of this provision is to limit the number of times that a new accrediting organization can submit an application to CMS. Every application received by CMS starts a 210-day timeclock once deemed complete. What CMS has found is that new organizations may apply four or even up to eight times per year. Even after these ample opportunities to meet our requirements, these applicants have subsequently been denied deeming authority due to a lack of understanding of the requirements, documentation, failure to meet the requirements, financial viability, etc. By limiting the number of times an application can be reviewed by CMS, we can prioritize our workload more effectively.

We appreciate the two commenters input on this request for information. We will take these comments into consideration for future rulemaking.

V. Severability of Provisions

To the extent a court may enjoin any part of the rule as finalized, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of the rule as finalized held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

We note here that virtually all of the provisions in this final rule with comment period are inherently severable, with the exception of a few areas of the rule that are dependent upon each other, where such provisions describe procedures and deadlines for the completion of activities and the submission of materials required by this rule. For example, the overall structure of 42 CFR 488.5(a) through (e), describing the steps necessary to submit

and receive approval of an accreditation program application, would not be severable to the extent that all steps in general of the process are needed in order to result in an approved entity. However, the individual items of information enumerated and being finalized in this rule at § 488.5(a), which describe the range of information that must be included in any application and re-application by a national accrediting organization for CMS approval of a specific accreditation program, are severable from each other because one impermissible requirement would not void the intent of an AO's application/re-application package submitted to CMS or make a decision impossible. This example is provided here to be illustrative of this final rule with comment periods' provisions that are not inherently severable, and it is not intended to be an exhaustive list of the provisions that are not severable in this rule.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including the use of automated collection techniques.

Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for all salary estimates (<https://data.bls.gov/oesprofile/>). In this regard, Table 3 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 3—U.S. BUREAU OF LABOR STATISTICS 2024 WAGE RATES²³

BLS occupation title	BLS occupation code	Mean hourly wage	Fringe benefits and overhead	Adjusted hourly wages
Registered Nurse *	29-1141	\$47.32	\$47.32	\$94.64
Medical or Health Services Manager **	11-9111	66.22	66.22	132.44
Medical Secretaries ***	43-6013	21.91	21.91	43.82
General and Operations Managers ****	11-1021	64.00	64.00	128.00
Physicians, All Other *****	29-1229	121.86	121.86	243.72
Radiologic Technologists *	29-2034	38.35	38.35	76.70
Medical Records Specialists *	29-2072	26.91	26.91	53.82
Chief Executive Officer *	11-1011	126.41	126.41	252.82
Healthcare Support Workers, All Other *	31-9099	23.44	23.44	46.88

* <https://www.bls.gov/oes/current/oes291141.htm>.

** <https://www.bls.gov/oes/current/oes119111.htm>.

*** <https://www.bls.gov/oes/current/oes436013.htm>.

**** <https://www.bls.gov/oes/current/oes111021.htm>.

***** <https://www.bls.gov/oes/current/oes291229.htm>.

***** <https://www.bls.gov/oes/current/oes292034.htm>.

***** <https://www.bls.gov/oes/current/oes292072.htm>.

***** <https://www.bls.gov/oes/current/oes111011.htm>.

***** <https://www.bls.gov/oes/current/oes319099.htm>.

A. Information Collection Requirements (ICRs) Related to Conflict-of-Interest Requirements

In this final rule with comment period, we are finalizing several requirements related to AO and AO surveyor conflicts of interest. We will address the cost and time burden associated with each of these requirements separately.

1. ICR Related to Conflict-of-Interest Policies & Procedures AOs Must Submit to CMS (§ 488.5(a)(10))

We are modifying § 488.5(a)(10) to add a requirement that the AOs must provide specific information with their conflict-of-interest policies and procedures with the application they submit to CMS. Specifically, the AO must submit the following policies and procedures: (1) the AO's policies and procedures for separation of its consulting services from its accreditation services; (2) policies and procedures for protecting the integrity of the AO's accreditation program, including the requirements of §§ 488.8(i) and (k); (3) policies and procedures for the prevention and handling of potential or actual conflicts of interest that could arise from situations in which an AO owner, surveyor, or other employee has a direct interest in or relationship with a State survey agency or with a healthcare facility to which the AO provides accreditation services, including being employed as an SA surveyor or having an ownership interest in a healthcare

facility, etc.; and (4) policies and procedures for notification of CMS when a conflict of interest is discovered.

The AO would need to modify their current conflict-of-interest policies and procedures to include the previously stated information required under the revisions to § 488.5(a)(10). We estimate that this task would be performed by a team of at least two AO staff members. The AO staff that would most likely perform this task would be a person whose background is an RN or a health or medical services manager. According to the 2024 U.S. Bureau of Labor statistics, the mean hourly wage for an RN is \$47.32. This wage adjusted for the employer's fringe benefits and overhead would be \$94.64. According to the U.S. Bureau of Labor statistics, the mean hourly wages for a medical or health services manager is \$66.22. This wage adjusted for the employer's fringe benefits and overhead would be \$132.44.

We estimate that it would be at least two persons working in a full-time basis for 3 days for the AO staff to revise their conflict-of-interest policies and procedures to add the required information. Therefore, we estimate that the total time required for the two team members to perform this task would be 48 hours (8 hours × 3 days = 24 hours per each person × 2 persons = 48 hours).

As of June 23, 2025, there are 9 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total time burden across these 9 AOs would be 432 hours (48 hours × 9 AOs).

We estimate that the cost burden related to the work performed by the RNs on the team would be \$2,271.36 (24 hours × \$94.64). We estimate that the

cost burden related to the work performed by the medical or health services manager on the team would be \$3,178.56 (24 hours × \$132.44). Finally, we estimate that the total burden costs related to the requirements for § 488.5(a)(10) would be \$5,449.92 per AO (\$2,271.36 + \$3,178.56). The total cost across the 9 AOs that accredit Medicare-certified providers and suppliers is \$49,049.28 (9 AOs × \$5,449.92).

We believe that the stated burden would be incurred by the AO once prior to the time that they submit their first application after this requirement becomes effective. However, we believe that after the AOs have made required modifications to their conflict-of-interest policies, they will not have to revise them again but will submit the same revised conflict-of-interest policies approximately every 6 years with their renewal applications, so this burden would not be incurred again. We do not count the burden related to the submission of the application because the AO would be required to submit the application approximately every 6 years to renew the CMS approval for their accreditation programs.

Comment: One commenter stated that CMS' time and cost estimates also fail to account for the areas in the proposed rule where current information sharing requirements still allow CMS to achieve its oversight objectives. For example, in the proposed changes (for example, proposed changes at § 488.5(a)(10)(i) through iv); § 488.5(a)(22); and § 488.8(i)(5)), CMS has not offered a reasoned explanation for concluding that oversight aims are not met with the current documentation requirements. As a result, the current requirements serve

²³ The May 2024 OEWS release does not include data for Colorado and its areas. For more information, see the Notice Regarding Suspension of Publication of Colorado Occupational Employment and Wage Statistics.

as a less burdensome means of achieving comparable goals.

Response: We respectfully disagree with this commenter's contention that CMS' current information sharing requirements still allow CMS to achieve its oversight objectives. We further disagree with this commenter's contention that CMS has not offered a reasoned explanation for concluding that oversight aims are not met with the current documentation requirements and that the proposed changes at § 488.5(a)(10) (i through iv); § 488.5(a)(22); and 488.8(i)(5) are not necessary.

In the proposed rule, we provided ample rationale for our proposed changes at § 488.5(a)(10) (i through iv); § 488.5(a)(22); and 488.8(i)(5), such as making the existing requirements more specific (84 FR 12006 through 12010).

As we have ample justification for our proposed changes, there is no need for CMS to "account for the areas in the proposed rule where current information sharing requirements still allow CMS to achieve its oversight objectives," as requested by the commenter.

2. ICR Related to Requirement That the AOs Submit Surveyor Declarations to CMS Upon Request and During Application Review Process (§ 488.5(a)(22))

We are adding a new paragraph (22) to § 488.5(a), which would require that the AO submit a declaration by each surveyor of any outside interests or relationships with the healthcare facilities that the AO accredits. This section would also require that the surveyor declarations must be updated and submitted to CMS upon request and during each application review process.

There would be a time and cost burden to the AO for having to collect declarations from each of their surveyors upon CMS request and during each application review process, which is currently every 6 years or less. There would also be a time and cost burden to the AO for the submission of the surveyor declarations to CMS.

We estimate that it would take at least two persons working on a full-time basis for 3 days (8 hours per day) to prepare the surveyor declarations, get each AO surveyor to complete a declaration and submit them to CMS. This would equate to 24 hours per person or 48 hours across both staff performing this task.

We believe that the AO staff that would be performing these tasks would be an RN and a management staff person, whose job duties meets the description of the U.S. Bureau of Labor Statistics job of category of health and

medical services manager. As stated previously, the adjusted mean hourly wage for an RN is \$94.64. The adjusted mean hourly wage for a medical and health services manager is \$132.44.

We estimate that the time burden for this task per each AO would be 48 hours (24 hours × 2 staff persons). We further estimate that the total time burden across all 9 AOs that accredit Medicare-certified providers and supplier would be 432 hours (48 hours × 9 AOs).

We estimate that the cost burden related to the work performed by the RN would be \$2,271.36 (24 hours × \$94.64). We estimate that the cost burden related to the work performed by the medical or health services manager would be \$3,178.56 (24 hours × \$132.44). Finally, we estimate that the cost burden associated with the requirements for § 488.5(a)(22) per each AO would be \$5,449.92 per AO (\$2,271.36 + \$3,178.56) if each had to submit these declarations annually. According to this requirement, CMS can request these submissions at any time from each AO, including annually. However, we expect that AOs will only have to submit surveyor declarations during each application review process, which generally occurs every 3 to 6 years, and as required under this provision. To estimate the total annual cost burden across the nine AOs that accredit Medicare-certified providers and suppliers for these submissions, we used the average of the every-3-to-6-years range for the AO application process. This resulted in an average of every 5 years (rounded up from 4.5 years) for each AO's period between application processes and its submission of the required surveyor declarations at a cost of \$5,449.92 per AO (or \$49,049.28 across 9 AOs) every 5 years, or \$1,090 distributed annually per AO (\$5,449.92/5 years = \$1,090), or \$9,810 across 9 AOs annually.

3. ICR Related to Requirement for Submission of Information About AO Fee-Based Consulting Services Provided (§ 488.8(i)(5))

We proposed a requirement at § 488.8(i)(5) that would require the AOs to provide CMS with the following information about the fee-based consulting services they provide to CMS on a bi-annual basis: (1) whether the AO or its fee-based consulting division or separate business entity (such as a company or corporation that provides fee-based consulting) provides fee-based consulting services; (2) the names and CCN numbers of all healthcare providers and suppliers to which the accrediting organization or its associated consulting division or

company has provided fee-based consulting services during the previous 6-month period; (3) the dates the AO fee-based consulting services were provided to each provider and supplier; (4) whether the accrediting organization has, at any time in the past provided, or is currently providing, accreditation services to each healthcare provider or supplier listed in said document; (5) for each healthcare provider and supplier listed in said document, the date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed; and (6) a description of the AO fee-based consulting services provided to each healthcare provider or supplier listed in said document.

The proposed regulation would further require that the document containing the information required by § 488.8(i)(5)(i) through (i)(5)(vi) must be submitted to CMS every 6 months.

Based on the public comments received on this proposed requirement, we are finalizing the requirements with a modification to require submission of the document to CMS upon request by CMS and during each application review process. We believe that this change in the requirements will be less burdensome for AOs while still providing CMS with the necessary information to maintain our AO oversight responsibilities.

We estimate that the burden associated with this requirement would include the time and costs associated with the gathering of the information necessary to prepare the required document, the time required to draft and update the document, and the time required to send the document to CMS. This burden would occur initially with the additional burden of updating the information when applicable. We would expect that AOs would most likely update the information on a yearly basis to keep the information as up to date as possible by documenting it on an ongoing basis.

We believe that the burden would be greater for the preparation of the first report. Thereafter, the AOs would have already prepared and formatted this report and would simply have to update the information prior to submitting to CMS upon request or prior to the beginning of each application review process.

We estimate that it would require at least two persons working on a full-time basis for 3 days to prepare and submit the first required statement to be submitted CMS. We further estimate that this team would consist of one RN and one Medical or Health Service Manager. Therefore, we estimate that

the total hourly time burden for each team member would be 24 hours (3 days $\times$ 8 hours per AO staff member).

We estimate that the time burden per each AO for the work performed by the two AO staff members to prepare each report would be 48 hours (2 team members $\times$ 8 hours $\times$ 3 days). The total initial time burden per each AO would be 48 hours (1 report $\times$ 48 hours).

This provision would apply to all 9 AOs that accredit Medicare-certified providers and suppliers because it would require each AO to, at a minimum, respond to the requirement at § 488.8(i)(5)(i), which asks whether the AO or an associated consulting division or company established by the AO provides consulting services. Those AOs, or associated consulting divisions or companies, that do not provide any type of consulting or consulting services would simply respond in the negative to this question and would not have to provide any further information.

The time and cost burden to the AOs that do not provide consulting would be negligible because they would send this notice to CMS via email. This task would take an AO staff member less than a minute to complete and submit to CMS upon request or prior to when each application review process begins. Therefore, as this task is so minimal, we have not assessed burden for this task for the AOs that do not provide consulting services.

The cost burden related to the work performed by RNs on the team would be \$2,271.36 (24 hours $\times$ \$94.64 per hour). The cost burden for the work performed by the medical or health services manager would be \$3,178.56 per each AO (24 hours $\times$ \$132.44). The total estimated cost burden per each AO would be \$5,449.92 (\$2,271.36 + \$3,178.56). The total estimated cost burden if all 9 AOs provided consulting services would be \$49,049.28 (\$5,449.92 $\times$ 9 AOs).

We believe that the previously mentioned time and cost burdens would be incurred by the AOs that provide consulting services only the first time that they prepare the required document and send it to CMS. We believe that after the AO has prepared their first report, they would have this report in an electronic format on their computers. Therefore, for the second and each subsequent report, we estimate that the preparation and submission of this report would only require the work of one RN and the time for that one RN would be reduced by at least two-thirds. This means that it would take only one RN a period of 8 hours to prepare the required statement and submit it to CMS. We estimate that the total time

burden across all nine AOs (based on either those that currently provide consulting services or might provide such services in the future) would be 72 hours (8 hours $\times$ 9 AOs).

We estimate that the cost burden per each AO related to the work performed by an RN to prepare the second or subsequent report would be \$757.12 (8 hours $\times$ \$94.64). The total cost burden across all nine AOs would be \$6,814.08 (\$757.12 $\times$ 9 AOs).

4. ICR Related to Requirement That Accrediting Organization Establish Fee-Based Consulting Firewall Policies and Procedures (§ 488.8(j))

We proposed at § 488.8(j) to require that an AO, its consulting division, or separate business entity, such as a company or corporation that provides fee-based consulting services to the healthcare providers and suppliers the accrediting organization accredits, must have written fee-based consulting firewall policies and procedures, which, at a minimum, include the following provisions: (1) the AO's fee-based consulting services must be provided by a separate division or company from the AO's accreditation division; (2) the AO's fee-based consulting division or separate company must maintain separate staff from that of the AO's accreditation divisions to ensure that the fee-based consulting division staff do not perform AO's accreditation division functions and that the AO's accreditation division staff do not perform fee-based consulting division functions; and (3) the AO's accreditation staff and surveyors are prohibited from marketing the AO's fee-based consulting services to the AO's accreditation clients. As we have noted elsewhere in this final rule with comment period, we are removing the proposed term, "fee-based", from the requirements of this section.

This requirement would only apply to the AOs that provide consulting services and would require these AOs establish new consulting firewall policies and procedures or revise their current policies and procedures to meet the requirements. It is our understanding, from review of the comments submitted by the AOs in response to the AO Conflict-of-Interest RFI, that these AOs already have such consulting firewall policies and procedures in place. If this is the case, then the time and cost burden associated with revising these policies and procedures would not be extensive.

In section VII.A.5. of the proposed rule, we estimated that it would take each AO that provides fee-based consulting services 80 hours to revise

their consulting business documents, such as their business charter, business documents, employee training information, informational documents that are distributed to prospective clients, and their policies and procedures.

For this final rule with comment period, we estimate that the total time burden across all nine AOs (based on either those that currently provide consulting services or might provide such services in the future) would be 720 hours (80 hours for each AO). We estimate that it would require at least two people working on a full-time basis for 5 days (or 40 hours for each staff member) to prepare and submit the first required statement to be submitted CMS. We further estimate that this team would consist of one RN and one Medical or Health Service Manager. Therefore, we estimate that the total hourly time burden for each team member would be 24 hours (3 days $\times$ 8 hours per AO staff member).

We estimate that the time burden per each AO for the work performed by the two AO staff members to prepare each report would be 48 hours (2 team members $\times$ 8 hours $\times$ 3 days). The total initial time burden per each AO would be 48 hours (1 report $\times$ 48 hours). However, we believe the time and cost burden associated with this requirement is included with the burden calculation for 488.8(i).

Comment: One commenter stated that they already maintain an effective conflict-of-interest requirement approved by CMS. This commenter stated that if the conflict-of-interest changes at § 488.8(k) are implemented as proposed, the structure of the AO's accreditation decision committee reviews would need to be reorganized in a manner that fully complies with the prohibition from having contact with or access to survey and accreditation records. Additionally, all current conflict-of-interest forms and disclosures will need to be updated and revised. Additionally, the size and structure of each AO with deeming authority varies greatly.

Many of the estimations based on assumed size, employment structure, and personnel count that have been presented by CMS throughout the ICR significantly understate the amount of investment that would be required.

Response: We are not privy to much of the AOs' business information. Because of this, we have had to use estimates in preparing our burden costs for the ICRs here.

B. ICR Associated With the Requirement That AOs Provide Detailed Crosswalks Identifying Incorporation of the CMS Standards

At § 488.5(a)(3), we will require AOs to incorporate the language of the CMS' Medicare conditions and provide CMS with a detailed crosswalk. While AOs are required to provide a similar crosswalk under the existing process, CMS previously only required a "comparable" standard, therefore through this new requirement, AOs will need to recreate their AO standards to incorporate the Medicare condition

language into their accreditation standards for their accreditation programs. We also note that this will require a one-time overhaul of AO standards and the cost burden would be imposed for the first year following the effective date of this rule and not be a reoccurring annual burden. Burden costs subsequent to changes to the conditions made by CMS through future rulemaking would remain as current practice with updates required to be reviewed and approved as outlined in existing § 488.5.

We would expect that the AOs will use the existing CFR language they are

required to crosswalk currently and assign an AO standard number or realign their existing AO standards in a manner which would allow for a one-to-one comparison to ensure their accreditation standards incorporate the CFR language. As previously noted, CMS is not restricting the AOs from exceeding the Medicare conditions. However, if the AO exceeded our standards, the AO would need to provide additional language or clearly delineate the exceeding language. For example, we would anticipate that the format used be similar to the one seen in Table 4.

TABLE 4—EXAMPLE OF PROPOSED CROSSWALK

CFR citation and survey tag	Medicare conditions language	AO standard No.	AO standards language
§ 482.13(h) A–0215	Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.	XX.000	Same as CMS. Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.
		XX.0001	Exceeds: The hospital must update these written policies on an annual basis with Governing body approval.

We anticipate that the AOs for each program type (that is, hospice, home health, outpatient physical therapy, hospitals, ESRD facilities, RHC, CAH, ASCs, psychiatric hospitals) for which the AO has deeming authority would be required to review and revise their existing crosswalk and standards into the required format. We further anticipate that the review and updating of AO standards crosswalk would be done by AO staff consisting of at least one RN and a medical secretary.

We estimate that the RN would spend 2 hours performing this task. We further estimate that a medical secretary would spend 198 hours performing this task. Therefore, the total time burden per each AO for this task would be 200 hours for each AO program. (2 hours per 1 RN + 198 hours per 1 medical secretary).

The adjusted mean hourly wage for an RN is \$94.64. We estimate that the cost for the work performed by the RN to perform the work on this task would be \$189.28 (2 hours × \$94.64).

The adjusted mean hourly wage for a medical secretary is \$43.82. We estimate that the cost burden for the work performed by the medical secretary on this task would be \$8,676.36 (198 hours × \$43.82). The total estimated cost burden for all work performed on this

task would be \$8,865.64 (\$189.28 + \$8,676.36).

CMS has 29 approved accreditation programs across nine AOs (as of 2026) for the eight distinct provider and supplier types:

- Ambulatory Surgical Centers (ASCs) (five AOs with CMS-approved programs)
- Critical Access Hospitals (CAHs) (four AOs with CMS-approved programs)
- Hospitals (including Psychiatric Hospitals) (four AOs with CMS-approved programs)
- Home Health Agencies (HHAs) (three AOs with CMS-approved programs)
- Hospices (3 three AOs with CMS-approved programs)
- End-Stage Renal Disease (ESRD) Facilities (two AOs with CMS-approved programs)
- Rural Health Clinics (RHCs) (three AOs with CMS-approved programs)
- Transplant Centers (four AOs with CMS-approved programs)
- Outpatient Physical Therapy/Speech Pathology (OPT/SP) (one AO with a CMS-approved program)

This requirement applies only to those AOs that accredit Medicare-certified providers and suppliers for deeming purposes. There are 9 AOs that accredit Medicare-certified providers and suppliers through 29 CMS-approved accreditation programs.

Therefore, the one-time, first-year cost burden for each of the 9 AOs for one program only would be \$8,865.64. The number of approved programs for each AO ranges from one to six. There are currently 3 AOs that have 1 approved program each (one-time, first-year cost burden for each of these 3 AOs would be \$8,865.64); 2 AOs that have 2 approved programs each (one-time, first-year cost burden for each of these 2 AOs would be \$17,731.28); 2 AOs that have 3 approved programs each (one-time, first-year cost burden for each of these 2 AOs would be \$26,596.92); and 2 AOs that have 6 approved programs each (one-time, first-year cost burden for each of these 2 AOs would be \$53,193.84).

With 29 total programs across 9 AOs, we assumed an average of 3 programs per AO ($29/9 = 3.2$ or 3) and an average one-time, first-year cost burden of \$26,598 per AO (3 programs per AO × \$8,866 cost burden per program = \$26,598).

C. ICRs Associated With the Requirement That AOs Use Survey Processes That Are Comparable to That Used by CMS and the SAs

The requirements from § 488.5(a)(4) through (13) will require the AOs to submit revised initial and renewal application information supporting comparability in the survey processes

and guidance established by CMS and used by the SA. However, we note that while additional regulatory language changes are being made under § 488.5(a)(4) through (13), AOs are already required to submit this type of documentation. Our intent is to clarify in regulation the minimum standards and required documentation that AOs show comparability to CMS survey process, forms, guidelines, and instructions to surveyors.

1. ICR Related to Revised Documentation Submission Requirements Imposed by Requirements That AOs Use Comparable Survey Process at § 488.5(a)(13)

The requirements under § 488.5(a)(13) will require AOs to submit specific information on the AOs' notification procedures, including timeframes for notification, to CMS in regard to a facility which the AO accredits if the facility fails to meet accreditation standards or its accreditation status is affected, as part of the documentation currently required under § 488.5(a)(13). Furthermore, the existing requirements currently require the AOs to have: (1) procedures for responding and investigating complaints; and (2) a process for decision-making as it relates to accrediting status. In addition to the added requirement, we are also adding a requirement that AOs must submit documentation regarding the AO's process for facilities that withdraw from accreditation, including notification procedures.

We believe this review and revision would be conducted by one RN, one general healthcare support member, one medical secretary, and the CEO to develop these procedures, review and approve all changes. The adjusted mean hourly wage for an RN is \$94.64. The adjusted mean hourly wage for a healthcare support staff person is \$46.88. The adjusted mean hourly wage for a medical secretary is \$43.82. The adjusted mean hourly wage for a CEO is \$252.82.

We anticipate it would take approximately 5 hours for the AO staff to review the new requirements set forth in this final rule with comment period and to determine what changes need to be made to their standards, policies and procedures. We also estimate that it would take an additional 5 hours for the AO staff to make the revisions required to align their accreditation standards and policies and procedures with our revisions. Therefore, the total estimated time burden for each AO would be 10 hours.

This requirement applies to the 9 AOs (as of 2026) that accredit Medicare-

certified providers and suppliers. Therefore, the total time burden across these 9 AOs would be 90 hours (10 hours × 9 AOs).

As stated, we believe that the AO staff that would perform this task would consist of an RN, a healthcare support staff person, a medical secretary, and the AO's CEO to review and approve all changes. We estimate that the cost burden for the work performed by the RN would be \$236.60 (2.5 hours × \$94.64 per hour). We estimate that the cost burden for the work performed by the healthcare support staff person would be \$117.20 (2.5 hours × \$46.88). We estimate that the cost burden for the work performed by the medical secretary would be \$109.55 (2.5 hours × \$43.82). We estimate that the cost burden for the work performed by the CEO would be \$632.05 (2.5 hours × \$252.82).

We estimate that the total cost burden for each AO for this task would be \$1,095.40 (\$236.60 + \$117.20 + \$109.55 + \$632.05). The burden across the 9 AOs that accredit Medicare-certified providers and suppliers would be \$9,858.60 (\$1,095.40 × 9 AOs).

2. ICR Associated With the Requirement That the AOs Provide Documentation to CMS About Its Staff Training Programs for Its Revised Survey Process (§ 488.5(a)(4)(xi))

The requirement at § 488.5(a)(4)(xi) will require the AO to submit documentation summarizing its staff training programs, either web-based or hard copy training materials, to CMS, on how the AO provides training or education to surveyors on the AO's survey processes, and, where applicable, highlight differences from CMS survey processes.

As AOs currently have existing training for their surveyors on their survey processes, we believe that the preparation of these materials would only require the AOs to extrapolate what they believe are the core differences between the CMS survey process and those of their respective organizations.

We believe it would take approximately 5 hours for the review of the current AO processes and approximately 25 hours to develop an abbreviated course of their survey processes for their accredited programs. We believe that the persons at the AO who would perform these tasks would be two RNs and a medical secretary. We estimate that each RN would spend approximately 25 hours performing the required work. We further estimate that the medical secretary would spend 5 hours performing work on this task. The

adjusted mean hourly wage for an RN is \$94.64. The adjusted mean hourly wage for a medical secretary is \$43.82.

We estimate that the total time burden for each AO would be 55 hours. This provision would apply to all 9 AOs that accredit Medicare-certified providers and suppliers. Therefore, the estimated total annual time burden for these tasks would be 495 hours (55 hours × 9 AOs). We estimate that the cost burden to each AO for the work performed by the RNs would be \$4,732 (\$94.64 × 50 hours). We further estimate that the cost burden to each AO for the work performed by the medical secretary would be \$219.10 (\$43.82 × 5 hours). The total estimated cost burden for each AO for this task would be \$4,951.10 (\$4,732 + \$219.10).

This requirement will apply to all 9 AOs that accredit Medicare-certified providers and suppliers for deeming purposes. Therefore, we estimate that the total cost would be \$44,559.90 (\$4,951.10 × 9).

3. ICR Related to Requirement for AO To Submit Survey Findings/Reports

As mentioned in section IV.C. of the proposed rule, we also proposed to require the AOs as part of their application under § 488.5(a)(4)(viii) to acknowledge that it will submit any requested survey findings and reports, to include complaint survey reports to CMS for internal use.

This requirement would not cause the AOs to incur any new additional burden as the submission of this information is already required by this regulation and is therefore a usual and customary component of initial and renewal applications. AOs are also already required to submit the deficiencies and facility non-compliance in a roll-up format. Therefore, this proposed requirement for a full survey report could potentially be seen as a burden reduction as CMS would not require a specific new entry or format and reduce time spent by the AO summarizing the survey activity.

4. ICR Related to Documentation Requirements for Submission to CMS for Approval of the AOs' Revised Accreditation Standards and Survey Process (§ 488.8(b))

The AOs will be required to resubmit their new survey processes and standards for a comparability review as required by § 488.8(b)(1).

We believe that the AO staff that would work on this task would be a medical secretary. We believe that the medical secretary would gather all required documents, complete the compilation of documents and

verification. The adjusted mean hourly wage for a medical secretary is \$43.82.

We anticipate the total burden hours for each AOs to compile each accreditation program and the revisions as required within §§ 488.4(a)(1) and 488.4(a)(2) for a resubmission to CMS for review and approval would be 80 hours. The total estimated cost burden for each AO program would be \$3,505.60 (80 hours × \$43.82).

CMS currently has 29 approved accreditation programs across nine AOs (as of 2026) for the eight distinct provider and supplier types:

- Ambulatory Surgical Centers (ASCs) (five AOs with CMS-approved programs)
- Critical Access Hospitals (CAHs) (four AOs with CMS-approved programs)
- Hospitals (including Psychiatric Hospitals) (four AOs with CMS-approved programs)
- Home Health Agencies (HHAs) (three AOs with CMS-approved programs)
- Hospices (three AOs with CMS-approved programs)
- End-Stage Renal Disease (ESRD) Facilities (two AOs with CMS-approved programs)
- Rural Health Clinics (RHCs) (three AOs with CMS-approved programs)
- Transplant Centers (four AOs with CMS-approved programs)
- Outpatient Physical Therapy/Speech Pathology (OPT/SP) (one AO with a CMS-approved program)

This requirement applies only to those AOs that accredit Medicare-certified providers and suppliers for deeming purposes. There are 9 AOs that accredit Medicare-certified providers and suppliers through 29 CMS-approved accreditation programs. Therefore, the one-time, first-year cost burden for each of the 9 AOs for one program only would be \$3,505.60. The number of approved programs for each AO ranges from one to six. There are currently 3 AOs that have 1 approved program each (one-time, first-year cost burden for each of these 3 AOs would be \$3,505.60); 2 AOs that have 2 approved programs each (one-time, first-year cost burden for each of these 2 AOs would be \$7,011.20); 2 AOs that have 3 approved programs each (one-time, first-year cost burden for each of these 2 AOs would be \$10,516.80); and 2 AOs that have 6 approved programs each (one-time, first-year cost burden for each of these 2 AOs would be \$21,033.60).

With 29 total programs across 9 AOs, we assumed an average of 3 programs per AO (29/9 = 3.2 or 3) and an average one-time, first-year cost burden of \$10,516.80 per AO (3 programs per AO × \$3,505.60 cost burden per program = \$10,516.80).

As mentioned in section IV.K. of this final rule with comment period, the changes would not implement a reoccurring annual burden, but rather have a one-time burden on the AOs until the survey processes and activities are aligned with our changes in this final rule with comment period. CMS would resume the current process for approval and re-approval of AOs and their accrediting programs as outlined within the revised § 488.5.

We note there is no direct burden associated with these changes to the deemed provider or supplier.

D. ICRs Associated With the Establishment of a Definition for “National in Scope” (§ 488.1)

As finalized at § 488.1, we will require the AO to provide documentation for meeting the definition of “national in scope” within their initial and reapplication process. As currently required by § 488.1, the AO must provide documentation that demonstrates the organization meets the definition of a “national accrediting organization” as it relates to the accreditation program. Therefore, we estimate the burden on AOs to be minimal as they are already required to provide documentation to this effect. Therefore, we estimate the following:

1. ICR Related to Documentation Requirements for “National in Scope”

We anticipate that a CEO of an AO would compile and verify that the AO meets the proposed definition of “national in scope”.

Since CMS is not requiring a specific format for this documentation, but suggests the AO provide a list which identifies the accredited facilities meeting the definition, we anticipate the compiling of this information would take approximately 40 minutes (0.66 hour) per each AO. For existing CMS approved AOs, the general re-application cycle is not to exceed 6 years. Therefore, we anticipate this burden to be applicable every 4 to 6 years. Therefore, we estimate that the total time burden across all 9 AOs would be 7.33 hours (or 7 hours & 20 minutes) every 4 to 6 years.

The average hourly wage of the AOs CEO is \$252.82. Therefore, we estimate that the total cost burden for this task per each AO would be \$168.56 (\$252.82 × .66). We further estimate that the total cost burden across the 9 AOs that accredit Medicare-certified providers and suppliers would be \$1,517.04 (\$168.56 × 9 AOs).

2. ICR Related to Incorporation of the “National in Scope” Requirements Into the AO’s Application

We anticipate that a medical secretary would finalize and package/send the application for CMS approval. We believe this additional document of meeting “national in scope” would take approximately 5 minutes (0.083 hours) per each AO to be included in the package which is already required under § 488.5. This requirement would apply only to the 9 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total time burden associated with this task across these 9 AOs would be 45 minutes (0.75 hour).

The adjusted mean hourly wage for a medical secretary is \$43.82. Therefore, we estimate that the cost burden per each AO for this task would be \$3.64 (5 minutes (0.083 hour) × \$43.82). We further estimate that the total cost burden would be \$40.16 (\$43.82/60 min. per hour = \$0.73 per min.) and (\$0.73 per min. × 55 min. = \$40.16 per 55 min) or (\$4.462 × 9 AOs = \$40.158).

This burden is imposed to ensure AOs submit verification of meeting the new definition. However, this burden would only be incurred by the AOs during the submission of their initial or renewal applications which would only take place every 4 to 6 years. The burden associated with these requirements will be submitted to OMB under OMB control number 0938–NEW.

We note that there is no direct burden associated with these changes to the deemed provider or supplier.

E. ICR Associated With the Revision of the AO Performance Measures and To Require a Publicly Reportable Plan of Correction

Traditionally, SAs performed validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, and HHAs) accredited by the AOs. These SA “look-back” validation surveys compared the survey findings of the AO to those of the SA to see if there were any disparities. The disparities found between an AO’s surveys and an SA’s surveys were used in a performance measure called the “disparity rate” and was tracked by CMS as an indication of the quality of the surveys performed by the AO as described earlier in this rule.

We are revising the validation process for Medicare-certified providers and suppliers by establishing a new type of validation survey known as a DOVS to replace the previous “look-back” validation survey performed by the SAs. As a result of the revisions made to the

validation process, and for the reasons discussed in section III.Y. of this final rule with comment period, we have established a new definition for “disparity rate” to revise the definition of disparity rate as a “process disparity rate”, which is defined as, “for a DOVS, the difference between the observed survey process findings and the expected survey process findings expressed as a percentage”, in this final rule with comment period. As a result of removing the “look-back” validation surveys in this final rule with comment period, we are also withdrawing and not finalizing the proposed definition of “outcome disparity rate.”

At § 488.8(a)(4), we require that the AO submit a publicly reportable plan of correction for performance that is less than an acceptable threshold for established performance measures.

This is a new requirement and therefore will be a new burden for AOs to complete. The plan of correction will be completed and submitted to CMS within 10 business days following the notification of the AO of their less than acceptable performance. It will address the areas of improvement and the specific actions to be taken to improve those areas on a sustainable basis, the process for ongoing monitoring of progress toward acceptable performance, as well as the individuals responsible for overseeing the plan of correction and the anticipated implementation dates of the proposed actions.

In the proposed rule (89 FR 12040) we stated the following in estimating the costs of these proposed requirements, we believe that this task would be performed by the AO’s CEO. We also anticipate that each AO would prepare approximately 123 plans of correction per year. We further estimate that it would take 80 hours of time by the AO’s CEO to prepare each plan of correction. This is using the overall average disparity rate of 33 percent. There are approximately 374 annual validation surveys performed across all provider types (374×0.33 total plans of correction). We further estimate that the total annual time burden per each AO for the completion of POCs would be 9,840 hours (80 hours $\times$ 123). We further estimate that the total annual time burden for the completion of all POCs across all 11 AOs that accredit Medicare-certified providers and suppliers would be 108,240 hours (9,840 hours $\times$ 11 AOs). We estimate that the cost burden to each AO for the completion of each POC would be \$16,385.60 (80 hours $\times$ \$204.82). We further estimate that the annual cost burden per each AO for the completion

of the estimated 123 POCs per year would be \$2,015,428.80 (9,840 hours $\times$ \$204.82). We further estimate that the total annual cost burden across all 11 AOs that accredit Medicare-certified providers and suppliers for the completion of all POCs annually would be \$22,169,716.80 (\$2,015,428.80 $\times$ 11 AOs).

In preparing and estimating the costs of this final rule with comment period for AOs, we recognized that our proposed estimates need to be revised in several areas. Based on our experience with AOs, we no longer believe that the plan of correction would be prepared by the AO’s CEO. We believe the plan of correction would be more appropriately prepared by one of the AO’s program managers and that it would not take 80 hours of the program manager’s time for each plan of correction. We believe that we grossly overestimated the burden hours for this task. Therefore, based on our experience working with the AOs and their program managers on past survey process performance issues, that it would only take approximately 8 to 16 hours for an AO program manager to complete a plan of correction and submit it to CMS. We have averaged this estimate to 12 hours of burden for this new requirement.

We also no longer anticipate that each AO would need to prepare approximately 123 plans of correction per year. This estimate was based on the approximate number of 374 annual validation surveys performed across all AOs and provider and supplier types using the overall average disparity rate of 33 percent. Both the average annual number of validation surveys and the average disparity rate are based on the proposed look-back validation survey model, including the outcome disparity rate, that we are withdrawing in this rule, and not on the DOVS model and the process disparity rate being finalized in this rule. We believe this invalidates our use of those numbers for this final rule with comment period since they do not apply to DOVS and the process disparity rate and performance measures based on that rate. Therefore, we are revising our proposed estimates of these numbers based on what we anticipate will be the annual number of DOVS performed for all nine AOs using a representative sample of their CMS-approved accreditation programs after this rule is finalized.

Beginning on October 30, 2023, and ending on September 12, 2024, there were 151 DOVS performed by CMS surveyors across all nine AOs from a representative sample of nine different CMS-approved accreditation program types, including three new program

types that had never been surveyed under the traditional look-back validation surveys. The DOVS pilot year was national in scope, taking place across 44 States.

Once CMS completed the DOVS scoring for the survey performance of each AO and its specific program type and surveyor team, CMS would send the scoring report to the applicable AO. The AO then had 10 days to review its scoring and request a reconsideration of its score if applicable. For the pilot year, CMS received 39 requests for reconsideration from AOs out of the 151 DOVS surveys performed and scored, or 26 percent. CMS reviewed each request and made its decisions for reconsideration of AO DOVS scores based on evidence submitted by the AO in addition to the applicable CMS regulations in the CFR and the specific survey guidance contained in the SOM. Of the 39 requests for reconsideration of DOVS scores, CMS either partially or completely upheld the original scoring for 25 of the surveys, or 17 percent of the 151 DOVS surveys and scores.

We believe that the number of DOVS surveys performed by CMS in the pilot year of 2023–2024 per year (151) will remain relatively constant after this rule is finalized and after the DOVS program is resumed. We also believe that the 25 (17 percent) DOVS survey scores in the pilot year that CMS upheld after reconsideration (and thus would most likely be those requiring an AO to correct deficiencies in its survey process through a plan of correction) are a reliable indicator of the number of DOVS findings and scores that will require plans of correction by AOs per year under the requirements being finalized in this rule.

Based on these assumptions drawn from the DOVS pilot, we believe that it would take approximately 8 to 16 hours for an AO program manager (at a salary of \$128 per hour) to complete a plan of correction and submit it to CMS. We have averaged this estimate to 12 hours of burden for this new requirement. We estimate that the burden hours for 25 plans of correction (divided equally among the 9 AOs for approximately three plans of correction for each AO) would be a total of 300 hours or 36 hours for each AO program manager. We estimate that the cost burden to each AO for the completion of each plan of correction would be \$1,536 (12 hours $\times$ \$128). We further estimate that the annual cost burden per each AO for the completion of the estimated three plans of correction per year would be \$4,608 (36 hours $\times$ \$128). We further estimate that the total annual cost burden across all 9 AOs that accredit Medicare-

certified providers and suppliers for the completion of all plans of correction annually would be \$41,472 (\$4,608 × 9 AOs).

F. Summary of Estimated Burden

Table 5 provides a summary of the estimated burden related to the

requirements of this final rule with comment period.

TABLE 5—SUMMARY OF COST BURDEN

Time & Cost Burden Summary Table		
Name of ICR	Time burden	Cost burden
A. Information Collection Requirements (ICRs) Related to Conflict-of-Interest Requirements.		
1. ICR Related to Conflict-of-Interest Policies & Procedures AOs Must Submit to CMS (§ 488.5(a)(10)).	• 48 hours per AO	• \$5,449.92 per AO for 1st report.
2. Requirement that AO surveyors submit conflict-of-interest declarations to CMS upon request and during application review process (§ 488.5(a)(22)).	• 432 hours across 9 AOs	• \$49,049.28 across all 9 AOs.
3. Requirement for Submission of Information About AO Fee-based Consulting Services Provided (§ 488.8(i)(5)).	• 48 hours per AO	• \$1,090 per AO annually.
	• 432 hours across 9 AOs	• \$9,810 across all 9 AOs annually.
	• 48 hours per AO for the 1st year report.	• \$5,449.92 per AO for 1st report.
	• 432 hours across 9 AOs for 1st year reports.	• \$49,049.28 across all 9 AOs for 1st reports.
	• 8 hours per AO for 2nd year report & all subsequent reports.	• \$757.12 per AO for the 2nd report & all subsequent reports.
	• 72 hours across all 9 AOs for 2nd year & all subsequent reports.	• \$6,814.08 across all 9 AOs for the 2nd year reports & all subsequent reports.
4. Requirement that Accrediting Organization Establish Fee-Based Consulting Firewall Policies and Procedures (§ 488.8(j)).	• 0 hours (The time burden associated with this requirement is included with burden calculation for 488.8(i)).	• \$0 (The cost burden associated with this requirement is included with burden calculation for 488.8(i)).
B. Requirement that the AO Incorporate the CMS standards to ensure improved evaluation of AO performance (§ 488.5(a)(3)).	• 200 hours per AO program for first-year, one-time burden.	• \$26,598 per AO for first-year, one-time cost.
	• 5,400 hours across all 9 AOs for first-year, one-time burden.	• \$239,382 across all 9 AOs for first-year, one-time cost.
C. Burden Related to Requirement that AOs Must Use Comparable Survey Processes to That Used by CMS and the SAs.		
1. Burden Related to Documentation Requirements Imposed By Requirement that AOs Use Comparable Survey Process (§ 488.5(a)(13)).	• 10 hours per AO	• \$1,095.40 per AO.
	• 90 hours across the 9 AOs that accredit Medicare-certified providers & suppliers.	• \$9,858.60 across 9 AOs.
2. Burden associated with the preparation of a presentation that AOs must prepare and provide to CMS to demonstrate how their survey processes are comparable to that of CMS.	• 55 hours per AO	• \$4,951.10 per AO.
	• 495 hours across the 9 AOs that accredit Medicare-certified providers & suppliers.	• \$44,559.90 across 9 AOs.
3. ICR Related to Requirement for AO to Submit Survey Findings/Reports.	• 0 hours	• \$0—because the AOs are already required to do this.
4. Burden Related to Submission of Revised Accreditation Standards and Survey Processes for review and approval by CMS as required by § 488.8(b).	• 80 hours per AO program for first-year, one-time burden.	• \$10,516.80 per AO for first-year, one-time cost.
	• 2,160 hours across all 9 AOs for first-year, one-time burden.	• \$94,651.20 across all 9 AOs for first-year, one-time cost.
	• 0.66 hour every 4–6 years	• \$168.56 per AO
D. Burden Related to Documentation Requirements for “National in Scope.”		
1. Documentation requirement for “National in Scope”	• 6 hours across the 9 AOs that accredit Medicare-certified providers & suppliers.	• \$1,517.04 across the 9 AOs that accredit Medicare-certified providers & suppliers.
	• 0.083 hour per AO	• \$4.46 per AO.
	• 0.75 hours across the 9 AOs that accredit Medicare-certified providers & suppliers.	• \$40.16 across the 9 AOs that accredit Medicare-certified providers & suppliers.
	• 12 hours per plan of correction	• \$1,536 per plan of correction.
	• 36 hours per AO annually for completion of 3 plans of correction per year.	• \$4,608 per AO for completion of 3 plans of correction per year.
	• 324 hours annually across all 9 AOs that accredit Medicare-certified providers and suppliers.	• \$41,472 across all 9 AOs that accredit Medicare-certified providers and suppliers.
E. Revision of the AO Performance Measures and Requirements to Submit a Publicly Reportable Plan of Correction.		
Total Estimated Time Burden	• 9,844 total burden hours across all AOs/accreditation programs	
Year 1 Costs		\$539,389.
Year 2 Costs		114,072.
Year 3 Costs		114,072.
Year 4 Costs		114,072.
Year 5 Costs		114,072.

TABLE 5—SUMMARY OF COST BURDEN—Continued

Time & Cost Burden Summary Table		
Name of ICR	Time burden	Cost burden
Average annual total costs over 5 years		199,135.
Total Average Annual ICR Cost Burden per AO		22,126.
Total ICR Cost Burden Across All AOs		199,135.
Total Net Cost Burden		199,135.

In the proposed rule, we solicited public comments to the collection of information section of this rule. We received the following comments regarding the time and burden calculations for the proposed rule.

Comment: One commenter stated that the Office of Management and Budget (OMB) completed a Summary of Cost Burden that AOs would incur to implement the proposed rule. The total net cost burden is \$25,505,274. When the total estimated loss of profit is added, the total net impact on AOs is \$39,114,116. This impact will be felt proportionately according to the number of programs the AO has approved deemed status for. The two largest AOs are projected to bear approximately \$10 million each of this burden. It raises serious concerns about the feasibility of expecting independent, not-for-profit AOs to absorb such a financial impact. This final rule with comment period poses a considerable threat to the financial stability and sustainability of these organizations.

Another commenter contended that even if the ICR calculations included within the proposed rule were accurate (and this commenter believes many of the burden calculations are significantly understated and burdensome), the cost impact would be more than \$2.5 million per AO, with nearly all requirements becoming effective within a year or less, potentially further escalating costs.

Response: We prepared this burden estimate based on what tasks we believed the AOs would be required to complete to implement the proposals made in the proposed rule if all proposals are finalized. The Collection of Information sections provide detailed descriptions of proposals, the tasks we believe would be required, and our estimated time and cost burdens for each.

It is important to note several facts about our burden estimates. First, these burden estimates are higher for the AOs that provide fee-based consulting and lower for those that do not. This is because the six proposals related to fee-based consulting services do not apply to the AOs that do not provide this

service. Thus, the time and cost burdens for these AOs will be lower.

Also, these are just *estimated* costs for the *possible* tasks that might be required of the AOs to implement our proposals and the associated time and cost burdens. The AOs may not need to perform the stated tasks if they already follow some of the requirements or already have the required policies and procedures. Or it may not take the AO as much time as we estimated it would to perform a task, thus the estimated cost would be lowered. In addition, as we have detailed above in the preamble to the applicable sections of this final rule with comment period, we have not finalized some of our proposed requirements or we have revised them based on public comments in ways that still strengthen our oversight of AOs but also significantly lower the estimated costs of this final rule with comment period versus the estimated costs of the proposed rule. Additionally, we believe that a degree of burden is justified when the rulemaking better aligns our requirements with our statutory authority to oversee AOs and their survey programs for Medicare-certified providers and suppliers to ensure that those providers and suppliers improve the safety and quality of care for patients nationwide.

Comment: One commenter stated that, in drafting the proposed rule, CMS may have made some errors in its calculations of cost and burden for AOs. This commenter cited to the cost and time burden estimate for the requirement that the AO surveyors take the CMS surveyor training as an example.

This commenter stated that in this burden estimate, CMS used an estimation of 75 surveyors per AO. This commenter stated that they employ several hundred surveyors. As a result, two-thirds of the total estimated cost and time burden used by CMS for all AOs (75 surveyors × 11 Medicare-deemed AOs) is in fact closer to a burden estimate for a single AO.

Response: We respectfully disagree that our burden estimate is erroneous. At the time of the publication of the

proposed rule, we did not have any information about how many surveyors are employed by each AO that accredited Medicare certified providers and suppliers. Therefore, we had to make an estimate of the number of surveyors employed by each AO.

Also, while this commenter is a larger AO that employs a larger number of surveyors, this is the exception rather than the rule. The remainder of the AOs are not as large and do not employ as many surveyors. Therefore, we chose to use, for the number of surveyors, a number that is more representative of the number of surveyors employed the majority of the AOs, and not just this commenter.

Further, to get the time and cost burden estimate that is representative of the number of surveyors they employ, this commenter could have just substituted their number of surveyors into the calculations to come up with a burden estimate for their AO. For example, in the proposed rule, we estimate that it would take each surveyor 35 hours to complete the required CMS surveyor training. If this commenter has 250 surveyors, then the total time burden across all its surveyors would be 8,750 hours (35 hours × 250 surveyors).

Also, in the proposed rule, we stated that the adjusted hourly wage for an RN is \$94.64. The cost burden for each surveyor to take the CMS online surveyor training would be \$3,312.40. (35 hours × \$94.64). If an AO employs 250 surveyors, the cost burden across all 250 surveyors would be \$828,100 (8,750 hours × \$94.64 per hour).

This commenter stated that they employ “several hundred” surveyors but did not provide the exact number, therefore we have used an estimated number of 250 surveyors. The commenter can insert the exact number of surveyors they employ to get the exact burden calculations.

Comment: One commenter expressed disagreement with the burden calculations estimated by CMS throughout this proposal. The impact calculated by the agency fails to take into account applicable administrative

costs for each proposed change. The additional administrative costs to each AO include additional support services and personnel, IT and systems costs, marketing and education efforts, etc. Even proposed changes that are presented by CMS as having \$0 estimated impact and noted as a usual and customary practice of the AO will require some level of investment for effective implementation to meet the proposals.

Response: In the collection of information section of the proposed rule, we provided estimates of the time and cost burdens we believe the AOs will incur if our proposals are finalized. However, these are just estimates and not exact figures.

We can only include time and cost burdens for those tasks we anticipate the AOs would be required to implement as a result of our proposals. However, each AO is an individual and separate business entity that have different business operations, practice, policies, etc. CMS is not privy to how the AOs run their businesses or structure their organizations. Therefore, we may not have anticipated some tasks that the AOs may incur related to our proposals.

Comment: One commenter was concerned that the burden calculations do not account for the additional time, cost, and resources that will be required from CMS and State agencies for review and enforcement. These additional costs will necessarily be passed on to taxpayers and the healthcare system; those burdens should be recognized by the agency and presented within the proposal.

Response: While this information was not stated in the proposed rule, the costs to the Federal government are calculated.

Comment: One commenter stated that the entire section of information collection and cost estimation required by the OMB grossly underestimates the time and cost of AOs to comply with this proposed rule. Not only are time estimates underestimated, but the wage data used is from 2021 before the explosion of labor cost inflation; and CMS is underestimating the cost burden and impact by at least 25 percent to 40 percent.

Response: The information collection section of the proposed rule contains our estimates of the time and cost burdens caused by the proposals in the rule. In these burden estimates, we include the time and costs burden for the tasks we anticipate each proposed requirement will require the AOs to perform. However, CMS is not able to anticipate every single time and cost

burden because each AO has different organizational structures, operating procedures, and varying numbers of staff and surveyors. Each AO may handle each proposed requirement differently. For example, while some AOs may use existing staff to perform the tasks associated with a proposed requirement, other AOs may decide to hire new staff to do so.

This commenter did not provide any information about which sections of our burden calculations are underestimated. We invite this commenter to provide CMS with the time and cost burden information we did not include in the Information Collection Request section of the rule. In the alternative, we suggest that this commenter calculate the additional time and cost burdens.

This commenter stated that CMS used outdated wage rates in the cost burden calculations. At the time of the writing of the proposed rule, we used the then-current wage rates from the U.S. Bureau of Labor Statistics. However, these wage rates have been updated in this final rule with comment period.

VII. Regulatory Impact Analysis

A. Statement of Need

We seek to strengthen the public trust in CMS-approved AOs' findings and to protect the health and safety of patients that seek services from Medicare and Medicaid-participating providers that are accredited by CMS-approved AOs. We believe that AOs that voluntarily seek approval for "deeming purposes" are taking on a critical quality assurance role for the American people. Patients need to be able to rely on the strength of that accreditation to be assured that their healthcare services will be safe and of high quality. Where there are gaps in that accreditation process, or where quality issues are not fully identified or investigated by the AO, it means that current and future patients may experience unnecessary harm or quality issues. Therefore, we are seeking to strengthen our oversight of AOs by revising existing regulations or implementing new regulations that would address the following issues: (1) place limitations on the fee-based consulting services AOs offer to the providers and suppliers they accredit; (2) implement remedies for violation of the prohibition against AO fee-based consulting; (3) require AOs to report information to CMS on a bi-annual basis about the fee-based consulting services they provide; (4) require AOs to report specific conflict-of-interest information to CMS with their initial and renewal applications; (5) require AOs to submit surveyor conflict-of-interest declarations

to CMS on an annual basis; (6) prohibit AO owners, surveyors and other employees, that currently or within the previous 2 years have had an interest in or relationship with a healthcare facility the AO accredits from doing the following: (a) participating in the survey of that healthcare facility; (b) having input into the results of the survey and accreditation for that healthcare facility; (c) having involvement with the pre-or post-survey activities for that healthcare facility, or (d) having contact with or access to the records for the survey and accreditation of that healthcare facility; (7) require AOs to incorporate the CMS conditions into their accreditation standards for its deeming programs; (8) use a comparable survey processes; (9) revise the validation process, implement new performance measures and the use of plans of correction for unacceptable performance measure scores; (10) revise the hospital application process for AOs that have an approved hospital accreditation program to incorporate surveys of psychiatric hospitals into their hospital programs; (11) add new definitions for the terms "unannounced survey", "national in scope", "geographic regions", "process disparity rate", and "outcome disparity rate"; and (12) place limitations on terminated providers or suppliers seeking re-entry into the Medicare program. We continue to review and revise our health and safety requirements and survey processes to ensure they are effective in driving quality of care for our accredited providers and suppliers.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13132, "Federalism"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96-354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts.). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory

action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities. Based on our estimates, the Office of Information and Regulatory Affairs (OIRA) has determined that this rulemaking is significant per section 3(f) of E.O. 12866. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Benefits

In developing this final regulation, we carefully considered its potential effects including both costs and benefits. The overall benefit of this rule would be to improve CMS' oversight of the AOs and to improve the overall quality and safety of healthcare. More specifically, the benefits of this rule include the prevention and removal of potential and actual conflicts of interest, the improvement of the validation process and anticipated reductions in the validation disparity rate, the additional performance measure and the implementation of plans of correction that would help AOs that have low performance measure scores to prepare a plan for how to improve their performance. We note that the generation of benefits is contingent upon behavior change, which entails costs; provisions that are discussed later in this section as having negligible costs would therefore be anticipated to have minimal benefits.

However, we have identified a quantifiable benefit that this final rule with comment period will generate for AOs on an annual basis. Currently, 42 CFR 488.4(a)(2) does not allow any national AO to submit an application to CMS for approval of its transplant center accreditation program and thus excludes transplant centers from being deemed as having met the applicable CMS requirements through an AO accreditation survey. With the revisions to § 488.4(a)(2) in this final rule with comment period we have removed this

transplant center exception from the regulatory language and will now allow AOs to develop accreditation programs for this provider type that they may submit to CMS for approval. CMS may then deem a transplant center to be in compliance with the applicable Medicare conditions or requirements if a CMS-approved AO accreditation program determines such compliance through its survey of the provider.

We believe that AOs will benefit from this potential new source of revenue since AOs charge providers and suppliers seeking participation in the Medicare program initial and annual fees for their accreditation services. A provider or supplier pays an AO to conduct the accreditation surveys so that it may be deemed by CMS as meeting the applicable conditions or requirements for participation in the Medicare and/or Medicaid programs. An AO may also charge its provider/supplier client for other services to assist them in maintaining their compliance with the CMS requirements, such as services it might provide through its fee-based consulting division or separate business entity. Accreditation by an AO is voluntary and is not required for Medicare participation.

There are currently 234 approved transplant centers participating in Medicare with 888 approved transplant programs nationwide. To be approved by Medicare, transplant programs must meet the requirements specified at § 482.72 through § 482.104. A transplant program is located in a Medicare-approved hospital and provides transplantation services for the following types of solid organs: heart, lung, liver, kidney, pancreas, or intestine. In addition to meeting the transplant CoPs, the transplant program must comply with the hospital CoPs (specified in 42 CFR 482.1 through § 482.57). Appendix X of the State Operations Manual contains the interpretive guidance and survey procedures for transplant programs.

To estimate the benefits of this change to the requirements for AOs, we made several assumptions based on our knowledge of and our experience with AOs and their accreditation programs as well as with the provider and supplier types that must meet the CoPs and other Federal requirements to participate in the Medicare and Medicaid programs. First, we believe that of the 234 currently approved transplant centers roughly 80 percent, or 187, of them would seek continued CMS certification through a CMS-approved accreditation program once this rule becomes effective. We base this assumption on

the current percentage of hospitals that use accreditation for deeming purposes, an accreditation rate that has remained relatively steady for several decades now.

Second, we believe that each of the four AOs with currently approved hospital accreditation programs would submit an application to CMS for approval of a new transplant center program. Because transplant centers also have to meet the hospital CoPs, we believe that an AO with an established and approved hospital accreditation program is well positioned to develop a transplant center program that would be approved by CMS. That does not prohibit an AO currently without an approved hospital program from developing a transplant center program and submitting an application to CMS for its approval; however, such an AO would also need to develop a hospital program that would need CMS approval.

Estimates of how much each AO may charge a transplant center for accreditation range from \$26,000 to \$130,000. This cost range is based on what is generally known regarding what one of the AOs charges on average for a "small" hospital (\$26,000) and for a "large" and more complex hospital/medical center (\$130,000). TJC states on its website that its accreditation fees are based on the services provided and daily patient census and include annual fees that are invoiced each year during the triennial accreditation cycle as well as on-site fees that are invoiced during the year the survey is conducted.²⁴

We believe that transplant centers fall under the category of a large hospital and have based our estimates on \$130,000 averaged over the 3-year accreditation cycle for an annual stream of revenue of approximately \$43,000 paid to the AO by a transplant center. We estimate that this represents a potential additional source of revenue of \$8,041,000 for AOs annually (\$43,000 – 187 transplant centers). We begin converting the revenue to a measure of producer surplus by multiplying this estimate by 20 percent for a total of \$1,608,200 for accreditation services, consistent with an assumption that 80 percent of the incremental revenue attributable to the final rule would be offset by quantifiable marginal costs of delivering accreditation services. We derived the 20 percent estimate by reviewing financials that AOs submit as part of their application packages and found that their operating costs average 80 percent. The \$1.6 million result

²⁴ <https://www.jointcommission.org/en-us/accreditation/pricing>.

reflects accounting profit, which provides an upper bound on economic profit (the amount that would appropriately be included as a welfare change in this regulatory impact analysis).

We have identified another benefit of this enabling provision that would generate additional annual revenue for these four AOs in the form of fee-based consulting services for those transplant centers that might contract for such services to achieve accreditation for deeming purposes. Recent industry surveys and analysis indicate that over 68 percent of hospitals have established budgets specifically for compliance consulting services such as those offered by AOs.²⁵ Using this number, we believe that of the 234 currently approved transplant centers roughly 68 percent, or 159, of them would seek to maintain CMS certification through AO fee-based consulting services once this rule becomes effective.

Healthcare consultants typically charge hospitals between \$100 to \$400 per hour, or \$10,000 to \$100,000+ per project.²⁶ For our estimates of AO fee-based consulting services cost, we believe that it is reasonable to use the same amount that we have used here to estimate how much AOs would charge annually on average for their accreditation services (\$43,000). Therefore, we estimate that this represents a potential additional source of revenue of \$6,837,000 for AOs annually (\$43,000 – 159 transplant centers). We begin converting the revenue to a measure of accounting profit (an intermediate step toward estimating economic profit or producer surplus) by multiplying this estimate by 20 percent for a total of \$1,367,400 for fee-based consulting services.

This serves as our estimate of an upper bound on the benefits accruing to AOs from this enabling provision of this final rule with comment period, valued at \$3 million per year (\$1.6 million + \$1.4 million).

2. Provision-Specific Costs, Benefits and Transfers

We have identified the direct costs associated with this final rule with comment period as the costs associated with reporting, recordkeeping, and other costs. These costs are discussed below.

a. Impact Related to Conflict-of-Interest Requirements

In this final rule with comment period, there are several requirements related to AO and AO surveyor conflicts of interest. In the 2018 AO Conflict-of-Interest RFI, many commenters stated that AOs tend to ignore deficiencies during surveys to promote the efficacy of their consulting services. These commenters also stated that the AOs may ignore deficiencies to avoid giving poor survey results to their clients, who have paid substantial fees for both accreditation and AO fee-based consulting services. These commenters further stated that the financial relationship between the AO and the healthcare facilities they accredit causes a conflict of interest. We believe that the restrictions on AO fee-based consulting in this rule will reduce these conflicts of interest and hopefully remove the incentive for AOs to ignore deficiencies during surveys. We further believe that the conflict-of-interest requirements in this final rule with comment period will prevent potential and new conflicts of interest from occurring. We will address the financial impacts associated with each of these proposals separately.

(1) Impacts Related to Restrictions on Fee-Based Consulting Provided by AOs to the Healthcare Providers and Suppliers They Accredite (\$ 488.8(i)(1) through (3))

In section IV.B.3. of this final rule with comment period, we are finalizing restrictions on AO fee-based consulting provided by accrediting organizations or their associated consulting divisions or companies. As finalized, § 488.8(i) will still allow AOs to provide consulting services to the providers and suppliers they accredit with restrictions that address the conflict-of-interest issues associated with these services.

The provision also requires the AOs that provide consulting to revise their consulting business documents, such as their business charter, business documents, employee training information, informational documents that are distributed to prospective clients, and their policies and procedures.

We believe that the AO staff that would be performing these tasks would be an RN and a management staff person that has a job that meets the U.S. Bureau of Labor Statistics job of category of health and medical services manager. The adjusted mean hourly wage for an RN is \$94.64. The adjusted mean hourly wage for a medical and health services manager is \$132.44.

We estimate that this rule will require the two AO staff members to work on a full-time basis for 1 week (that is, 40 hours per person) to complete the required revisions to the AO's consulting business documents initially when this rule becomes effective. Therefore, we estimate that the one-time burden per each AO for the two AO staff members to perform the required tasks would be 80 hours (2 team members × 40 hours).

At this time, there are only four AOs that provide fee-based consulting. However, because we are revising the term to include all consulting services, this requirement would apply to any AO that provides consulting services. Therefore, for purposes of this estimate, we must assume that all 9 AOs may provide consulting services as described in this rule and that the total one-time burden would be 720 hours (80 hours × 9 AOs).

The cost burden related to the work performed by the RN on this task would be \$3,785.60 (40 hours × \$94.64). The cost burden related to the work performed by the medical or health services manager on this task would be \$5,297.60 (40 hours × \$132.44).

Finally, we estimate that the first-year, one-time cost burden per each AO related to the requirements for § 488.8(i)(1) through (3) would be \$9,083.20 (\$3,785.60 + \$5,297.60). We estimate that the total first-year, one-time cost burden to all nine AOs would be \$81,748.80 (\$9,083.20 × 9 AOs).

(2) Impact of Loss of Revenue to AOs Due to Requirement for Fee-based Consulting Services

We also believe that there will be a further financial impact to all AOs that provide fee-based consulting from the restrictions on fee-based consulting due to the requirements of this rule. Although the 2018 AO Conflict-of-Interest RFI gathered information about the nature of these relationships, they did not provide enough information for us to accurately calculate the financial impact that the requirements of § 488.8(i)(1) would have on the AO. We do estimate that the AOs would have a decrease in approximately 25 percent of the fee-based consulting business due to the restriction on providing fee-based consulting prior to initial surveys. We say this because AOs perform accreditation on a 3-year cycle, following the initial survey. We estimate that 25 percent of the fee-based consulting performed by an AO on an annual basis would be for new clients prior to their initial survey. We further estimate that the remaining 75 percent of the AOs fee-based consulting

²⁵ <https://www.modernhealthcare.com/providers/mh-healthcare-consultants-trends-ai-mergers/>.

²⁶ <https://www.fiercehealthcare.com/providers/pricer-management-consultants-brought-little-no-observable-benefits-nonprofit-hospitals>.

business would be provided to providers and suppliers prior to a reaccreditation survey.

According to Internal Revenue Service financial disclosure statements filed by the AO that provides the most fee-based consulting through an associated fee-based and other consulting division or company, this AO realized gross revenue from fee-based consulting services in the amount of \$44,960,143 in 2020 and \$55,970,543 in 2021.²⁷ This equates to an average annual revenue of \$50,465,298 from fee-based consulting.

We estimate that new accreditation clients make up approximately 33 percent of an AO's client base and that the remaining 66 percent consist of existing clients that require reaccreditation surveys. We further estimate that, currently, only 25 percent (out of the 33 percent) of an AO's new clients elect to have fee-based consulting prior to the initial survey. Therefore, if the AOs are restricted from performing fee-based consulting prior to the initial survey of new clients, they would lose 25 percent of the revenue they receive from their fee-based consulting business. We estimate that the restrictions on fee-based consulting would cause the AO that provides the most fee-based consulting services to incur lost revenue in the amount of \$12,616,324 per year (\$50,465,298 divided by 4); due to data limitations, the portion of this revenue effect that consists of reduced profit (and thus would qualify as a cost in this regulatory impact analysis) has not been quantified.

While we do not have any independent information about the amount of profits the other AOs realize from their fee-based consulting services, we presume that these AOs do not realize as much revenue from the provision of fee-based consulting as this large AO. We say this for several reasons. First, the other AOs are smaller businesses and have a smaller client base than does this large AO. It is our understanding that these AOs provide fee-based consulting on a smaller scale because they have less clients and some that are smaller businesses that may not have the funds to pay for fee-based consulting services. Therefore, we are not able to provide an accurate estimate of how much loss in revenue will result from the restrictions in AO fee-based consulting.

We estimate that the AOs charge between \$100,000 and \$500,000 for the

fee-based consulting they provide to each healthcare provider or supplier. We do not know how many providers or suppliers currently use the fee-based and other consulting services of their AO prior to their initial survey. Therefore, we are not able to provide an accurate estimate of the total amount of consulting services shifting to new consultants and away from AOs no longer permitted to provide such services to the providers and suppliers for whom they conduct initial surveys.

(3) Impact Related to Requirement That Accrediting Organizations Establish Fee-Based Consulting Firewall Policies and Procedures (§ 488.8(j))

At § 488.8(j) we will require any AO that provides fee-based consulting services, or its associated fee-based consulting division or company, to have robust, written fee-based consulting firewall policies and procedures. We would require that these firewall policies and procedures, at a minimum, include the following provisions: (1) the AO's fee-based consulting services must be provided by a separate division or company from the AO's accreditation division; (2) the AO's fee-based consulting division or separate company must maintain separate staff from that of the AO's accreditation divisions to ensure that the fee-based consulting division staff do not perform AO's accreditation division functions and that the AO's accreditation division staff do not perform fee-based consulting division functions; and (3) the AO's accreditation staff and surveyors are prohibited from marketing the AO's fee-based consulting services to the AO's accreditation clients.

This requirement only applies to those AOs that provide fee-based consulting and requires that these AOs establish new fee-based consulting firewall policies or revise their policies and procedures to meet the requirements.

We believe that the burden associated with the revision of the AO's fee-based consulting firewall policies and procedures would fall under the time and cost burden estimated in section VI.A.3. of this final rule with comment period. As such, we will not assess a separate burden here.

(4) Impact Related to Regulation to Prevent AO Owners, Surveyors or Other Employees That Have an Interest in or Relationship With a Healthcare Facility Accredited by the AO from Participating in Survey Activities for That Facility (§ 488.8(k))

We are finalizing requirements for AOs to avoid conflicts of interest related

to employment relationships between AO surveyors and healthcare facilities that are accredited by the AO. At § 488.8(k) we will require the AOs to prohibit their owners, surveyors and other employees from doing the following: (1) participating in the survey of facilities with which they have a relationship; (2) having input into or influence the outcome of any survey performed for facilities with which they have a relationship; (3) having any involvement with the pre or post survey activities for the healthcare facilities with which they have a relationship; or (4) having any contact with the records from the surveys for any healthcare facilities with which they have a relationship. We believe that this should already be a usual and customary practice of the AOs and therefore there should be no additional burden to the AOs to comply with the requirements of this section.

b. Impacts Associated With the Requirement that AOs Incorporate the Medicare Conditions (§ 488.4(a)(1))

(1) Impacts Related to AO Providing Notice of the Revised Accreditation Standards to Their Accredited Providers and Suppliers via Their Website

In addition to changing the survey standards under § 488.4(a)(1), the AOs would be required to provide the newly revised AO standards to the facilities they accredit. There are approximately 15,143 accredited facilities across all program types. We believe that the majority of AOs have a website portal on which they make their standards available to their accredited providers and suppliers.

We believe that each AO would have an administrative assistant or secretary upload the revised standards to the AO's website for each AO program at an hourly rate of \$43.82. We estimate that this would take no more than 2 hours. We estimate that the total impact across the 29 CMS-approved AO programs that accredit Medicare-certified providers and suppliers for providing notice of their revised accreditation standards on their website would be a one-time, first-year cost of \$2,542 (\$43.82 × 2 hours × 29 AO programs). Using our previous assumption of an average of three programs per AO, this would be a one-time, first-year cost of \$282 per AO.

(2) Impact Related To Providing Notice of the Revised Accreditation Standards to the Accredited Providers and Suppliers via Email

We also believe an AO would need to provide notice of their revised accreditation standards to their

²⁷ See <https://www.jcrinc.com/-/media/jcr-jcr-documents/about-jcr/financial-statements/2021-jcr-form-990-redacted-pdc.pdf>.

accredited providers and suppliers directly via email. We believe this will be a group email that will be sent out to all of the AO's accredited providers and suppliers within each of the 29 different AO programs. We estimate that it will take only 1 hour for an AO administrative assistant or secretary (at an hourly rate of \$43.82) to prepare and send this email to all 15,143 accredited providers and suppliers across 29 AO programs. Therefore, the total estimated financial impact for all 9 AOs for providing notice of the AO revised accreditation standards via email would be a one-time, first-year cost of \$1,271 (\$43.82 – 1 hour – 29 AO programs). Using our previous assumption of an average of 3 programs per AO, this would be a one-time, first-year cost of \$141 per AO.

(3) Impacts Related to Education of Providers and Suppliers Regarding New Standards

In the proposed rule (89 FR 12050) we stated the following in estimating the costs of these proposed requirements, we believe that the AOs that accredit Medicare-certified providers and suppliers would be required to provide education to their accredited providers and suppliers about their new Medicare accreditation standards, which must be revised to be the same as the CMS standards, or more stringent. We believe that this training would most likely be provided by webinar. There are approximately 14,904 deemed facilities. We estimate that the cost impact to each facility would be \$200.46 (\$79.56 per RN + \$120.90 per general or services manager). We further estimate that the total annual cost burden across all 14,904 accredited facilities would be \$2,987,655.84.

In preparing and estimating the costs of this final rule with comment period for AOs, we recognized that our proposed estimates related to AOs providing education on their new standards through webinars needed to be revised in several areas. We now recognize that we were in error when we used the number of deemed facilities as a multiplier for the number of webinars that AOs would need to develop and present. AOs would only need to develop and present an educational webinar on their revised standards for each of their AO programs, which could then be made available for all of their accredited providers and suppliers. There is a total of 25 individual and specific programs across the 9 AOs. AOs would not need to develop and present a webinar for each individual facility as our estimates of the costs indicate in the proposed rule

but instead for each individual and specific program. We believe that our assumptions for the cost impact of this requirement were grossly overestimated in the proposed rule and so we are revising our estimates in this final rule with comment period.

Additionally, we recognize that we significantly underestimated the burden hours that it would take an AO's RN and program manager to develop and present each program-specific webinar in the proposed rule, where we estimated that it would only take each AO staff member one hour to do this. We are correcting this underestimation in this final rule with comment period to what we believe will be 120 hours of burden for each pair of RNs and program managers working together to develop and present these educational webinars, and we have also updated their respective hourly rates using the most current BLS data in making these revisions here (\$94.64 and \$128).

We estimate that the total impact across the 29 CMS-approved AO programs that accredit Medicare-certified providers and suppliers for AOs to develop and present their revised accreditation standards through a program-specific webinar would be \$774,787 ($\$222.64 \times 120 \text{ hours} \times 29 \text{ programs} = \$774,787$). Using our previous assumption of an average of 3 programs per AO, this would be a one-time, first-year cost of \$86,087 per AO.

c. Impact Related to the Requirement That the AO Surveyors Take the CMS Online Surveyor Training

At § 488.5(a)(8), we added a new requirement that will require the AO to include a statement in their application for CMS approval of its program acknowledging that all AO surveyors have completed or will complete two CMS mandatory documentation courses and the relevant program-specific CMS online trainings established for SA surveyors, initially, and thereafter.

CMS provides a number of online surveyor training modules that are available to the SA surveyors. We will require the AO surveyors to take this training in an attempt to decrease the historically high disparity rate between the AOs' survey results and those of the validation surveys performed by the SA surveyors.

There are a total of 163 online training programs that are available the SA surveyors on the CMS Quality, Safety and Education Portal (QSEP) website. This website provides courses that are general in nature such as "Principles of Documentation for Non-Long Term Care" and "Basic Writing Skills for Surveyor Staff", infection control,

patient safety, Emergency Preparedness. The CMS QSEP website also offers courses related to specific healthcare settings such as hospitals, CAHs, ASCs, Laboratories, Community Mental Health Centers, Emergency Medical Treatment and Labor Act, Federally Qualified Health Centers (FQHCs), Home Health Agencies and Outcome and Assessment Information Set, Hospices, Nursing Homes and the Minimum Data Set, Outpatient Physical Therapy/Outpatient Speech Therapy. These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace at which the trainee completes the training. The basic surveyor training courses for specific programs range in time from 16–82 hours for completion. We estimate the average time it takes to take one of the basic surveyor courses is 27 hours. This could be more or less depending upon the specific program that AO surveyors need to take.

We will require that each AO surveyor take the two mandatory documentation courses (that is "Principles of Documentation for Non-Long-Term Care" and "Basic Writing Skills for Surveyor Staff") and the basic surveyor course for the care setting for which they perform surveys. We further estimate that it would take approximately 4 hours to complete each of these courses; however, these courses are self-paced and could take more or less time, depending on the individual surveyor. Therefore, an AO surveyor would incur a time burden of approximately 35 hours for the completion of all of the required CMS surveyor training courses.

Based upon this information, we estimate that the financial impact to the AOs will be \$3,312.40 for each surveyor that completes the CMS online surveyor training (An AO RN surveyor at \$94.64 per hour $\times$ 35 hours = \$3,312.40).

We are not able to accurately estimate the total time and cost burden for each AO for the wages incurred for the time spent by all surveyors from each AO to take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 75 surveyors, the estimated financial impact to each AO associated with this requirement would be \$248,430 ($\$3,312.40 \times 75 \text{ surveyors} = \$248,430$). As of March 2026, there are currently 9 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total estimated financial impact across these 9 AOs

would be \$2,235,870 (\$248,430 × 9 AOs = \$2,235,870).

Summary of Financial Impact Caused by the Requirements in This Final Rule With Comment Period

Table 6 summarizes the financial impact of the requirements that we are finalizing in this rule.

TABLE 6—SUMMARY OF IMPACT

Summary of Impact	
A. Conflict-of-Interest Requirements: Impacts Related to Restrictions on Fee-Based Consulting Provided by AOs to the Healthcare Providers and Suppliers They Accredite (§ 488.8(i)(1) through (3)).	- One-time, first-year cost of \$81,749 across all 9 AOs that currently provide fee-based consulting services. - One-time, first-year cost of \$9,083 per AO.
B. Requirement that the AO Incorporate the Medicare standards to ensure improved evaluation of AO performance:	
1. Burden related to AO providing copies of their revised accreditation standards to their accredited providers and suppliers through the AO's website.	- One-time, first-year cost of \$2,542 across all 29 accreditation programs. - One-time, first-year cost of \$282 per AO. - One-time cost of \$1,271 across all 29 accreditation programs. - One-time, first-year cost of \$141 per AO. - One-time cost of \$774,787 across all 29 accreditation programs. - One-time, first-year cost of \$86,087 per AO. \$248,430 per each AO per 75 surveyors. \$2,235,870 across 9 AOs. - One-time cost of \$2,384 across 9 AOs.
2. Burden to AO related to providing copies of their revised accreditation standards to their accredited providers and suppliers via email.	
3. Burden to AO to provide education to its accredited providers and suppliers about the AO's revised accreditation standards.	
C. Impact of Requirement for AO Surveyors to Take CMS Surveyor Training	
D. Impact of AO Staff to Review This Final Rule With Comment Period	
Year 1 Costs	\$3,098,603.
Year 2 Costs	\$2,235,870.
Year 3 Costs	\$2,235,870.
Year 4 Costs	\$2,235,870.
Year 5 Costs	\$2,235,870.
Average annual total costs over 5 years	\$2,408,417.
Average annual cost per AO over 5 years	\$267,602.
Total Regulatory Impact Costs Across All AOs	\$2,408,417.
Total of ICR Costs (Table 5)	\$199,135.
TOTAL ESTIMATED COSTS OF FINAL RULE WITH COMMENT PERIOD	\$2,607,552.
TOTAL ESTIMATED COSTS OF FINAL RULE WITH COMMENT PERIOD PER AO.	\$289,728.
TOTAL NET IMPACT	\$2,607,552.
TOTAL ESTIMATED PRODUCER SURPLUS (Section VII.C.1)	≤\$2,975,600.

3. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters to the 2018 AO Conflict-of-Interest Request for Information (December 20, 2018, 83 FR 65331) will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the 2018 AO Conflict-of-Interest Request for Information in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review the proposed rule. We did

not receive any public comments specific to our solicitation.

We believe that persons reviewing this rule would consist of AO management staff, healthcare association management staff, and healthcare facility management staff. We believe all of these persons would have positions that fall under the U.S. Bureau of Labor Statistics job category of medical and health services manager. Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review this final rule with comment period. Using the wage information from the BLS for Medical and Health Service Managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$264.88 (\$132.44 per hour × 2 hours) × 9 AOs = \$2,383.92 ([https://](https://www.bls.gov/oes/current/oes_nat.htm)

www.bls.gov/oes/current/oes_nat.htm).²⁸

D. Alternatives Considered

1. Changes to AO Fee-based Consulting

We considered proposing a complete ban on AO fee-based consulting because of the conflicts of interest associated with the provision of these services by the AOs to the healthcare providers and suppliers they accredit. However, we presume the financial impact to the AOs associated with a complete ban on fee-based consulting would be larger. For example, the AO that provides the most fee-based consulting realized over \$50 million dollars annually from providing these services. A complete or almost complete ban on the provision of AO fee-based consulting services would eliminate or severely limit this revenue source.

²⁸ <https://www.bls.gov/oes/current/oes119111.htm>.

Therefore, we decided to finalize more limited restrictions on AO fee-based consulting services that would still address the conflicts of interest while greatly reducing the cost burden and potential loss of revenue on AOs.

2. Changes to the Validation Program

We considered several alternatives for changes to the validation program. First, we considered making no changes to the validations program, which would mean that we would continue performing only look-back surveys. We also considered performing only direct observation surveys. After considering the alternative, we decided to finalize performing a combination of both look-back and direct observation surveys because this would result in a cost savings to providers and suppliers. If we were to continue the validation program as is, there would be no change in provider burden. If we modify the validation program by performing only DOVS, burden to providers and suppliers would be reduced significantly; however, the workload on the SAs would be increased significantly. The SAs have indicated during the pilot program that they would not be able to handle such an increased workload. Therefore, by only using the direct observation method for 100 percent of the validation surveys performed annually and continuing to use CMS surveyors (instead of SA surveyors), this would provide a significant decrease in provider and supplier burden while essentially removing this workload from the SAs.

By removing the look-back validation survey method and keeping only the direct observation validation survey process in this final rule with comment period, we believe that provider burden will be greatly reduced by not requiring an additional validation survey, thus essentially eliminating the number of healthcare providers that would have to undergo two full surveys within a 60-day period. We further believe this approach enhances the validation program, addresses the public comments we received, and will be welcomed by both the AOs, and the providers and suppliers.

3. Additional Alternatives to the Proposed Rule That Minimize Significant Economic Impacts on Small Entities

After consideration of the comments received regarding our proposal to require the AOs to submit surveyor conflict-of-interest declarations to CMS on an annual basis, we have decided not to finalize this proposal as proposed. We are not finalizing our proposal to

require the AOs to obtain and submit the surveyor declarations to CMS annually. We will instead require the AOs to submit the surveyor conflict-of-interest declarations for CMS to review upon request and during each application review process. Finalizing this change will reduce the reporting burden on AOs while ensuring CMS can address conflicts of interest.

Based on public comments, we are also revising the proposed rule to clarify which AO consulting services will be restricted under this final rule with comment period, that is, an AO's (or its consulting division's) review of a [particular] facility's compliance with the Medicare standards through simulation of a real survey, such as a "mock" survey with comprehensive written reports of findings, for a facility accredited by the AO prior to an initial accreditation survey and within the 12 months prior to the next scheduled re-accreditation survey. This limitation does not apply to consulting or general education services for entities the AO does not accredit, or to education provided to their accredited entities.

We note here that the definition of fee-based consulting services that we are finalizing in this rule is not only based on the comments we received regarding the terms, but that, in its specificity and its parameters, the definition better aligns with our original intent in proposing these requirements.

By finalizing this definition in this rule, we are pointing more clearly to what type of consulting services we believe may lead to potential conflicts of interest for an AO that provides such services for a provider or supplier it accredits. We then support this specific definition with the application of the requirements at §§ 488.8(i) and (j) that further specify at what times and under what circumstances in the accreditation and deeming process that these types of consulting services are restricted.

We believe that the changes in this final rule with comment period to more narrowly define the restricted consulting services (versus the more broadly defined restrictions in the proposed rule) will lessen the cost burden on AOs as well as potentially reduce the impact on the revenues that AOs derive from the provision of fee-based consulting services.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small

governmental jurisdictions. Six of the nine AOs impacted by this rule are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than \$24 million in any 1 year as of 2023).

According to the SBA's website at <http://www.sba.gov/content/small-business-size-standards>, AOs fall into the North American Industrial Classification System (NAICS) code 813920, Professional Organizations. The SBA defines small professional organizations as businesses having less than \$24 million in total annual revenue.

Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent.

According to the most recent tax data from ProPublica as well as the most recent audited financial statements that each AO must submit to CMS when applying for CMS approval or re-approval of its accreditation program(s) (at § 488.5(a)(16)), the 9 AOs impacted by this rule can be categorized as having current annual revenues as follows: one (1) AO with less than \$1 million; two (2) AOs between \$1 million and \$5 million; one (1) AO between \$5 million and \$10 million; one (1) AO between \$10 million and \$15 million; and four (4) AOs greater than \$15 million.²⁹ As such, the requirements in this final rule with comment period will have a significant economic impact on a substantial number of small entities, which are defined as greater than 5 percent of impacted small entities. As shown in Table 6, three (3) of the nine (9) AOs, or 33 percent, would be significantly impacted by the requirements in this final rule with comment period, with a change in revenue of more than 3 to 5 percent for these AOs. We note here that, in the RFA section of the proposed rule (89 FR 12058), we included a statement that the Secretary certified that "this proposed rule would not have a significant economic impact on a substantial number of small entities". We did not receive any public

²⁹ <https://projects.propublica.org/nonprofits/organizations/362229255>; <https://projects.propublica.org/nonprofits/organizations/561540225>; <https://www.causeiq.com/organizations/american-association-for-accreditation-of-ambulatory/363180580/>; <https://projects.propublica.org/nonprofits/organizations/363016881>; and <https://projects.propublica.org/nonprofits/organizations/363016881>.

comments on this certification statement.

In our preparation of the COI, RIA, and RFA analysis sections of this final rule with comment period, we noted that we sometimes made assumptions about the applicability of the requirements to all of the AOs that may have overestimated the economic impact of this rule on the smallest AOs. For example, in our analysis of the impact of the requirement at § 488.5(a)(8), which will require AO surveyors to take the CMS surveyor training, we assumed an average of 75 surveyors for each AO. This number is most likely significantly higher than the number of surveyors, the 3 smallest AOs actually employ and for whom they would be paying 35 hours of each surveyor’s salary to take the CMS training. Our use of this higher number on average led to our estimate of \$248,430 per AO in annual costs for this requirement, a significant impact on the revenues of the three smallest AOs with

a change in revenue ranging from 7 percent to 29 percent.

Additionally, we assumed the impact of this requirement as an annual cost for each AO when it is highly unlikely that each AO will have 75 or more of its surveyors taking the CMS training every year. We expect the annual numbers to be much lower for the nine AOs, especially for the three smallest AOs. After we published the proposed requirement in February 2024, we also realized that many of the AOs would most likely substitute or add the CMS training to their own individual surveyor training programs for which they are already paying their surveyors to take. Therefore, we believe that the requirement at § 488.5(a)(8) might not add any, or very little, additional cost burden to an AO’s annual costs, with any required surveyor trainings constituting usual and customary business practices for all nine AOs.

We also considered whether the impact of the requirements related to AO fee-based consulting services and our estimated cost burden should be

attributed equally to each AO (as we have done in this section), regardless of its size and/or whether the AO actually provides such consulting services. Our decision to attribute these costs equally across all nine AOs certainly accounts for more significant costs for the three smallest AOs than it does for the four largest AOs in terms of its impact on revenues. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule pertains solely to AOs. Therefore, the Secretary has certified that this final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

TABLE 7—REGULATORY FLEXIBILITY ACT ANALYSIS

Revenue group	Number of AOs in group	Average annual revenue per group	Estimated average annual cost per firm	Average cost divided by average revenue (%)
≤ \$1 million	1	\$1,000,000	\$287,341	29
> \$1 million				
≤ \$5 million	2	3,950,000	287,341	7
> \$5 million				
≤ \$10 million	1	6,300,000	287,341	5
> \$10 million				
≤ \$15 million	1	11,400,000	287,341	3
> \$15 million	4	79,200,000	287,341	<1
All AOs	9	20,370,000	287,341	1

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$193 million. This final rule with comment period will not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$193 million in any 1 year.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

H. E.O. 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, entitled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” This final rule with comment period is neither a regulatory nor a deregulatory action, due to

imposing no more than *de minimis* costs.

VIII. Waiver of Notice of Proposed Rulemaking

At § 488.4 in this final rule with comment period, we have made technical changes with minor rewording of the proposed requirements and the existing requirements to make the provisions more understandable. These changes were made in the interest of clarity and do not constitute any changes in policy, nor they do establish any new requirements in addition to those already proposed and finalized in this rule.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under

which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Because, as we have explained here, the changes to § 488.4 that we are making in this final rule with comment period are for the purposes of greater clarity in the wording of the provisions and are not intended as new policy or additional requirements beyond what already exists in the CFR or what has been previously proposed with public comments received and addressed in this final rule with comment period, we believe that a notice-and-comment procedure is both impracticable and unnecessary, and that it would be contrary to the public interest to delay this rule through such a procedure.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule with comment period.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

IX. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 11, 2026.

List of Subjects

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and

Medicaid Services amends 42 CFR chapter IV, as set forth below:

PART 488 SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 1. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302; and 1395hh.

■ 2. Section 488.1 is amended by—

- a. Adding the definitions of “Fee-based consulting services” and “Geographic regions” in alphabetical order;
- b. Revising the definition of “National accrediting organization”;
- c. Adding the definitions of “National in scope”, and “Process disparity rate”;
- c. Removing the definition of “Rate of disparity”; and
- d. Adding the definition of “Unannounced survey” in alphabetical order.

The additions and revision read as follows:

§ 488.1 Definitions.

* * * * *

Fee-based consulting services mean those services provided by an accrediting organization (AO), or its consulting division or separate business entity (such as a company or corporation) that provides such services, for the review of a [particular] facility’s standards, processes, policies, and functions for compliance with the AO’s standards and the Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey.

* * * * *

Geographic regions—CMS uses specified geographic regions of the United States to measure whether an accrediting organization’s accreditation program meets the definition of “national in scope.” For this purpose, the United States is divided into the following five geographic regions:

(1) *Northeast*: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont;

(2) *Southeast*: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee;

(3) *Midwest*: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin;

(4) *Central*: Iowa, Kansas, Missouri, and Nebraska; Colorado, Montana,

North Dakota, South Dakota, Utah, Wyoming;

(5) *South*: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas;

(6) *Western*: American Samoa, Arizona, California, Hawaii, Commonwealth of the Northern Mariana Islands, Guam, Alaska, Idaho, Nevada, Oregon, Washington.

* * * * *

National accrediting organization means an accrediting organization that is national in scope and accredits provider or suppliers, under a specific accreditation program.

National in scope means that the providers and suppliers accredited by an accrediting organization under a specific accreditation program, are widely located geographically across the United States. The requirement for “national in scope” has two components. First, the accrediting organization must have accredited at least five providers or suppliers under the accreditation program in question. Second, the five providers or suppliers accredited by the accrediting organization under that accreditation program must be geographically located in at least five out of the six geographic regions.

Process disparity rate means, for a direct observation validation survey, the difference between the observed survey process findings and the expected survey process findings expressed as a percentage.

* * * * *

Unannounced survey means a survey that is conducted without any prior notice of any type, through any means of communication or forums, to the facility to be surveyed, and therefore, is unexpected to the facility until the arrival onsite by surveyors. This also means that the accrediting organizations must schedule their surveys so that the facility is unable to predict when they will be performed.

* * * * *

■ 3. Section § 488.4 is revised to read as follows:

§ 488.4 General rules for a CMS-approved accreditation program for providers and suppliers.

(a) CMS approves a national provider or supplier accreditation program and grants it “deeming authority” if, after the application procedures set out in § 488.5, CMS finds under § 488.5(e)(2)(i) that such accreditation program provides CMS with reasonable assurance as defined at § 488.1, and that all providers and suppliers accredited by such program are in compliance with all applicable Medicare conditions or requirements.

(1) Accreditation by a CMS-approved accreditation acts as a recommendation that CMS deem such provider or supplier to be in compliance with such conditions or requirements, and to certify such provider or supplier to participate in Medicare.

(2) A provider or supplier granted deemed status is subject to validation surveys as set out at § 488.9.

(3) The accrediting organizations that accredit Medicare-certified providers and suppliers must include the applicable Medicare regulatory language as their minimum accreditation standards.

(4) The accrediting organizations that accredit Medicare-certified providers and suppliers must use a survey process comparable to the processes set out in the CMS State Operations Manual, or as issued via policy memorandums, and approved by CMS, as defined in § 488.5.

(b) The following requirements apply for termination of a provider's or supplier's Medicare participation agreement on CMS recognition of its accreditation provided by an Accrediting Organization:

(1) If CMS terminates the participation agreement of a provider or supplier, CMS will no longer recognize or accept the accreditation provided by an accreditation organization to that provider or supplier as demonstrating that the Medicare requirements have been met by such provider or supplier; and

(2) If CMS terminates the participation agreement of a provider or supplier, the terminated provider or supplier must meet all requirements set forth at § 489.57 before a new agreement with that provider or supplier for Medicare participation will be approved.

■ 4. Section 488.5 is amended by—

■ a. Revising paragraphs (a)(3), (4), (5), (6), (8), (10), (12) and (13); and

■ b. Adding paragraphs (a)(21) and (22).

The revisions and additions read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations. (a) * * *

(3) A detailed crosswalk (in table format, as specified by CMS) that identifies, for each of the applicable Medicare conditions (as defined in § 488.1) or requirements, the exact language of the organization's comparable accreditation requirements and standards. Such crosswalk must include the language of the CMS requirements and standards, and those accreditation standards that exceed the CMS conditions.

(4) A detailed description of the organization's survey process including, but not limited to, the core activities of the survey process such as, but not limited to, documentation supporting Pre Survey Preparation/Offsite Preparation, Entrance Interview/Activities, Information Gathering/Investigation, Analysis of Information, Exit Conference, Post Survey Activities/Statement of Deficiencies activities, to confirm that a provider or supplier meets or exceeds the Medicare program requirements, and maintains the integrity of the survey process, which is intended to be a non-biased evaluation of a facility's ability to provide safe care and protect the health and safety of patients. This description must include all of the following information:

(i) Frequency of surveys performed and an agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting Federal Medicare surveys for the same provider or supplier type, in accordance with the applicable requirements or conditions of participation or conditions for coverage or certification.

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors, including, but not limited to, specific processes of how surveyors survey facilities for the core survey activities: Governing Body, Patient Rights, Emergency Preparedness, Quality Assessment and Performance Improvement, Medical Staff, Nursing Services, Medical Records Services, and Infection Control. This would also include interpretive guidelines and survey probes, including patient and staff interview questions, and processes used by surveyors when interviewing facilities for compliance based on each of the specific survey standards, comparable to those instructions required for State survey.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare CoPs, CfCs, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process, to include, but not limited to, processes for review of medical records; medical staff credentialing procedures based on services provided; staff record review to review for competency and personnel files; adequate number of patient observations; and confidential patient interviews and staff interviews.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards, including the deadlines for initial and reaccreditation surveys, accreditation decisions, as well as the investigative and organizational process which the accrediting organization uses to make these determinations.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with the following information as part of its initial and renewal applications and, upon request from CMS, and as part of the data submissions required under paragraph (a)(11)(ii) of this section:

(A) a copy of all survey reports, including, but not limited to, initial, re-survey, and complaint survey reports, upon request by CMS, and

(B) any other information related to survey activities as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 489.3 of this chapter. Using the format specified by CMS, the accrediting organization must notify CMS within 2 business days from the date the accrediting organization identifies the immediate jeopardy.

(x) For accrediting organizations applying for approval or re-approval of CMS-approved hospice programs, a statement acknowledging that the accrediting organization (AO) will include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

(xi) Documentation summarizing the AO's staff training programs, whether web-based electronic or hard-copy materials, on how the AO provides training or education to surveyors on the AO's survey processes, and, where applicable, highlight differences from CMS survey processes.

(5) The criteria the accrediting organization uses in determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited. These criteria at a minimum should address survey team size and composition based on:

- (i) The size of the facility to be surveyed, based on average daily census;
- (ii) The complexity of services offered, including outpatient services;
- (iii) The type of survey to be conducted;
- (iv) Whether the facility has special care units or off-site clinics or locations;
- (v) Whether the facility has a historical pattern of serious deficiencies or complaints; and
- (vi) Whether new surveyors are to accompany a team as part of their training.

(6) The overall adequacy of the number of the organization's surveyors to ensure sufficient amount of time is allotted to complete all survey activities, including how the organization will increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

* * * * *

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel, including the training materials provided, and, with respect to CMS training, a statement acknowledging that:

- (i) The accrediting organization will ensure all of its surveyors complete two mandatory CMS online documentation courses and the relevant program-specific CMS online basic surveyor training course (established for State survey agency surveyors), initially, and thereafter when updates are necessary;
- (ii) The required CMS online surveyor training will be completed by each existing surveyor before serving on a survey team (except as a trainee); and
- (iii) The accrediting organization must document in the staff personnel records for each surveyor, that the CMS online surveyor documentation and basic training courses were completed and the date of completion. The statement must acknowledge that the accrediting

organization will maintain documentation of the initial completion and any subsequent completions.

* * * * *

(10) The organization's policies and procedures to avoid conflicts of interest, (as defined in paragraph (a)(10)(v) of this section) including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions. These policies and procedures will include the following:

(i) The accrediting organization's policies and procedures for separation of its fee-based consulting services from its accreditation services;

(ii) The accrediting organization's policies and procedures for protecting the integrity of the accrediting organization's accreditation program, including the requirements of § 488.8(i) and (k);

(iii) The accrediting organization's policies and procedures for the prevention and handling of potential or actual conflicts of interest that could arise from situations in which an accrediting organization owner, surveyor, or other employee has an interest in or relationship with a State survey agency or with a healthcare facility to which the accrediting organization provides accreditation services. Such interests or relationships include, but are not limited to:

(A) Being employed as a State survey agency surveyor;

(B) Being employed in a healthcare facility that is accredited by the accrediting organization;

(C) Having an ownership, financial, or investment interest in a healthcare facility that is accredited by the accrediting organization;

(D) Serving as a director of or trustee for a healthcare facility that is accredited by the accrediting organization;

(E) Serving on a utilization review committee of a healthcare facility that is accredited by the accrediting organization;

(F) Accepting fees or payments from a health facility or group of health facilities that is/are accredited by the accrediting organization;

(G) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a healthcare facility that is accredited by the accrediting organization;

(H) Providing consulting services to a healthcare facility that the accrediting organization accredits;

(I) Having members of their immediate family engaged in any of the above stated activities. The term

"immediate family member" is defined as any person with which the accrediting organization owner(s), surveyors or other employees have a lineal or immediate familial or marital relationship, including a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

(J) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

(iv) The accrediting organization's policies and procedures for notification of CMS when a conflict of interest is discovered.

(v) For the purposes of this section, a conflict of interest exists when an accrediting organization, the accrediting organization's successors, transferees, or assigns, the accrediting organization owner(s), surveyors, or other employees, or the immediate family members of the accrediting organization owners(s), surveyors, and other employees have an employment, business, financial, or other type of interest in or relationship with a healthcare facility the accrediting organization accredits.

* * * * *

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals to appropriate licensing bodies and ombudsman programs, when applicable. This would also include:

(i) Accrediting organization's process for triaging and categorizing complaints about the surveyed facility;

(ii) Timeframes for responding to complaints and a method to track and trend complaints received with respect to the accrediting organization's accredited facilities;

(iii) Procedures and persons responsible for the review of plans of corrections and procedures for follow up if the plans of corrections are not adequate;

(iv) Accrediting organization requirements for plans of corrections for standard-level deficiencies;

(v) Follow-up survey procedures and monitoring of condition-level findings;

(vi) Procedures for addressing immediate jeopardy deficiencies; and

(vii) Sharing of previous deficiency findings or complaints with survey teams.

(13) The organization's accreditation status decision-making process,

including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which approval is sought, including the duration of each.

(ii) The accrediting organization's general notification procedures to notify CMS, including the timeframes for notification of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier. Such notification must be made within 3 business days from the date the organization takes an action.

(iii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier, within 3 business days from the date the organization takes an action.

(iv) The organization's process for facilities that withdraw from accreditation, to include timeframes for notification to CMS and the process for surveying facilities which may require an upcoming survey.

* * * * *

(21) A statement certifying that, in response to a written notice from CMS notifying the organization that one of its accredited providers or suppliers has been terminated from the Medicare/Medicaid program, the accrediting organization agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5 business days from receipt of said written notice, and not re-accredit the provider until CMS has approved the provider or supplier for participation in Medicare.

(22) A declaration by each surveyor of any employment, business, financial or other interests in or relationships with a State survey agency or a healthcare facility the accrediting organization accredits as described in paragraph (a)(10)(iii) of this section, which must be updated and submitted to CMS upon request and during each application review process.

* * * * *

■ 5. Section 488.8 is amended by—

■ a. Revising paragraph (a)(2); and

■ b. Adding paragraphs (a)(4), (i), (j) and (k).

The revision and additions read as follows:

§ 488.8 Ongoing review of accrediting organizations.

(a) * * *

(2) Analysis of the results of the validation surveys under § 488.8(a)(4), surveys from substantial allegations of noncompliance, and the process disparity rate as determined from direct observation validation surveys.

* * * * *

(4) When an accrediting organization's performance measure scores, as determined from 1 direct observation validation surveys, reveal that the accrediting organization's accreditation survey activities do not meet an acceptable performance threshold established by CMS, the accrediting organization will be required to submit an acceptable plan of correction that meets the requirements set forth below:

(i) The accrediting organization's acceptable plan of correction must be submitted to CMS for review within 10 business days of CMS notification of not meeting acceptable performance. An acceptable plan of correction must:

(A) Document specific actions being taken by the accrediting organization to address improving performance.

(B) Document the timeframe for implementation of this plan.

(C) Plan for ongoing monitoring of the plan of correction toward achieving an acceptable level of performance.

(D) Identify the individual responsible for implementation and monitoring of the acceptable plan of correction.

(ii) Upon review and approval of the plan of correction, CMS will provide ongoing evaluation of the progress of plan implementation.

(iii) The accrediting organization's plan of correction is subject to public reporting by CMS.

* * * * *

(i) *Restrictions on fee-based consulting provided by accrediting organizations or their fee-based consulting divisions or separate fee-based business entities.* (1) Except as provided in paragraph (i)(4) of this section, an accrediting organization, or its fee-based consulting division or separate business entity (such as a company or corporation that provides fee-based consulting), may not provide fee-based consulting services (as defined at § 488.1) to any new healthcare provider or supplier before the initial accreditation survey has been completed. For purposes of this paragraph, the term "initial survey"

means the first accreditation survey performed of a healthcare provider or supplier by an accrediting organization that has not previously received accreditation services from that accrediting organization. If a healthcare provider or supplier is terminated or withdraws from the services of an accrediting organization and later retains the services of the same or a new accrediting organization, the first survey performed by the same or new accrediting organization of that healthcare provider or supplier would be considered an initial accreditation survey.

(2) Except as provided in paragraph (i)(4) of this section, an accrediting organization, its fee-based consulting division or separate business entity, such as a company or corporation that provides fee-based consulting, may not provide fee-based consulting services to a healthcare provider or supplier the accrediting organization accredits within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. For purposes of this paragraph, the term "re-accreditation survey" means any subsequent accreditation surveys performed by the accrediting organization following the initial survey.

(3) Except as provided in paragraph (i)(4) of this section, an accrediting organization, its fee-based consulting division, or separate business entity, such as company or corporation that provides fee-based consulting, may not provide fee-based consulting services to a healthcare provider or supplier, to which the accrediting organization provides accreditation services, in response to a complaint received by the accrediting organization regarding that provider or supplier.

(4) An accrediting organization, its fee-based consulting division, or separate business entity, such as a company or corporation that provides fee-based consulting, may provide fee-based consulting to the healthcare providers and suppliers it accredits only under the following circumstances:

(i) During the 24-month period after an initial or re-accreditation survey is performed.

(ii) To address complaints received and investigated by the State survey agency regarding an accrediting organization's accredited provider or supplier in which one or more condition-level or immediate jeopardy deficiencies are identified. Such fee-based consulting by an accrediting organization may occur only after the State survey agency complaint investigation and survey has been

completed and must only address those issues identified by the complaint survey.

(iii) Fee-based consulting services provided to healthcare providers or suppliers the accrediting organization does not accredit at the time the consulting services are furnished.

(iv) Non-fee-based consulting or general education provided by the accrediting organization about their accreditation program.

(5) The accrediting organization must provide to CMS, upon request and during each application review process, a document which contains the following information:

(i) Whether the accrediting organization or an associated consulting division or company established by the accrediting organization provides fee-based consulting services;

(ii) The names and CCN numbers of all healthcare providers and suppliers to which the accrediting organization or its associated consulting division or company has provided fee-based consulting services during the previous 6-month period;

(iii) The dates the fee-based consulting services were provided to each provider and supplier;

(iv) Whether the accrediting organization has, at any time in the past provided, or is currently providing accreditation services to each healthcare provider or supplier listed in said document;

(v) For each healthcare provider and supplier listed in said document, the date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed; and

(vi) A description of the fee-based consulting services provided to each healthcare provider or supplier listed in said document.

(6) If an accrediting organization provides fee-based consulting services to a healthcare provider or supplier it accredits, in violation of the restrictions set forth in paragraphs (i)(1), (2) and (3) of this section, CMS may take the following actions:

(i) CMS may place the accrediting organization on a CMS-approved accreditation program review in accordance with paragraph (c) of this section; or

(ii) CMS may involuntarily terminate the CMS approval for the accreditation programs in accordance with paragraph (g) of this section.

(j) *Accrediting organization fee-based consulting firewall policies and procedures.* (1) An accrediting organization, its fee-based consulting division, or separate business entity,

such as a company or corporation that provides fee-based consulting services to the healthcare providers and suppliers the accrediting organization accredits, must have written fee-based consulting firewall policies and procedures, which, at a minimum, include the following provisions:

(i) The accrediting organization's fee-based consulting services must be provided by a separate division of the accrediting organization or separate business entity, such as a company or corporation, that is separate from the accrediting organization's accreditation division;

(ii) An accrediting organization's fee-based consulting division or separate business entity must maintain separate staff from that of the accrediting organization's accreditation divisions to ensure that the fee-based consulting division staff do not perform the accrediting organization's accreditation division functions, and that the accrediting organization's accreditation division staff do not perform fee-based consulting division functions; and

(iii) An accrediting organization's accreditation staff and surveyors are prohibited from marketing the accrediting organization's fee-based consulting services to the accrediting organization's accreditation clients.

(2) An accrediting organization that provides fee-based consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application submitted seeking renewal of the CMS approval for their accreditation programs as required at § 488.5(a)(10).

(k) *Conflict of interest due to accrediting organization owner, surveyor, or other accrediting organization employee relationship with a healthcare facility accredited by the accrediting organization.* (1) If an accrediting organization owner, surveyor, or other employee, currently or within the previous 2 years, has an interest in or relationship (as defined in § 488.5(a)(10)(iii)(B) to (J)) with a healthcare facility accredited by the accrediting organization, the accrediting organization owner, surveyor or other employee must not be permitted to:

(i) Participate in the survey of that healthcare facility;

(ii) Have input into the results of the survey and accreditation for that healthcare facility;

(iii) Have involvement with the pre-or post-survey activities for that healthcare facility; or

(iv) Have contact with, or access to, the records for the survey and accreditation of that healthcare facility.

(2) For the purposes of this section, the term "immediate family member" is defined as any person with which the accrediting organization owner(s), surveyors or other employees have a lineal or immediate familial or marital relationship, including a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

■ 6. Section 488.9 is revised to read as follows:

§ 488.9 Validation surveys.

(a) *Basis for survey.* CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation of noncompliance, the SA surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) *Validation surveys.* Direct observation validation surveys are performed at the discretion of CMS, on a sample of the accrediting organization's surveys and are performed concurrently by the accrediting organization and the State survey agency or CMS. The State survey agency or CMS surveyors are present to observe the accrediting organization's survey process.

(c) *Rules for direct observation validation surveys.* (1) All direct observation validation surveys will be unannounced to the accrediting organization and the facility being surveyed.

(2) The State survey agency or CMS surveyors will generally be assigned to the accrediting organization surveyors on a 1:1 basis, matching the experience of the accreditation surveyor where possible, and using the CMS-approved standards and processes to determine compliance with the Medicare conditions.

(3) The State survey agency or CMS surveyors will observe the accrediting organization survey in accordance with CMS established policies and procedures and will report the findings directly to CMS.

(4) Where the State survey agency or CMS surveyors disagree with the findings of the accrediting organization surveyors, and these differences cannot be reconciled, CMS will render a final decision. Such decisions would not be appealable under part 498 of this chapter.

(d) *Provider or supplier not in compliance.* A provider or supplier will be deemed non-compliant with the validation process, in accordance with this section, if any of the following conditions are present:

(1) The provider or supplier refuses to authorize its accrediting organization to release a copy of their current accreditation survey to CMS; or

(2) The provider or supplier refuses to allow a validation survey.

(e) *Consequences for a finding of non-compliance.* CMS may take actions for any deficiencies identified in the direct observation validation survey in accordance with § 488.24, or may first direct the State survey agency to, or CMS may, conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(f) *Re-instating deemed status.* An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section, if, in addition to substantive re-approval of the facility, the following requirements are met, as applicable:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a direct observation validation survey, if applicable.

(g) *Impact of adverse actions.* The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 7. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 8. Section 489.20 is amended by adding paragraph (z) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(z) In the case of a provider that has been involuntarily terminated by CMS under § 489.53, or by the OIG under § 489.54, reinstatement of the provider agreement is subject to § 489.57(b).

■ 9. Section § 489.57 is revised to read as follows:

§ 489.57 Reinstatement after termination.

When a provider agreement has been terminated by CMS under § 489.53, or by the OIG under § 489.54, a new agreement with that provider will not be accepted unless:

(a) CMS or the OIG, as appropriate, finds —

(1) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(2) That the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of the statutory and regulatory

responsibilities of its previous agreement.

(b) The terminated provider or supplier that had deemed status meets the following requirements before a new agreement with that provider or supplier may be approved:

(1) The terminated provider or supplier must become and remain under the exclusive oversight of the State survey agency for a reasonable assurance period of a length of time to be determined by CMS, for the purposes of the initial survey, certification and demonstration of compliance with the Medicare conditions.

(2) The terminated provider or supplier must remain under the exclusive oversight of the State survey agency until the State survey agency or CMS has certified that the provider or supplier is in compliance with all applicable Medicare conditions and the agreement for participation in the Medicare/Medicaid program has been approved.

(3) During the time period in which a terminated provider or supplier is not certified to participate in the Medicare program, while the prospective provider or supplier is under the oversight of the State survey agency, and while the new agreement for Medicare participation is pending, CMS will not accept or recognize accreditation from a CMS-approved accrediting organization for deeming purposes until the applicable Medicare requirements have been met or exceeded, as described in § 488.4 of this chapter.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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Part IV

Nuclear Regulatory Commission

10 CFR Parts 15, 170, and 171

Fee Schedules; Fee Recovery for Fiscal Year 2026; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 15, 170, and 171

[NRC–2023–0212]

RIN 3150–AL12

Fee Schedules; Fee Recovery for Fiscal Year 2026

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending the licensing, inspection, special project, and annual fees charged to its applicants and licensees. These amendments are necessary to comply with the Nuclear Energy Innovation and Modernization Act, which requires the NRC to recover, to the maximum extent practicable, approximately 100 percent of its annual budget, less certain amounts excluded from this fee recovery requirement. In addition, the NRC is making amendments to establish fixed caps on service fees to implement section 5(a) of Executive Order 14300, “Ordering the Reform of the Nuclear Regulatory Commission.” The fixed fee caps will provide cost predictability and drive increased efficiency and accountability in the NRC’s licensing and other activities requested by applicants and licensees.

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

ADDRESSES: Please refer to Docket ID NRC–2023–0212 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2023–0212.
- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, the ADAMS accession numbers are provided in the “Availability of Documents” section of this document.
- *NRC’s PDR:* The PDR, where you may examine and order copies of

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For additional direction on obtaining information, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

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SUPPLEMENTARY INFORMATION:

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I. Background

A. Statutory Authority

The NRC’s fee regulations are primarily governed by two laws: (1) the Independent Offices Appropriation Act, 1952 (IOAA) (31 U.S.C. 9701); and (2) the Nuclear Energy Innovation and Modernization Act (NEIMA) (42 U.S.C. 2215). The IOAA authorizes and encourages Federal agencies to recover, to the fullest extent possible, costs attributable to services provided to identifiable recipients. Under NEIMA, the NRC must recover, to the maximum extent practicable, approximately 100 percent of its annual budget, less the budget authority for excluded activities. Under section 102(b)(1)(B) of NEIMA, “excluded activities” include any fee-relief activity as identified by the Commission, generic homeland security activities, waste incidental to reprocessing activities, Nuclear Waste Fund activities, Inspector General (IG) services for the Defense Nuclear Facilities Safety Board, research and development at universities in areas relevant to the NRC’s mission, a nuclear science and engineering grant program, advanced reactor regulatory infrastructure activities, international

nuclear export and innovation activities, mission-indirect program support and agency support costs that may not be included in the reduced hourly rate charged for fees assessed to advanced nuclear reactor applicants and pre-applicants (Reduced Hourly Rate), and costs for application reviews and pre-application activities related to an early site permit (ESP) to demonstrate an advanced nuclear reactor on a Department of Energy (DOE) or critical national security infrastructure site. In fiscal year (FY) 2026, the NRC is expanding the existing fee-relief activity, “Medical isotope production infrastructure,” to include additional non-power production or utilization facilities program budgeted resources to ensure the equitability and stability of annual fees for the non-power production or utilization facilities fee class since the majority of non-power production or utilization facilities licensees are exempt from annual fees under part 171 of title 10 of the *Code of Federal Regulations* (10 CFR), “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.” The remaining fee-relief activities identified by the Commission are consistent with prior fee rules (see table I, “Excluded Activities,” of this document for the list of all excluded activities).

Under NEIMA, the NRC must use its IOAA authority first to collect service fees for NRC work that provides specific benefits to identifiable recipients (such as licensing work, inspections, and special projects). The NRC’s regulations in 10 CFR part 170, “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended,” explain how the agency collects service fees from specific beneficiaries. Because the NRC’s fee recovery under the IOAA (10 CFR part 170) will not equal 100 percent of the agency’s total budget authority for this FY (less the budget authority for excluded activities), the NRC also assesses “annual fees” under 10 CFR part 171 to recover the remaining amount necessary to comply with NEIMA.

Additionally, on July 9, 2024, the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) was signed into law, and, among other things, it amended fee-related provisions in NEIMA. Specifically, the ADVANCE Act includes three fee-related provisions

and provides an effective date of October 1, 2025 (FY 2026), for each of these provisions: (1) section 101, “International Nuclear Export and Innovation Activities,” establishes a new excluded activity for “[c]osts for international nuclear export and innovation activities described in section 101(a)” of the ADVANCE Act; (2) section 201, “Fees for Advanced Nuclear Reactor Application Review,” requires a Reduced Hourly Rate for advanced nuclear reactor applicants and pre-applicants for certain activities and creates new excluded activities associated with the Reduced Hourly Rate; and (3) section 204, “Enabling Preparations for the Demonstration of Advanced Nuclear Reactors on Department of Energy Sites or Critical National Security Infrastructure Sites,” establishes two more excluded activities for costs for application reviews and pre-application activities for an ESP to demonstrate an advanced nuclear reactor on a DOE or “critical national security infrastructure” site.

The NRC implemented section 201 of the ADVANCE Act in the FY 2025 final fee rule (90 FR 26730; June 24, 2025) to provide greater regulatory certainty to external stakeholders and avoid burdens associated with having to delay billing for activities eligible for the Reduced Hourly Rate. As described in Section II, Discussion, “FY 2026 Fee Collection—Professional Hourly Rate and Reduced Hourly Rate,” of this document, in the FY 2025 final fee rule, the NRC amended § 170.20, “Average cost per professional staff-hour,” to establish two hourly rates: (1) the professional hourly rate; and (2) the Reduced Hourly Rate for advanced nuclear reactor applicants and pre-applicants. The amendments to § 170.20 in the FY 2025 final fee rule included language indicating that the Reduced Hourly Rate did not take effect until October 1, 2025, consistent with the statutory effective date in section 201 of the ADVANCE Act, and the professional hourly rate applied prior to October 1, 2025. This final rule includes revisions to § 170.20 to reflect the continued implementation of the Reduced Hourly Rate and to ensure that the changes to the Reduced Hourly Rate

coincide with the effective date of the final fee rule for the FY.

In addition, this final rule includes changes to implement sections 101 and 204 of the ADVANCE Act, as reflected in table I, “Excluded Activities.” This final rule also includes revisions to footnote 12 in § 170.31, “Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses,” and footnote 8 in § 171.16, “Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC,” to reflect section 101 of the ADVANCE Act.

B. Executive Order 14300: “Ordering the Reform of the Nuclear Regulatory Commission”

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, “Ordering the Reform of the Nuclear Regulatory Commission” (90 FR 22587; May 29, 2025). Section 5, “Reforming and Modernizing the NRC’s Regulations,” requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5(a), which states a policy for the NRC to establish “fixed deadlines” for final decisions for requested activities of the Commission “as directed under the Nuclear Energy Innovation and Modernization Act,” as well as fixed caps on service fees to enforce those deadlines. This final rule includes revisions to the NRC’s fee regulations for FY 2026 to implement the E.O. 14300’s policies. This final rule includes revisions to 10 CFR part 15, “Debt Collection Procedures,” and 10 CFR part 170 to establish fixed caps on service fees for requested activities of the Commission that involve the issuance of a final safety evaluation, consistent with NEIMA and E.O. 14300. The NRC will address the E.O. 14300 policy to establish fixed deadlines for final decisions (including the 12- and

18-month periods cited in section 5(a) of E.O. 14300) in a future rulemaking. The revisions to implement E.O. 14300, as well as related changes to the rule upon consideration of public comments, are further described in Section II, “FY 2026—Policy Change,” and in Section IV.

II. Discussion

FY 2026 Fee Collection—Overview

The NRC is issuing this FY 2026 final fee rule based on its enacted budget in the Commerce, Justice, Science; Energy and Water Development; and Interior and Environment Appropriations Act, 2026, Public Law 119–74, which was signed into law on January 23, 2026. The final fee rule reflects a total budget authority in the amount of \$971.5 million, which is an increase of \$27.4 million from FY 2025. The increase is primarily to support advanced reactor pre-application and licensing activities and specialized construction costs associated with the Three White Flint North relocation project.

As explained previously, certain portions of the NRC’s total budget authority are excluded from the fee recovery requirement under section 102(b)(1)(B) of NEIMA. Based on the FY 2026 enacted budget, these exclusions total \$152.6 million, which is an increase of \$15.5 million from FY 2025. These excluded activities consist of \$76.4 million for fee-relief activities, \$20.6 million for ADVANCE Act section 101 international nuclear export and innovation activities, \$19.4 million for ADVANCE Act section 201 mission-indirect program support and agency support associated with the Reduced Hourly Rate, \$19.2 million for advanced reactor regulatory infrastructure activities, \$14.4 million for generic homeland security activities, \$1.6 million for IG services for the Defense Nuclear Facilities Safety Board, and \$1.0 million for waste incidental to reprocessing activities. Table I summarizes the excluded activities for the FY 2026 final fee rule. The FY 2025 amounts are provided for comparison purposes.

TABLE I—EXCLUDED ACTIVITIES
[Dollars in millions]

	FY 2025 final rule	FY 2026 final rule
Fee-Relief Activities:		
International activities	\$31.4	\$1.7
Agreement State oversight	12.7	10.7
Non-power production or utilization facilities program (including medical isotope production infrastructure)	1.3	7.5
Fee exemption for nonprofit educational institutions	18.2	13.7

TABLE I—EXCLUDED ACTIVITIES—Continued
[Dollars in millions]

	FY 2025 final rule	FY 2026 final rule
Costs not recovered from small entities under 10 CFR 171.16(c)	10.1	10.4
Regulatory support to Agreement States	9.6	14.2
Generic decommissioning/reclamation activities (not related to the operating power reactors and spent fuel storage fee classes)	6.2	10.4
Uranium recovery program and unregistered general licensees	4.3	6.9
Potential Department of War remediation program Memorandum of Understanding activities	0.8	0.8
Non-military radium sites	0.2	0.2
Minority Serving Institutions Grant Program	2.0	0.0
Subtotal Fee-Relief Activities	96.8	76.4
Activities under section 102(b)(1)(B)(ii) of NEIMA (generic homeland security activities, waste incidental to re-processing activities, and the Defense Nuclear Facilities Safety Board)	16.5	17.0
Activities under section 102(b)(1)(B)(iii) of NEIMA (advanced reactor regulatory infrastructure activities)	23.8	19.2
Activities under section 102(b)(1)(B)(iv)–(vii) of NEIMA, as amended by the ADVANCE Act (ADVANCE Act Section 101 international nuclear export and innovation activities, Section 201 mission-indirect program support and agency support associated with the Reduced Hourly Rate, and Section 204 activities related to advanced nuclear reactors on DOE or critical national security infrastructure sites)	N/A	40.0
Total Excluded Activities	137.1	152.6

After accounting for the exclusions from the fee recovery requirement and net 10 CFR part 171 billing adjustments (*i.e.*, for FY 2026 invoices that the NRC estimates will not be paid during the FY, less payments received in FY 2026 for prior year invoices), the NRC must recover approximately \$818.8 million in fees in FY 2026. Of this amount, the NRC estimates that \$188.2 million will

be recovered through 10 CFR part 170 service fees, and approximately \$630.6 million will be recovered through 10 CFR part 171 annual fees. Table II of this document summarizes the fee recovery amounts for the FY 2026 final fee rule using the FY 2026 enacted budget and takes into account the budget authority for excluded activities and net 10 CFR part 171 billing

adjustments. For all information presented in the following tables in this final rule, individual values may not sum to totals due to rounding. Please see the work papers, available as indicated in the “Availability of Documents” section of this document, for actual amounts. The FY 2025 amounts are provided for comparison purposes.

TABLE II—BUDGET AND FEE RECOVERY AMOUNTS
[Dollars in millions]

	FY 2025 final rule	FY 2026 final rule
Total Budget Authority	\$944.1	\$971.5
Less Budget Authority for Excluded Activities	– 137.1	– 152.6
Balance	807.0	818.9
Fee Recovery Percent	100.0	100.0
Total Amount to be Recovered	807.0	818.9
Less Estimated Amount to be Recovered through 10 CFR part 170 Fees	– 205.4	– 188.2
Estimated Amount to be Recovered through 10 CFR part 171 Fees	601.6	630.7
10 CFR part 171 Billing Adjustments		
Unpaid Current Year Invoices (estimated)	5.5	4.5
Less Payments Received in Current Year for Previous Year Invoices (estimated)	– 3.7	– 4.6
Adjusted 10 CFR part 171 Annual Fee Collections Required	603.4	630.6
Adjusted Amount to be Recovered through 10 CFR parts 170 and 171 Fees	808.8	818.8

FY 2026 Fee Collection—Professional Hourly Rate and Reduced Hourly Rate

This section discusses the methodology for calculating the NRC’s professional hourly rate and the methodology for calculating the Reduced Hourly Rate.

The NRC uses a professional hourly rate to assess fees under 10 CFR part 170 for specific services it provides. The professional hourly rate also helps

determine flat fees (which are used for the review of certain types of materials license applications). The full costs of fees under §§ 170.21, “Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses,” and 170.31 will be determined based on either the professional hourly rate or the Reduced Hourly Rate, which went into

effect on October 1, 2025 (FY 2026). The FY 2026 professional hourly rate and the FY 2026 Reduced Hourly Rate will go into effect the first full pay period after the effective date of the FY 2026 final fee rule.

The NRC’s professional hourly rate is derived by adding budgeted resources for: (1) mission-direct program salaries and benefits; (2) mission-indirect program support; and (3) agency

support (corporate support and the IG).¹ The NRC then subtracts certain offsetting receipts and divides this total by the mission-direct full-time equivalent (FTE) converted to hours (the mission-direct FTE converted to hours is the product of the mission-direct FTE multiplied by the estimated annual mission-direct FTE productive hours). Consistent with the Office of

Management and Budget (OMB) Circular A–25, “User Charges,” the professional hourly rate encompasses the “full cost” of NRC review and thus includes the NRC’s budgeted resources for mission-direct program salaries and benefits, mission-indirect contract resources along with salaries and benefits, plus the agency support program contract resources along with

salaries and benefits. The only budgeted resources excluded from the professional hourly rate are those for mission-direct contract resources, which are generally billed to licensees and applicants separately. The following shows the professional hourly rate calculation:

$$\text{Professional Hourly Rate} = \frac{\text{Budgeted Resources}}{\text{Mission-Direct FTE Converted to Hours}} = \frac{\$788.9 \text{ million}}{1,582.1 \times 1,481} = \$337$$

For FY 2026, the NRC is increasing the professional hourly rate from \$318 to \$337. The approximately 5.9 percent increase in the professional hourly rate is primarily due to the decrease in mission-direct FTE compared to FY 2025. The professional hourly rate is inversely related to the mission-direct FTE amount; therefore, as the number of mission-direct FTE decreases, the professional hourly rate may increase. Based on the FY 2026 enacted budget, the number of mission-direct FTE is expected to decrease by approximately 121, primarily due to the Deferred Resignation Program (DRP) and other voluntary resignations. In addition, there was a decrease in mission-direct FTE because section 101 of the ADVANCE Act created a new excluded activity for international nuclear export and innovation activities, causing the FTE for these activities to be removed from the professional hourly rate calculation.

Additionally, the professional hourly rate is increasing due to a reduction in the estimate for annual mission-direct FTE productive hours from 1,507 to 1,481, or 1.7 percent, compared to FY 2025. The professional hourly rate is also inversely related to the annual mission-direct FTE productive hours amount; therefore, as the annual mission-direct FTE productive hours amount decreases, the professional hourly rate may increase. The estimate for annual mission-direct FTE productive hours reflects the average number of hours that a mission-direct employee spends on mission-direct work annually. This estimate, therefore, excludes hours charged to annual leave, sick leave, holidays, training, and general administrative tasks.

The decrease in the estimate for annual mission-direct FTE productive hours, compared to FY 2025, is attributable mainly to an increase in direct staff hours for annual leave and training attendance, which are excluded

from the estimate for annual mission-direct FTE productive hours computation. The estimate for annual mission-direct FTE productive hours is developed during budget formulation and is currently based on a rolling average of actual hours to account for any fluctuations in any given year. The reduction in productive hours seen here is, in part, the result of abnormally high productivity rates (e.g., less use of annual leave) seen during the COVID–19 public health emergency being phased out of the rolling average. Table III of this document shows the professional hourly rate calculation methodology. The FY 2025 amounts are provided for comparison purposes.

The decrease in mission-direct FTE and in the annual mission-direct FTE productive hours amount is partially offset by a reduction in the budgeted resources of approximately \$26.9 million, or 3.3 percent, compared to FY 2025.

TABLE III—PROFESSIONAL HOURLY RATE CALCULATION

[Dollars in millions, except as noted]

	FY 2025 final rule	FY 2026 final rule
Mission-Direct Program Salaries & Benefits	\$380.5	\$361.3
Mission-Indirect Program Support	\$121.5	\$115.3
Agency Support (Corporate Support and the IG)	\$313.8	\$312.3
Subtotal	\$815.8	\$788.9
Less Offsetting Receipts ²	\$0.0	\$0.0
Total Budgeted Resources Included in the Professional Hourly Rate	\$815.8	\$788.9
Mission-Direct FTE	1,703.3	1,582.1
Annual Mission-Direct FTE Productive Hours (Whole numbers)	1,507	1,481
Mission-Direct FTE Converted to Hours (Mission-Direct FTE multiplied by Annual Mission-Direct FTE Productive Hours)	2,566,873	2,343,090

¹ Please see the work papers for more detailed information on all the components of the professional hourly rate calculation.

² The fees collected by the NRC for Freedom of Information Act (FOIA) services and indemnity fees (financial protection required of all licensees for

public liability claims at 10 CFR part 140) are subtracted from the budgeted resources amount when calculating the 10 CFR part 170 professional hourly rate, per the guidance in OMB Circular A–25, “User Charges.” The budgeted resources for FOIA activities are allocated under the product for

Information Services within the Corporate Support Business Line. The budgeted resources for indemnity activities are allocated under the Licensing Actions and Research and Test Reactors products within the Operating Reactors Business Line.

TABLE III—PROFESSIONAL HOURLY RATE CALCULATION—Continued

[Dollars in millions, except as noted]

	FY 2025 final rule	FY 2026 final rule
Professional Hourly Rate (Total Budgeted Resources Included in the Professional Hourly Rate Divided by Mission-Direct FTE Converted to Hours) (Whole numbers)	\$318	\$337

The FY 2025 final fee rule included revisions to 10 CFR part 170 to implement section 201 of the ADVANCE Act, which went into effect on October 1, 2025 (FY 2026). In short, the NRC has two hourly rates: (1) the professional hourly rate, as described above in this section; and (2) the Reduced Hourly Rate for advanced nuclear reactor applicants and pre-applicants, as described below in this section.

Section 201 of the ADVANCE Act amended NEIMA to specify that the Reduced Hourly Rate is the FTE rate for mission-direct program salaries and benefits for the Nuclear Reactor Safety Program, divided by the productive hours assumption, for that FY. The methodology for calculating the Reduced Hourly Rate is similar to that

of the professional hourly rate, discussed above in this section, but with certain budgeted resources not included. Under section 201 of the ADVANCE Act, the Reduced Hourly Rate does not include mission-direct program salaries and benefits for the Nuclear Materials and Waste Safety Program, mission-indirect program support for the Nuclear Reactor Safety Program and the Nuclear Materials and Waste Safety Program, and agency support.

The NRC calculates the Reduced Hourly Rate by taking the budgeted resources for the mission-direct program salaries and benefits for the Nuclear Reactor Safety Program, then dividing this total by the mission-direct FTE for the Nuclear Reactor Safety Program converted to hours. This methodology

follows section 201 of the ADVANCE Act because the FTE rate for mission-direct program salaries and benefits for the Nuclear Reactor Safety Program is derived by dividing the budgeted resources for the mission-direct program salaries and benefits for the Nuclear Reactor Safety Program by the mission-direct FTE for the Nuclear Reactor Safety Program. The mission-direct FTE for the Nuclear Reactor Safety Program converted to hours is the product of the mission-direct FTE for the Nuclear Reactor Safety Program multiplied by the estimated annual mission-direct FTE productive hours. The productive hours assumption refers to the estimated annual mission-direct FTE productive hours.

The following shows the Reduced Hourly Rate calculation:

$$\begin{array}{rcccl} \text{Reduced} & & \text{Mission-Direct Budgeted} & & \\ \text{Hourly} & & \text{Resources for the Nuclear} & & \\ \text{Rate} & & \text{Reactor Safety Program} & = & \\ & & \text{Mission-Direct FTE for the} & & \\ & & \text{Nuclear Reactor Safety Program} & & \\ & & \text{Converted to Hours} & & \\ & & & = & \frac{\$282.8 \text{ million}}{1,236.6 \times 1,481} = \$154 \end{array}$$

Thus, in this FY 2026 final fee rule, the Reduced Hourly Rate is \$154 per hour and represents an over 50 percent reduction from the professional hourly rate of \$337 per hour. The NRC is increasing the Reduced Hourly Rate from \$148 to \$154, or approximately 4.0 percent, primarily due to the decrease in mission-direct FTE for the Nuclear Reactor Safety Program compared to FY 2025. The Reduced Hourly Rate is inversely related to the number of mission-direct FTE for the Nuclear Reactor Safety Program; therefore, as the number of mission-direct FTE for the Nuclear Reactor Safety Program decreases, the Reduced Hourly Rate may increase. Based on the FY 2026 enacted

budget, the number of mission-direct FTE for the Nuclear Reactor Safety Program is expected to decrease by approximately 96, primarily due to the DRP and other voluntary resignations.

Additionally, the Reduced Hourly Rate is increasing due to a reduction in the estimate for annual mission-direct FTE productive hours from 1,507 to 1,481, or 1.7 percent, compared to FY 2025. Similar to the professional hourly rate, the Reduced Hourly Rate is also inversely related to the annual mission-direct FTE productive hours amount; therefore, as the annual mission-direct FTE productive hours amount decreases, the Reduced Hourly Rate may increase. The estimate for annual

mission-direct FTE productive hours used for the Reduced Hourly Rate is the same as the estimate for annual mission-direct FTE productive hours used for the professional hourly rate, as described above in this section.

The decrease in mission-direct FTE for the Nuclear Reactor Safety Program and in the annual mission-direct FTE productive hours amount is partially offset by a reduction in the mission-direct budgeted resources for the Nuclear Reactor Safety Program of approximately \$14.7 million, or 4.9 percent, compared to FY 2025, primarily due to the DRP and other voluntary resignations.

TABLE IV—REDUCED HOURLY RATE CALCULATION

	FY 2025 final rule	FY 2026 final rule
Mission-Direct Budgeted Resources for the Nuclear Reactor Safety Program (Dollars in millions)	\$297.5	\$282.8
Mission-Direct FTE for the Nuclear Reactor Safety Program	1,332.9	1,236.6
Annual Mission-Direct FTE Productive Hours (Whole numbers)	1,507	1,481

TABLE IV—REDUCED HOURLY RATE CALCULATION—Continued

	FY 2025 final rule	FY 2026 final rule
Mission-Direct FTE for the Nuclear Reactor Safety Program Converted to Hours (Mission-Direct FTE for the Nuclear Reactor Safety Program multiplied by Annual Mission-Direct FTE Productive Hours) (Whole numbers)	2,008,680	1,831,405
Reduced Hourly Rate (Mission-Direct Budgeted Resources for the Nuclear Reactor Safety Program divided by Mission-Direct FTE for the Nuclear Reactor Safety Program Converted to Hours) (Whole numbers)	\$148	\$154

Both the professional hourly rate and the Reduced Hourly Rate provided in this final rule are based on the FY 2026 enacted budget.

FY 2026 Fee Collection—Flat Application Fee Changes

The NRC is amending the flat application fees it charges in its schedule of fees in § 170.31 to reflect the professional hourly rate of \$337. The NRC charges these fees to applicants for materials licenses and other regulatory services, as well as to holders of materials licenses. The NRC calculates flat fees by multiplying the average professional staff hours needed to process the licensing actions by the FY 2026 professional hourly rate. Biennially, the NRC analyzes the actual hours spent performing licensing actions and estimates the five-year average of professional staff hours that are needed to process licensing actions. The biennial review is required by section 205(a) of the Chief Financial Officers Act of 1990 (31 U.S.C. 902(a)(8)). The NRC performed this review for the FY 2025 proposed fee rule and will perform this review again for the FY 2027 proposed fee rule. The higher professional hourly rate of \$337 is the primary reason for the increase in flat application fees (see the work papers).

In order to simplify billing, the NRC rounds these flat fees to a minimal degree. Specifically, the NRC rounds these flat fees (up or down) in such a way that ensures both convenience for its stakeholders and minimal effects due

to rounding. Accordingly, fees under \$1,000 are rounded to the nearest \$10, fees between \$1,000 and \$100,000 are rounded to the nearest \$100, and fees greater than \$100,000 are rounded to the nearest \$1,000.

The flat fees are applicable for certain materials licensing actions (see fee categories 1.C. through 1.D., 2.B. through 2.F., 3.A. through 3.S., 4.B. through 5.A., 6.A. through 9.D., 10.B., 15.A. through 15.L., 15.R., and 16 of § 170.31). Applications filed on or after the effective date of the FY 2026 final fee rule will be subject to the revised fees in the final rule. Because section 101 of the ADVANCE Act created a new excluded activity for international nuclear export and innovation activities, which includes the budgeted resources under the Licensing Export/Import product, fees continue to not be assessed for import and export licensing actions under 10 CFR parts 170 and 171.

FY 2026 Fee Collection—Low-Level Waste Surcharge

The NRC is assessing a generic low-level waste (LLW) surcharge of \$3.258 million. In comparison to FY 2025, the FY 2026 surcharge is decreasing primarily due to a decline in budgeted resources in the FY 2026 enacted budget as a result of the DRP and other voluntary resignations. Disposal of LLW occurs at commercially operated LLW disposal facilities that are licensed by either the NRC or an Agreement State. Four existing LLW disposal facilities in the United States accept various types of LLW. All are regulated by an Agreement

State, rather than the NRC. Because the NRC does not regulate the existing LLW disposal facilities, the NRC is allocating this surcharge for LLW budgeted resources to NRC licensees that generate LLW, based on data available in DOE's Manifest Information Management System. This database contains information on total LLW volumes disposed of by four generator classes: academic, industrial, medical, and utility. The ratio of waste volumes disposed of by these generator classes to total LLW volumes disposed over a period of time is used to estimate the portion of this surcharge that will be allocated to the operating power reactors, fuel facilities, and materials users fee classes. The materials users fee class portion is adjusted to account for the large percentage of materials licensees that are licensed by the Agreement States rather than the NRC.

In March, DOE updated its Manifest Information Management System with 2026 data. Because of the update, the following changes occurred compared to the FY 2025 final fee rule: the LLW surcharge for the operating power reactors fee class decreased from \$3.251 million to \$2.978 million; the LLW surcharge for the fuel facilities fee class decreased from \$0.433 million to \$0.222 million; and the LLW surcharge for the materials users fee class decreased from \$0.114 million to \$0.059 million.

Table V of this document shows the allocation of the LLW surcharge and its allocation across the various fee classes.

TABLE V—ALLOCATION OF LLW SURCHARGE, FY 2026

[Dollars in millions]

Fee classes	LLW surcharge	
	Percent	\$
Operating Power Reactors	91.4	2.978
Spent Fuel Storage/Reactor Decommissioning	0.0	0.000
Non-Power Production or Utilization Facilities	0.0	0.000
Fuel Facilities	6.8	0.222
Materials Users	1.8	0.059
Transportation	0.0	0.000
Rare Earth Facilities	0.0	0.000
Uranium Recovery	0.0	0.000

TABLE V—ALLOCATION OF LLW SURCHARGE, FY 2026—Continued

[Dollars in millions]

Fee classes	LLW surcharge	
	Percent	\$
Total	100.0	3.258

FY 2026 Fee Collection—Revised Annual Fees

In accordance with SECY-05-0164, “Annual Fee Calculation Method,” the NRC rebaselines its annual fees every year. “Rebaselining” entails analyzing the budgeted resources in detail and then allocating the budgeted resources to various classes or subclasses of licensees. Rebaselining also includes updating the number of NRC licensees

in its fee calculation methodology. As shown in Table II, the NRC calculates the total amount to be recovered through 10 CFR part 171 annual fees by first taking the annual budget (less the budget authority for excluded activities) and subtracting the estimated amount to be recovered through 10 CFR part 170 fees. The NRC then makes certain 10 CFR part 171 billing adjustments to arrive at the total adjusted amount to be recovered through 10 CFR part 171 fees.

The NRC is revising its annual fees in § 171.15, “Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses,” and § 171.16 based on the FY 2026 enacted budget.

Table VI of this document shows the rebaselined fees for FY 2026 for a sample of licensee categories. The FY 2025 amounts are provided for comparison purposes.

TABLE VI—REBASELINED ANNUAL FEES

[Actual dollars]

Class/category of licensees	FY 2025 final annual fee	FY 2026 final annual fee
Operating Power Reactors	\$5,319,000	\$5,554,000
+ Spent Fuel Storage/Reactor Decommissioning	326,000	325,000
Total, Combined Fee	5,645,000	5,879,000
Spent Fuel Storage/Reactor Decommissioning	326,000	325,000
Non-Power Production or Utilization Facilities	96,800	98,200
High Enriched Uranium Fuel Facility (Category 1.A.(1)(a))	6,101,000	5,827,000
Low Enriched Uranium Fuel Facility (Category 1.A.(1)(b))	2,068,000	1,975,000
Uranium Enrichment (Category 1.E)	2,659,000	2,539,000
UF ₆ Conversion and Deconversion Facility (Category 2.A.(1))	1,295,000	1,237,000
Basic <i>In Situ</i> Recovery Facilities (Category 2.A.(2)(b))	27,700	50,300
Typical Users:		
Radiographers (Category 3.O.)	31,700	34,300
All Other Specific Byproduct Material Licensees (Category 3.P.)	15,600	16,700
Medical Other (Category 7.C.)	21,600	23,300
Device/Product Safety Evaluation—Broad (Category 9.A.)	27,200	28,500

The work papers that support this final rule show in detail how the NRC allocates the budgeted resources for each class of licensees and calculates the fees.

Paragraphs a. through h. of this section describes the budgeted resources

allocated to each class of licensees and the calculations of the rebaselined fees. For more information about detailed fee calculations for each class, please consult the accompanying work papers for this final rule.

a. Operating Power Reactors

The NRC will collect \$527.6 million in annual fees from the operating power reactors fee class in FY 2026, as shown in table VII of this document. The FY 2025 operating power reactors fees are shown for comparison purposes.

TABLE VII—ANNUAL FEE SUMMARY CALCULATIONS FOR OPERATING POWER REACTORS

[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources	\$668.9	\$682.4
Less estimated 10 CFR part 170 receipts	-174.1	-158.6
Net 10 CFR part 171 resources	494.7	523.8
Allocated generic transportation	0.5	0.9
Allocated LLW surcharge	3.3	3.0
Billing adjustment	1.5	-0.1
Total required annual fee recovery	500.0	527.6
Total operating reactors	94	95

TABLE VII—ANNUAL FEE SUMMARY CALCULATIONS FOR OPERATING POWER REACTORS—Continued
[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Annual fee per operating reactor	5.319	5.554

In comparison to FY 2025, the FY 2026 annual fee for the operating power reactors fee class is increasing primarily due to: (1) an increase in the budgeted resources in the FY 2026 enacted budget that are allocated to the operating power reactors fee class; and (2) an expected decrease in the 10 CFR part 170 estimated billings. The increase in the total required annual fee recovery amount for the operating power reactors fee class is offset primarily due to the transition of the Palisades Nuclear Plant (Palisades) back to the operating power reactors fee class, increasing the number of reactors in the operating power reactors fee class by one. Palisades has transitioned back to the operating power reactors fee class consistent with \$171.15 because (1) Palisades was previously included in the operating power reactors fee class; (2) it transitioned back to an operational licensing basis in late FY 2025; and (3) a notification was previously provided to the Atomic Energy Commission (the NRC's predecessor) of the successful completion of power ascension testing for Palisades.

The increase in budgeted resources for the operating power reactors fee class is primarily due to the following: (1) an increase in contract support for specialized, mission-related construction costs associated with the Three White Flint North relocation project; (2) an increase in contract support to maintain the agency's security and privacy tools that support federal mandates and the modernization of the Reactor Program System; and (3) an increase in contract support in research in areas including steam generator integrity, water stress corrosion cracking testing, irradiation-assisted degradation, cybersecurity research, structural and geotechnical evaluations, and thermal hydraulic and neutronics computer code development.

The increase in budgeted resources is also mitigated by the following: (1) a reduction in licensing resources due to efficiencies gained from the ADVANCE Act and E.O. 14300; (2) the transition of Palisades back to the operating power reactors fee class; (3) a reduction in oversight resources due to streamlining inspection workload that includes vendor inspections and event

evaluations; and (4) a reduction in research in areas including structural codes and standards, systems analysis research, external hazard research and risk analysis computer code development, and regulatory guide updates.

The 10 CFR part 170 estimated billings are expected to decrease primarily due to the following: (1) the staff completed implementation of the license renewal roadmap and other efficiency efforts, which significantly decreased the staff hours and contract resources needed to complete license renewal and subsequent license renewal application reviews; (2) the completion of NuScale Power LLC US460 small modular reactor (SMR) standard design approval application review in FY 2025; and (3) a decrease in 10 CFR part 170 estimated billings due to the government shutdown.

The annual fee is also affected by the following contributing factors: (1) a decrease in the 10 CFR part 171 billing adjustment due to the collection of prior year invoices; (2) a decrease in the LLW surcharge related to the coordination of the National LLW Program, including development of guidance; and (3) an increase in the generic transportation resources allocated to the operating power reactors fee class to support activities related to two new Certificates of Compliance (CoCs).

The fee-recoverable budgeted resources are divided equally among the 95 reactors in the operating power reactors fee class, resulting in an annual fee of \$5,554,000 per operating power reactor. Additionally, each licensed operating power reactor will be assessed the FY 2026 spent fuel storage/reactor decommissioning annual fee of \$325,000 (see table VIII of this document and the discussion that follows). The combined FY 2026 annual fee for each operating power reactor will be \$5,879,000.

Section 102(b)(3)(B)(i) of NEIMA established a cap for the annual fees charged to operating reactor licensees; under this provision, the annual fee for an operating reactor licensee, to the maximum extent practicable, shall not exceed the annual fee amount per operating reactor licensee established in the FY 2015 final fee rule (80 FR 37432; June 30, 2015), adjusted for inflation.

The NRC included an estimate of the operating power reactors fee class annual fee in appendix B, "Estimated Operating Power Reactors Annual Fee Per Licensee," of the NRC's FY 2026 Congressional Budget Justification (CBJ) (NUREG-1100, Volume 41) to increase transparency for stakeholders. The NRC developed this estimate based on the staff's allocation of the FY 2026 budget request to fee classes under 10 CFR part 170, and allocations within the operating power reactors fee class under 10 CFR part 171. The fee estimate included in the FY 2026 CBJ assumed 95 operating power reactors in FY 2026 and applied various data assumptions from the FY 2024 final fee rule. Based on these allocations and assumptions, the annual fee for the operating power reactors fee class included in the FY 2026 CBJ was estimated to be \$5.540 million.

The assumptions made between budget formulation and the development of this final rule have changed such that the annual fee for the operating power reactors fee class is \$5.554 million, compared to the estimated \$5.540 million in appendix B of the FY 2026 CBJ. These changes are primarily due to the decrease in the 10 CFR part 170 estimated billings for the FY 2026 final fee rule compared to the estimates for 10 CFR part 170 billings at the time of the FY 2026 budget request. The annual fee for the operating power reactors fee class in this final rule is \$0.983 million below the FY 2015 operating power reactors annual fee amount adjusted for inflation of \$6.537 million. The FY 2015 operating power reactors annual fee amount adjusted for inflation of \$6.537 million included in this final rule differs from the amount included in appendix B of the FY 2026 CBJ of \$6.681 million due to the CBJ using an average for inflation for multiple years to project the Consumer Price Index. The fee rule utilizes the Consumer Price Index for the most recent completed calendar year to build off the prior year annual fee amount adjusted for inflation.

In FY 2016, the NRC amended § 171.15 to establish a variable annual fee structure for light-water reactor (LWR) SMRs (81 FR 32617; May 24, 2016). In FY 2023, the NRC further

amended § 171.5, “Definitions,” to: (1) expand the applicability of the SMR variable fee structure to include non-LWR SMRs; and (2) establish an additional minimum fee and variable rate applicable to SMRs with a licensed thermal power rating of less than or equal to 250 megawatts-thermal (MWt) (88 FR 39120; June 15, 2023). This revision to the SMR variable annual fee structure retained the bundled unit concept for SMRs and the approach for

calculating fees for reactors, or bundled units, with licensed thermal power ratings greater than 250 MWt.

Currently, there are no operating SMRs; therefore, the NRC will not assess an annual fee in FY 2026 for this type of licensee.

b. Spent Fuel Storage/Reactor Decommissioning

The NRC will collect \$40.3 million in annual fees from power reactor

licensees, and from 10 CFR part 72 licensees that do not hold a 10 CFR part 50 or part 53 operating license or a 10 CFR part 52 or part 53 combined license, to recover the budgeted resources for the spent fuel storage/reactor decommissioning fee class in FY 2026, as shown in table VIII of this document. The FY 2025 spent fuel storage/reactor decommissioning fees are shown for comparison purposes.

TABLE VIII—ANNUAL FEE SUMMARY CALCULATIONS FOR SPENT FUEL STORAGE/REACTOR DECOMMISSIONING
[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources	\$50.7	\$49.0
Less estimated 10 CFR part 170 receipts	-12.3	-10.8
Net 10 CFR part 171 resources	38.4	38.2
Allocated generic transportation	1.9	2.0
Billing adjustments	0.1	0.0
Total required annual fee recovery	40.4	40.3
Total spent fuel storage facilities	124	124
Annual fee per facility	0.326	0.325

In comparison to FY 2025, the FY 2026 annual fee for the spent fuel storage/reactor decommissioning fee class is decreasing primarily due to a decrease in budgeted resources in the FY 2026 enacted budget that are allocated to the spent fuel storage/reactor decommissioning fee class.

The decrease in budgeted resources is primarily due to the following: (1) the potential restart of the Christopher M. Crane Clean Energy Center (CCEC) and Duane Arnold Energy Center (DAEC), which, if approved, would result in these reactors transitioning back to the operating power reactors fee class; (2)

the completion of major decommissioning taskings at the Vallecitos Nuclear Center and Fort Calhoun Station; and (3) a reduction in staffing due to the DRP and other voluntary resignations.

The decrease in budgeted resources is partially offset by an expected decrease in the 10 CFR part 170 estimated billings, which in turn is primarily due to the following: (1) the transition of Palisades back to the operating power reactors fee class; (2) the potential restart of CCEC and DAEC; (3) the completion of major decommissioning taskings at Vallecitos and Fort Calhoun;

and (4) a decrease in 10 CFR part 170 estimated billings due to the government shutdown.

The total required annual fee recovery amount is divided equally among 124 facilities, resulting in a FY 2026 annual fee of \$325,000 per facility.

c. Fuel Facilities

The NRC will collect \$23.0 million in annual fees from the fuel facilities fee class in FY 2026, as shown in table IX of this document. The FY 2025 fuel facilities fees are shown for comparison purposes.

TABLE IX—ANNUAL FEE SUMMARY CALCULATIONS FOR FUEL FACILITIES
[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources	\$31.5	\$30.3
Less estimated 10 CFR part 170 receipts	- 10.0	- 10.0
Net 10 CFR part 171 resources	21.5	20.3
Allocated generic transportation	2.0	2.5
Allocated LLW surcharge	0.4	0.2
Billing adjustments	0.1	0.0
Total required annual fee recovery	\$24.1	\$23.0

In comparison to FY 2025, the FY 2026 total required annual fee recovery amount for the fuel facilities fee class is decreasing primarily due to a decrease in the budgeted resources in the FY 2026 enacted budget that are allocated

to the fuel facilities fee class. This decrease in budgeted resources is partially offset by an increase in the allocated generic transportation resources. As a result, there is a decrease in the total required annual fee

recovery amount for the fuel facilities fee class compared to FY 2025.

The budgeted resources allocated to the fuel facilities fee class decreased primarily due to the following: (1) a reduction in resources for

environmental reviews for routine license amendment requests and renewal applications, complex license amendment requests associated with major modifications of existing fuel cycle facilities, and new fuel cycle facility license applications to reflect historical execution data and expected high confidence submittals; and (2) a reduction in staffing due to the DRP and other voluntary resignations. These decreases are partially offset by increased resources due to: (1) the maintenance and operation of the Nuclear Material Management and Safeguards System, a national database for special nuclear material reporting to fulfill domestic requirements and international agreements; and (2) the Orano Enrichment USA LLC Project IKE Enrichment Facility license application.

Compared to FY 2025, the 10 CFR part 170 estimated billings are remaining stable because while there are increases in 10 CFR part 170 estimated billings in FY 2026, these increases were offset by decreases in 10 CFR part 170 estimated billings. In FY 2026, there are increases in 10 CFR part 170

estimated billings due to the following: (1) the review of several licensing actions; (2) the review of the Global Laser Enrichment, LLC, Paducah Laser Enrichment Facility application; (3) significant pre-application engagement activities for potential new fuel facilities; and (4) oversight for the production of high assay low enriched uranium at the American Centrifuge Plant. These increases in 10 CFR part 170 estimated billings are offset by the following: (1) the completion of the review of the National Institute of Standards and Technology's (NIST's) license renewal application for possession and use of special nuclear material; (2) the completion of the review of the Purdue University license renewal application for possession and use of special nuclear material; (3) the completion of the review of the Urenco USA license amendment request to increase its enrichment limit to less than 10 weight percent uranium-235; (4) the implementation of process improvements to decrease the schedule/resources for licensing reviews; and (5) a decrease in 10 CFR part 170 estimated

billings due to the government shutdown. Overall, this resulted in the FY 2026 estimated 10 CFR part 170 billings for the fuel facilities fee class remaining the same as FY 2025.

The NRC continues to allocate annual fees to individual fuel facility licensees based on the effort/fee determination matrix developed in the FY 1999 final fee rule (64 FR 31448; June 10, 1999). In short, the matrix groups licensees within this fee class into various fee categories. The matrix lists processes that are conducted at licensed sites and assigns effort factors for the safety and safeguards activities associated with each process (these effort levels are reflected in table X of this document). The annual fees are then distributed across the fee class based on the regulatory effort assigned by the matrix. The effort factors in the matrix represent regulatory effort that is not recovered through 10 CFR part 170 fees (*e.g.*, rulemaking and guidance). Regulatory effort for activities that are subject to 10 CFR part 170 fees, such as the number of inspections, is not applicable to the effort factor.

TABLE X—EFFORT FACTORS FOR FUEL FACILITIES, FY 2026

Facility type (fee category)	Number of facilities	Effort factors	
		Safety	Safeguards
High Enriched Uranium Fuel (1.A.(1)(a))	2	88	91
Low Enriched Uranium Fuel (1.A.(1)(b))	3	70	21
Limited Operations (1.A.(2)(a))	1	3	22
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	0	0	0
Hot Cell (and others) (1.A.(2)(c))	0	0	0
Uranium Enrichment (1.E.)	1	16	23
UF ₆ Conversion and Deconversion (2.A.(1))	1	12	7
Total	8	189	164

In FY 2026, the total required annual fee recovery amount, \$23.0 million, is attributable to safety activities, safeguards activities, and the LLW surcharge. For FY 2026, the total budgeted resources to be recovered as annual fees for safety activities are approximately \$12.2 million. To calculate the annual fee, the NRC allocates this amount to each fee category based on its percentage of the

total regulatory effort for safety activities. Similarly, the NRC allocates the budgeted resources that the NRC estimates to be recovered as annual fees for safeguards activities, \$10.6 million, to each fee category based on its percentage of the total regulatory effort for safeguards activities. Finally, the fuel facilities fee class portion of the LLW surcharge—\$0.2 million—is allocated to each fee category based on

its percentage of the total regulatory effort for both safety and safeguards activities. The annual fee per licensee is then calculated by dividing the estimated total allocated budgeted resources for the fee category by the number of licensees in that fee category. The annual fee for each facility is summarized in table XI of this document.

TABLE XI—ANNUAL FEES FOR FUEL FACILITIES

[Actual dollars]

Facility type (fee category)	FY 2025 final annual fee	FY 2026 final annual fee
High Enriched Uranium Fuel (1.A.(1)(a))	\$6,101,000	\$5,827,000
Low Enriched Uranium Fuel (1.A.(1)(b))	2,068,000	1,975,000
Facilities with limited operations (1.A.(2)(a))	1,704,000	1,628,000
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	N/A	N/A
Hot Cell (and others) (1.A.(2)(c))	N/A	N/A
Uranium Enrichment (1.E.)	2,659,000	2,539,000

TABLE XI—ANNUAL FEES FOR FUEL FACILITIES—Continued

[Actual dollars]

Facility type (fee category)	FY 2025 final annual fee	FY 2026 final annual fee
UF ₆ Conversion and Deconversion (2.A.(1))	1,295,000	1,237,000

d. Uranium Recovery Facilities facilities fee class in FY 2026, as shown in table XII of this document. The FY 2025 uranium recovery facilities fees are shown for comparison purposes.

The NRC will collect \$0.2 million in annual fees from the uranium recovery

TABLE XII—ANNUAL FEE SUMMARY CALCULATIONS FOR URANIUM RECOVERY FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources	\$1.8	\$2.2
Less estimated 10 CFR part 170 receipts	– 1.6	– 1.9
Net 10 CFR part 171 resources	0.2	0.2
Billing adjustments	0.0	0.0
Total required annual fee recovery	\$0.2	\$0.2

In comparison to FY 2025, the total required annual fee recovery amount for the fee class is increasing slightly, primarily due to an increase in the budgeted resources in the FY 2026 enacted budget that are allocated to the uranium recovery facilities fee class. This increase in budgeted resources is primarily to support (1) the NRC's review of license renewal applications and (2) inspection procedural modifications associated with improvements resulting from the ADVANCE Act. This increase in budgeted resources is partially offset by an expected increase in 10 CFR part 170 estimated billings to support the NRC's review of license renewal applications for the Crow Butte Resources, Inc. site; Powertech USA, Inc. Dewey-Burdock

site; and NuFuels, Inc. Crownpoint Uranium Project.

As discussed in this document, the uranium recovery facilities fee class includes DOE and non-DOE licensees. Compared to FY 2025, the annual fee amount for DOE and the annual fee amount for the non-DOE licensee are both increasing. The annual fee amount for DOE is increasing primarily because of a decrease in 10 CFR part 170 estimated billings due to the government shutdown. The decrease in 10 CFR part 170 estimated billings is partially offset by an increase in 10 CFR part 170 estimated billings for work associated with various DOE Uranium Mill Tailings Radiation Control Act (UMTRCA) sites. The annual fee amount for the non-DOE licensee is increasing primarily due to an increase in resources for inspection procedural

modifications associated with improvements resulting from the ADVANCE Act.

The NRC regulates DOE's Title I and Title II activities under UMTRCA.³ The NRC described the overall methodology for determining fees for UMTRCA in the FY 2002 final fee rule (67 FR 42612; June 24, 2002), and the NRC continues to use this methodology. The annual fee assessed to DOE includes the resources specifically budgeted for the NRC's UMTRCA Title I and Title II activities, as well as 10 percent of the remaining budgeted resources for this fee class. The NRC assesses the remaining 90 percent of its budgeted resources to the non-DOE licensee in this fee class, which is reflected in table XIII. For additional information, please see the work papers.

TABLE XIII—COSTS RECOVERED THROUGH ANNUAL FEES; URANIUM RECOVERY FACILITIES FEE CLASS

[Actual dollars]

Summary of costs	FY 2025 final annual fee	FY 2026 final annual fee
DOE Annual Fee Amount (UMTRCA Title I and Title II) General Licenses:		
UMTRCA Title I and Title II budgeted resources less 10 CFR part 170 receipts	\$153,324	\$184,223
10 percent of generic/other uranium recovery budgeted resources	3,073	5,594
Total Annual Fee Amount for DOE (rounded)	156,000	190,000
Annual Fee Amount for Other Uranium Recovery Licenses:		
90 percent of generic/other uranium recovery budgeted resources less the amounts specifically budgeted for UMTRCA Title I and Title II activities	27,654	50,343
Total Annual Fee Amount for Other Uranium Recovery Licensees	27,700	50,300

³ Congress established the two programs, Title I and Title II, under UMTRCA to protect the public and the environment from hazards associated with uranium milling. The UMTRCA Title I program is

for remedial action at abandoned mill tailings sites where tailings resulted largely from production of uranium for weapons programs. The NRC also regulates DOE's UMTRCA Title II program, which

is directed toward uranium mill sites licensed by the NRC or Agreement States in or after 1978.

Further, for any non-DOE licensees, the NRC continues to use a matrix to determine the effort levels associated with conducting generic regulatory actions for the different licensees in the uranium recovery facilities fee class; this is similar to the NRC's approach for fuel facilities, described in the "c. Fuel Facilities" section of this document.

The matrix methodology for uranium recovery licensees first identifies the licensee categories included within this fee class (excluding DOE). These categories are conventional uranium mills and heap leach facilities, uranium *in situ* recovery (ISR) and resin ISR facilities, and mill tailings disposal facilities. The matrix identifies the types

of operating activities that support and benefit these licensees, along with each activity's relative weight (see the work papers). Currently, there is only one non-DOE licensee, which is a basic ISR facility. Table XIV of this document displays the benefit factors for the non-DOE licensee in that fee category.

TABLE XIV—BENEFIT FACTORS FOR URANIUM RECOVERY LICENSES, 2026

Fee category	Number of licensees	Benefit factor per licensee	Total value	Benefit factor percent total
Conventional and Heap Leach facilities (2.A.(2)(a))	0			0
Basic <i>In Situ</i> Recovery facilities (2.A.(2)(b))	1	190	190	100
Expanded <i>In Situ</i> Recovery facilities (2.A.(2)(c))	0			0
Section 11e.(2) disposal incidental to existing tailings sites (2.A.(4))	0			0
Total	1	190	190	100

Given that there is only one non-DOE licensee in the fee class, the application of the matrix does not result in any adjustment to the licensee's annual fee. As such, the FY 2026 annual fee for the non-DOE licensee is \$50,300 (rounded), as shown in table XV of this document. While the FY 2026 annual fee for the non-DOE licensee reflects an increase of

\$22,600 compared to FY 2025, the annual fee remains consistent with fiscal years prior to FY 2025 and is less than the annual fee included in the FY 2024 final fee rule for this fee category, which was \$53,200. Additionally, as explained in the FY 2019 final fee rule (84 FR 22331; May 17, 2019), the NRC includes some uranium recovery

program budgeted resources in a fee-relief activity to ensure the equitability and stability of annual fees for the uranium recovery facilities fee class since the majority of uranium recovery licensees are currently in Agreement States.

TABLE XV—ANNUAL FEES FOR URANIUM RECOVERY LICENSEES

[Other than DOE] [Actual dollars]

Facility type (fee category)	FY 2025 final annual fee	FY 2026 final annual fee
Conventional and Heap Leach facilities (2.A.(2)(a))	N/A	N/A
Basic <i>In Situ</i> Recovery facilities (2.A.(2)(b))	\$27,700	\$50,300
Expanded <i>In Situ</i> Recovery facilities (2.A.(2)(c))	N/A	N/A
Section 11e.(2) disposal incidental to existing tailings sites (2.A.(4))	N/A	N/A

e. Non-Power Production or Utilization Facilities

The NRC will collect \$0.196 million in annual fees from the non-power

production or utilization facilities fee class in FY 2026, as shown in table XVI of this document. The FY 2025 non-power production or utilization

facilities fees are shown for comparison purposes.

TABLE XVI—ANNUAL FEE SUMMARY CALCULATIONS FOR NON-POWER PRODUCTION OR UTILIZATION FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources	\$0.782	\$1.739
Less estimated 10 CFR part 170 receipts	– 0.621	– 1.580
Net 10 CFR part 171 resources	0.161	0.160
Allocated generic transportation	0.030	0.037
Billing adjustments	0.002	0.000
Total required annual fee recovery	0.194	0.196
Total non-power production or utilization facilities licensees	2	2
Total annual fee per licensee (rounded)	0.096	0.098

Compared to FY 2025, the FY 2026 annual fee for the non-power production or utilization facilities fee class is increasing primarily due to an increase in allocated generic transportation surcharge for this fee class. The rise in the generic transportation allotment is due to the increase in budgeted resources within the transportation fee class in the FY 2026 final fee rule.

Although the budgeted resources in the FY 2026 enacted budget that are allocated to this fee class represent an increase compared to FY 2025, this increase in budgeted resources is offset by an increase in the 10 CFR part 170 estimated billings for this fee class overall. The increase in budgeted resources compared to FY 2025 is primarily due to work associated with application reviews for medical isotope production facilities and advanced reactors.

While the 10 CFR part 170 estimated billings for this fee class overall increased compared to FY 2025, the 10 CFR part 170 estimated billings for the current fleet subject to annual fees decreased. The 10 CFR part 170

estimated billings with respect to medical isotope production facilities and advanced reactors applicants (*i.e.*, those not subject to annual fees) have increased when compared with FY 2025 primarily due to the following: (1) conducting pre-application activities for Eden Radioisotopes future operating license application in addition to the anticipation of their construction permit application for review, and (2) the review of a new advanced non-power reactor application, including topical reports and white papers. The 10 CFR part 170 estimated billings associated with the current fleet of operating non-power production or utilization facilities licensees subject to annual fees have declined slightly compared to FY 2025 primarily as a result of the NIST shutdown status extending into FY 2026, reducing the NRC's expected oversight workload.

The total required annual fee recovery amount is divided equally among the two non-power production or utilization facilities licensees subject to annual fees and results in an FY 2026 final annual fee of \$98,200 for each licensee. While the annual fee for the non-power

production or utilization facility fee class is increasing, the NRC is expanding the existing fee-relief activity, "Medical isotope production infrastructure," to include additional non-power production or utilization facilities program budgeted resources to ensure the equitability and stability of annual fees for the non-power production or utilization facilities fee class since the majority of non-power production or utilization facilities licensees are exempt from annual fees under 10 CFR part 171.

f. Rare Earth

The NRC has not allocated any budgeted resources to this fee class; therefore, the NRC will not assess an annual fee for this fee class in FY 2026.

g. Materials Users

The NRC will collect \$47.3 million in annual fees from materials users licensed under 10 CFR parts 30, 40, and 70 in FY 2026, as shown in table XVII of this document. The FY 2025 materials users fees are shown for comparison purposes.

TABLE XVII—ANNUAL FEE SUMMARY CALCULATIONS FOR MATERIALS USERS

[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources for licensees not regulated by Agreement States	\$45.1	\$45.3
Less estimated 10 CFR part 170 receipts	– 0.8	– 0.9
Net 10 CFR part 171 resources	44.3	44.4
Allocated generic transportation	2.2	2.9
Allocated LLW surcharge	0.1	0.1
Billing adjustments	0.1	0.0
Total required annual fee recovery	46.7	47.3

In comparison to FY 2025, there is an increase in the total required annual fee recovery amount primarily due to (1) an increase in the allocated generic transportation resources for this fee class as a result of an additional CoC in the materials users fee class; and (2) a decrease in the number of materials users licensees not regulated by Agreement States and thus the number of licensees in the fee class. In addition, there is a slight increase in the budgeted resources in the FY 2026 enacted budget that are allocated to the materials users fee class. This increase is primarily due to a rise in contract support to address skill gaps in health physics specialties and support the agency's strategic workforce planning. This increase in budgeted resources is offset by a reduction in staffing due to many

materials users licensing actions nearing completion.

The NRC continues to use its established methodology for equitably and fairly allocating the total required annual fee recovery amount of \$47.3 million among approximately 2,200 diverse licensees in the fee class. The total number of licensees in the fee class decreased from approximately 2,300 to 2,200, compared to FY 2025, as a result of Connecticut becoming an Agreement State effective at the end of FY 2025. The NRC continues to calculate the annual fees for each fee category within this fee class based on the 10 CFR part 170 application fees and estimated inspection costs for each fee category. Because the application fees and inspection costs are indicative of the complexity of the materials license, this

approach provides a proxy for allocating the generic and other regulatory costs to the diverse fee categories. This methodology also considers the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory costs associated with the categories of licenses.

The methodology for calculating 10 CFR part 171 annual fees for the various categories of materials users in this fee class includes using a formula that considers application fees, inspection costs, inspection priority (or frequency), and unique category costs. This formula is described in detail in the work papers. At a high level, this formula includes three main components: (1) recovery of general costs, (2) recovery of inspection costs, and (3) unique category costs. The total required annual

fee recovery amount of \$47.3 million for FY 2026, as shown in table XVII of this document, consists of \$36.7 million for general costs (including the allocated generic transportation resources), and \$10.6 million for inspection costs; there are no unique category costs for any fee categories in FY 2026.

As part of calculating the recovery for the general costs and inspection costs, respectively, the NRC derives two multipliers: the constant multiplier and the inspection multiplier. A constant multiplier is established to recover the total general costs for the fee class (\$36.7 million in FY 2026). To derive the constant multiplier, the general cost amount is divided by the sum of all fee categories (application fee plus the average inspection cost divided by inspection priority) then multiplied by the number of licensees. The average inspection cost is the average inspection hours for each fee category multiplied by the FY 2026 professional hourly rate of \$337. The inspection priority is the interval between routine inspections, expressed in years. This calculation

results in a constant multiplier of 1.36 for FY 2026.

The inspection multiplier is established to recover inspection costs for the fee class (\$10.6 million in FY 2026). To derive the inspection multiplier, the amount of inspection costs for the fee class is divided by the sum of all fee categories (average inspection cost divided by inspection priority) then multiplied by the number of licensees. This calculation results in an inspection multiplier of 2.09 for FY 2026.

Additionally, the unique category costs would recover costs unique to a particular fee category; however, there are no unique category costs for FY 2026.

The FY 2026 total required annual fee recovery amount of \$47.3 million for the materials users fee class also includes approximately \$0.1 million in LLW surcharge costs (see table V, “Allocation of LLW Surcharge, FY 2026,” of this document). The LLW surcharge costs for the fee class are not included in the formula described above; rather, the surcharge amount for the fee class is

divided by the number of licensees and then assessed to each licensee. See the work papers for the LLW surcharge amount per licensee.

Based on these calculations, the total required annual fee recovery amount for the materials users fee class is increasing compared to FY 2025. For the individual categories within the fee class, the FY 2026 annual fees for all fee categories are increasing compared to FY 2025. The increase for these fee categories is primarily due to the following: (1) an increase in the generic transportation resources allocated to this fee class; and (2) decrease in the number of licensees in the fee class due to Connecticut becoming an Agreement State. The annual fee for each fee category is shown in the revision to § 171.16(d).

h. Transportation

The NRC will collect \$2.4 million in annual fees to recover generic transportation budgeted resources in FY 2026, as shown in table XVIII of this document. The FY 2025 fees are shown for comparison purposes.

TABLE XVIII—ANNUAL FEE SUMMARY CALCULATIONS FOR TRANSPORTATION

[Dollars in millions]

Summary fee calculations	FY 2025 final rule	FY 2026 final rule
Total budgeted resources	\$11.8	\$13.7
Less estimated 10 CFR part 170 receipts	–3.3	–3.1
Net 10 CFR part 171 resources	8.6	10.6
Less generic transportation resources	–6.6	–8.3
Billing adjustments	0.0	0.0
Total required annual fee recovery	2.0	2.4

In comparison to FY 2025, the FY 2026 annual fee for the transportation fee class is increasing primarily due to (1) an increase in the budgeted resources in the FY 2026 enacted budget that are allocated to this fee class; and (2) a decrease in the 10 CFR part 170 estimated billings due to the completion of multiple transportation package reviews at the end of FY 2025 and the delay of an anticipated submittal by Radiant Industries Kaleidos to late FY 2026. This increase in budgeted resources is primarily to support an increase in licensing and transportation certification activities for microreactors, including reviews associated with the Radiant Industries Kaleidos microreactor. This increase in budgeted resources is partially offset by (1) a rise in the transportation percentage distribution of resources for the

operating power reactors fee class (to support activities related to CoCs) and for the materials users fee class (because of the new CoC under the materials users fee class) in FY 2026; and (2) the discontinuation of resources associated with the Project Pele application in FY 2025. Consistent with the policy established in the NRC’s FY 2006 final fee rule (71 FR 30722; May 30, 2006), the NRC recovers generic transportation resources unrelated to DOE by including those resources in the annual fees for licensee fee classes. The NRC continues to assess a separate annual fee under § 171.16, fee category 18.A., for DOE transportation activities. The amount of the allocated generic resources is calculated by multiplying the percentage of total CoCs used by each fee class (and DOE) by the total generic transportation resources to be recovered.

This resource distribution to the licensee fee classes and DOE is shown in table XIX of this document. Note that for the non-power production or utilization facilities fee class, the NRC allocates the distribution to only those licensees that are subject to annual fees. Although five CoCs benefit the entire non-power production or utilization facilities fee class, only two out of 29 operating non-power production or utilization facilities licensees are subject to annual fees. Consequently, the number of CoCs used to determine the proportion of generic transportation resources allocated to the non-power production or utilization facilities fee class has been adjusted to 0.3 so these licensees are charged a fair and equitable portion of the total fees (see the work papers).

TABLE XIX—DISTRIBUTION OF TRANSPORTATION RESOURCES, FY 2026

[Dollars in millions]

Licensee fee class/DOE	Number of CoCs benefiting fee class or DOE	Percentage of total CoCs	Allocated generic transportation resources
Materials Users	27.0	27.2	\$2.9
Operating Power Reactors	8.0	8.1	0.9
Spent Fuel Storage/Reactor Decommissioning	19.0	19.1	2.0
Non-Power Production or Utilization Facilities	0.3	0.3	0.04
Fuel Facilities	23.0	23.2	2.5
Subtotal of Generic Transportation Resources	77.3	77.9	8.3
DOE	22.0	22.1	2.4
Total	99.3	100.0	10.6

The NRC assesses an annual fee to DOE based on the 10 CFR part 71 CoCs held by DOE. The NRC, therefore, does not allocate these DOE-related resources to other licensees' annual fees because these resources specifically support DOE.

FY 2026—Policy Change

The NRC is making one policy change to its fee regulations for FY 2026 to implement E.O. 14300 and improve regulatory certainty for applicants.

Establishing Fixed Caps on Service Fees in Response to Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," Section 5(a)

Section 5(a) of E.O. 14300 announces a policy for the NRC to replace its "nonbinding 'generic milestone schedules'" with "fixed deadlines" for requested activities of the Commission "as directed under the Nuclear Energy Innovation and Modernization Act." Section 5(a) also announces a policy for the NRC to establish fixed caps on service fees to enforce those deadlines. Section 5(a) further provides that the "regulations should not provide for tolling those deadlines except in instances of applicant failure, and must allow a reasonably diligent applicant" to complete the licensing process within the allotted time.

Section 5(a) references NEIMA specifically and the requirement in section 102(c) of NEIMA, as amended by section 504 of the ADVANCE Act. Section 102(c) requires development of performance metrics and milestone schedules for "requested activities of the Commission" and imposes reporting requirements for certain delays in issuing a final safety evaluation for these activities. NEIMA section 3 defines "requested activity of the Commission" to include the processing of applications for design certifications or approvals, licenses, permits, license amendments, license renewals, CoCs,

and power uprates, and "any other activity requested by a licensee or applicant." In contrast to NEIMA section 102(c), section 5(a) of E.O. 14300 refers to the "final decision on an application" and not the "final safety evaluation."

Although fixed fee caps apply to only requested activities of the Commission that involve the issuance of a final safety evaluation, the NRC will continue to establish and communicate schedule and resource estimates for other activities, such as pre-application engagement, and will be held accountable for efficiency, timeliness, and quality of these reviews through multiple performance management mechanisms such as Annual Performance Plan performance indicators, internal tracking dashboards, and quarterly performance reviews.

a. Purpose of This Change

The NRC is making this change in the FY 2026 final fee rule to establish fixed caps on service fees for requested activities of the Commission that involve the issuance of a final safety evaluation, consistent with NEIMA and to implement E.O. 14300. The fixed fee caps will provide cost predictability and drive increased efficiency and accountability in the NRC's licensing and other activities requested by applicants and licensees. The NRC will address fixed deadlines for final decisions (including the 12- and 18-month periods cited in section 5(a) of E.O. 14300) in a future rulemaking.

The NRC does not expect to exceed the fixed fee caps for reasons not attributable to applicant failure. In the unlikely event of such an exceedance, the NRC will continue to work diligently to complete the licensing review as soon as practicable consistent with the NRC's authorizing legislation, including the Atomic Energy Act of 1954 (AEA), and NEIMA, as well as E.O. 14300. Consistent with section 5(a) of

E.O. 14300, any exceedance of a fixed fee cap not attributable to applicant failure will not be borne by applicants or licensees as either service fees or annual fees. NEIMA requires the NRC to recover through service fees and annual fees, to the maximum extent practicable, approximately 100 percent of its total budget authority for the FY, less the budget authority for excluded activities, including fee-relief activities identified by the Commission. These statutory mechanisms allow the NRC to address fee cap exceedances, in the unlikely event they occur, consistent with law.

To implement fixed fee caps, the NRC is establishing § 170.33, "Executive Order 14300 fixed fee caps," and amending § 170.3, "Definitions," and § 15.31, "Disputed debts." These changes include a table of fixed fee caps for categories of requested activities of the Commission that involve the issuance of a final safety evaluation (categorical caps); a process for lower tailored caps based on the specific application for the requested activity; a definition of applicant failure, which is the sole basis for increasing the fixed fee cap; and procedures for fee cap disputes.

b. Tailored Caps

The new § 170.33 provides a process for the NRC to set a tailored cap below the categorical cap based on the specific application for the requested activity, to the maximum extent practicable. Under § 170.33, the fixed fee cap will be the lesser of the categorical cap or the tailored cap. The NRC will communicate the fixed fee cap in its written communication on schedule and resources for the requested activity provided to the applicant.

The NRC is establishing tailored caps because, depending on the complexity of the requested activity, it would be more appropriate to hold the NRC accountable to a tailored cap below the bounding categorical cap. In certain

cases, due to the bounding nature of the categorical caps, categorical caps may be higher than the resources needed for a specific application and thus fail to provide the efficiency and accountability benefits that fixed fee caps are designed to offer. For example, the resources needed to review an application that relies on a previously approved topical report are likely to be lower than the categorical cap because categorical caps bound the range of resources needed for activities falling within a particular category.

Tailored caps will reflect the content and complexity of the specific application and will be provided to applicants as part of the NRC's established practice of communicating schedule and resource estimates. Consistent with E.O. 14300, section 5(a), § 170.33 augments this established practice by directing the inclusion of a fixed fee cap in the written communication on schedule and resources and providing for a tailored cap that is lower than the categorical cap to the maximum extent practicable, enhancing NRC accountability and efficiency. The NRC is not able to determine if it could set a fixed fee cap lower than the categorical cap until it receives a specific complete application that can be accepted for review because the resources needed for the NRC to review and issue a final decision on a requested activity depend, in part, on the specific application submitted, as the complexity, completeness, and quality of an application can vary. Allowing for tailored caps will encourage applicants to engage early with the NRC and submit a complete, high-quality application. To ensure proper management and control, the NRC will continue to closely monitor project resources, schedules, and early indicators to enable it to identify potential risks of exceeding estimates well in advance.

c. Starting and Ending Points for Fixed Fee Caps

Section 5(a) of E.O. 14300 specifies that the fixed deadlines enforced by the fixed fee caps "commenc[e] with the first required step in the regulatory process" and end with the "final decision on an application." Consistent with E.O. 14300, the starting point for the fixed fee cap is when a complete application for the requested activity has been accepted for review by the NRC. For a license application, for example, that is when the NRC has completed its acceptance review and docketed the complete application. The ending point for the fixed fee cap is issuance of the final decision (*i.e.*, the

NRC's approval of the requested activity if the NRC's evaluation determines that pertinent requirements are met). For a license application, for example, that is when the NRC issues the license if the NRC's evaluation determines that pertinent requirements are met. Consistent with longstanding policy, as reflected in § 170.11(a)(2), 10 CFR part 170 fees are assessed for mandatory hearings, but not contested hearings, except for limited circumstances. The application of fee policy changes associated with E.O. 14300 does not change this policy.

d. Applicant Failure

Section 5(a) of E.O. 14300 specifies that the "regulations should not provide for tolling [the fixed] deadlines [enforced by the fixed fee caps] except in instances of applicant failure." Consistent with this policy, § 170.33 states that fixed fee caps will not be increased except in instances of applicant failure. If applicant failure occurs, the NRC will notify the applicant in writing of the new fixed fee cap and will set the new fixed fee cap equal to the lowest practicable amount necessary to account for the applicant failure.

In addition, the NRC is adding a definition for the term "applicant failure" to § 170.3. Given the focus on "applicant failure" and a "reasonably diligent applicant" in section 5(a) of E.O. 14300, § 170.3 defines applicant failure as actions or inaction that:

- (1) are within the reasonable control of a diligent applicant;
- (2) are not due to actions or inaction of the NRC; and
- (3) will cause substantial delays or require a significant increase in resources.

The definition includes, as an example of applicant failure, explicit applicant requests for the NRC to pause or delay review. The NRC is developing guidance to provide further examples of applicant failure and support consistent application of the definition of applicant failure. As discussed in Section IV, Public Comment Analysis, the NRC received a comment requesting clarification if all three criteria in the definition in § 170.3 need to be met to have applicant failure. In response to this comment, the NRC is stating explicitly that all three criteria in the definition in § 170.3 need to be met to have applicant failure.

e. Fee Cap Disputes

The new § 170.33(f) and amendments to § 15.31 clarify how applicants may submit disputes associated with the fixed fee cap by making clear that fee

cap disputes must be submitted in accordance with the NRC's established processes for disputes of 10 CFR part 170 fees. The NRC established these processes in the FY 2021 final fee rule (86 FR 32146; June 16, 2021), in accordance with NEIMA section 102(d)(3), including creation of the NRC Form 529 for disputes of 10 CFR part 170 fees.

Consistent with the NRC's established dispute processes, and with § 170.51, "Right to dispute assessed fees," § 170.33(f) states the following: "Consistent with § 170.51 of this part, any disputes associated with the Executive Order 14300 fixed fee cap must be submitted in accordance with § 15.31 of this chapter." The revisions to § 15.31(a) specify that (1) for disputes associated with the fixed fee cap, the applicant must submit an NRC Form 529 within 45 days of the NRC written communication pertaining to the cap; and (2) the form must be submitted to the Office of the Chief Financial Officer, consistent with existing regulatory requirements governing submission of fee disputes.

f. Effective Date of October 1, 2026

Fixed fee caps will be effective starting October 1, 2026. For requested activities for which a complete application has been accepted for review on or after that date, the fixed fee cap will be the lesser of the categorical cap or the tailored cap. Applications accepted for review before that date will receive a tailored cap representing the lowest practicable amount based on the specific application.

The NRC's current billing system, Financial Accounting and Integrated Management Information System, does not possess the capabilities required to support fixed fee caps through automation. The NRC is currently in the process of implementing a new fee billing engine, which is expected to be operational on October 1, 2026, and will have the capabilities to track and administer the fixed fee caps through automation. Rather than making duplicative system enhancements to these two billing systems, the NRC has aligned the effective date for the fixed fee caps with the expected operational date for the new fee billing engine. Regardless of when the new fee billing engine becomes operational, the NRC will implement fixed fee caps as of the October 1, 2026, effective date.

Because the effective date means that the fixed fee caps will take effect before other rulemakings implementing E.O. 14300, the NRC anticipates issuing updated categorical caps to align with additional efficiencies realized as a

result of the E.O. 14300 rulemakings. As discussed in Section IV, Public Comment Analysis, the NRC is clarifying that the categorical caps in table 1 in § 170.33 will be updated annually to reflect any changes to the professional hourly rate or Reduced Hourly Rate. In this final rule, the NRC has changed the Fixed Caps on Service Fees in table 1 in § 170.33 to reflect the \$337 professional hourly rate, which increased by \$1 from the FY 2026 proposed fee rule. There is no change in table 1 in § 170.33 for the \$154 Reduced Hourly Rate since there was no change in the Reduced Hourly Rate from the FY 2026 proposed fee rule. The NRC will also evaluate categorical caps biennially to closely review the staff hours and contract costs used to establish the categorical caps, consistent with the Chief Financial Officers Act of 1990. Updated categorical caps will apply only to applications accepted for review after the effective date for the updated categorical cap.

g. Methodology for Categories of Requested Activities

The NRC developed the categories of requested activities for table 1 in § 170.33 by aligning them with the requested activities with established NEIMA milestone schedules and creating separate categories and subcategories where significant variations could support development of significantly different categorical caps. For example, table 1 in § 170.33 includes separate rows for construction permits, ESPs, and limited work authorizations because the data supported development of significantly different categorical caps for these categories of requested activities. As an example of new subcategories, table 1 in § 170.33 has separate rows for two subcategories for standard design approvals because significantly different categorical caps would apply for an application referencing an approved design certification or standard design approval, in comparison to an application with no prior approvals.

In the FY 2026 proposed fee rule, the NRC stated that table 1 in § 170.33 “would be updated to reflect any new requested activities that involve the issuance of a final safety evaluation, including any resulting from the 10 CFR part 53 rulemaking or other future rulemakings.” In this final rule, the NRC has incorporated new requested activities under 10 CFR part 53 in table 1 in § 170.33. The NRC is not establishing separate categorical caps for requested activities under 10 CFR part 53 because the NRC does not currently have the data necessary to support

establishment of separate categorical caps for the new 10 CFR part 53 rule. The NRC will use tailored caps to address expected efficiencies under 10 CFR part 53 and may consider establishing separate categorical caps for requested activities under 10 CFR part 53 in a future fee rule after it has execution data gained from experience implementing the new 10 CFR part 53 rule.

h. Methodology for Categorical Caps

Table 1 in § 170.33 includes two sets of categorical caps: (1) Fixed Caps on Service Fees; and (2) Fixed Caps on Service Fees for Advanced Nuclear Reactor Applicants. The Fixed Caps on Service Fees are based on staff hours multiplied by the professional hourly rate, plus contract costs. The Fixed Caps on Service Fees for Advanced Nuclear Reactor Applicants are based on the Reduced Hourly Rate established by the ADVANCE Act and apply only to qualifying applications and not to amendments and renewals due to the definition of advanced nuclear reactor applicant included in the ADVANCE Act’s Reduced Hourly Rate provisions and the legislative history.

The categorical caps in table 1 in § 170.33 reflect a data-driven evaluation of future resource needs for requested activities, based on a detailed analysis of actual past performance, current execution experience, and expected improvements. These caps are based on historical, inflation-adjusted data for the range of activities included in each category; removal of outliers in the historical data (e.g., a review that did not involve a reasonably diligent applicant consistent with the focus of E.O. 14300, section 5(a)); efficiencies achieved to date; additional efficiencies from E.O. 14300 and the ADVANCE Act not requiring rulemaking; alignment with the updated NEIMA milestone schedules that took effect on May 23, 2025; and current execution experience. For categories with limited historical data, the categorical caps were developed using recent comparable data, such as execution data from recent activities or estimated resources data from recent applications accepted for review.

In terms of expected improvements, the categorical caps reflect efficiencies that the NRC expects to realize from implementation of the ADVANCE Act, particularly those in response to section 505, and E.O. 14300 that do not require rulemaking. Some examples of these efficiencies are associated with streamlined licensing processes (such as the use of dedicated core review teams), improved regulatory guidance, and

greater standardization in application content and review procedures. Future updates to the categorical caps will reflect additional efficiencies that are realized as a result of implementation of E.O. 14300 and the ADVANCE Act—both from E.O. 14300 rulemakings and other actions taken by the NRC.

FY 2026—Administrative Changes

The NRC is making three administrative changes in FY 2026:

1. *Amend § 171.15(d)(1) to clarify the frequency with which the SMR variable rate will be calculated and updated, as appropriate.*

The NRC is amending § 171.15(d)(1) by adding “Each fiscal year, the variable rate will be calculated based on October 1 of the fiscal year and updated, as appropriate, to determine the variable fee for the current fiscal year.” Currently, § 171.15(d)(1) does not include language about the frequency with which the SMR variable rate will be calculated for potential updates. Since § 171.15(d)(1) applies to all SMR annual fees, this amendment provides additional clarity to all licensees paying SMR annual fees for their annual fee payments under 10 CFR part 171.

2. *Amend § 170.11(d) to update where a fee exemption request submitted via email should be sent.*

The NRC is amending paragraph (d) of § 170.11, “Exemptions,” by adding a generic resource email box to ensure that the processing of fee exemption requests submitted via email will not be delayed in the event of a change of the Chief Financial Officer (CFO). Currently, a person, including a licensee or applicant, can submit a fee exemption request via email to the CFO, and if that individual is no longer working at the NRC, there can be a short-term delay in processing the fee exemption request. With this change, the NRC ensures that a person interested in requesting a fee exemption via email will not have to identify the current CFO and will be able to submit their fee exemption request directly to the generic resource email box. The NRC is amending § 170.11(d) to add a new sentence clarifying that fee exemption requests submitted via email should be submitted to the NRC at cfofeeexemptionrequests.resource@nrc.gov. This amendment eliminates the possibility that the processing of fee exemption requests via email will be delayed.

3. *Add § 171.11(f) to include where a fee exemption request submitted via email should be sent to be consistent with the fee exemption requirements in § 170.11.*

The NRC is adding a new paragraph (f) to § 171.11, “Exemptions,” to include a generic resource email box and ensure that the processing of fee exemption requests via email will not be delayed if there is a change in the CFO. Currently, § 171.11 does not specify how fee exemption requests must be submitted. By adding the new language to § 171.11, the fee exemption regulations in both § 171.11 and § 170.11 will be consistent and clarify how a person should submit a fee exemption request via email. With this change, the NRC ensures that a person interested in requesting a fee exemption via email will not have to identify the current CFO and would be able to submit their fee exemption request directly to the generic resource email box. This amendment eliminates the possibility that the processing of fee exemption requests via email will be delayed.

III. Opportunities for Public Participation

The NRC published a proposed rule on March 12, 2026 (91 FR 12084). The NRC held a public meeting on March 27, 2026, where the NRC provided background on the proposed changes. Comments received on the proposed rule can be found at <https://www.regulations.gov> under Docket ID NRC–2023–0212.

IV. Public Comment Analysis

The public comment period for the proposed rule closed on April 13, 2026. By the close of the comment period, the NRC received 10 comment submittals. The public comment submissions are available from the Federal Rulemaking website at <https://www.regulations.gov> under Docket ID NRC–2023–0212.

In general, commenters acknowledged the NRC’s efforts to implement the ADVANCE Act provisions for the Reduced Hourly Rate for advanced nuclear reactor applicants and pre-applicants and to improve predictability associated with fees. However, commenters raised concerns or suggestions related to the overall implementation of E.O. 14300, section 5(a). Several comments expressed concerns about the overall size of the NRC’s budget, transparency, and budget formulation activities. Some commenters’ concerns were outside the scope of the fee rule. The NRC has carefully considered the public comments received on the proposed rule. The comments have been organized by topic. The NRC separated these comments into 16 categories based on their relevance to particular topics.

A. Establishment of Fixed Fee Caps as Contemplated by E.O. 14300

Comment: Some commenters supported the establishment of fixed fee caps as contemplated by E.O. 14300. Some commenters raised concerns about the fixed fee caps, including concerns about fee caps violating statutory requirements and causing negative consequences.

Response: The NRC disagrees that establishing the fixed fee caps violates statutory requirements and will cause negative consequences. The fixed fee caps will provide cost predictability and accountability while remaining consistent with the statutory fee recovery requirements. NEIMA requires the NRC to recover through service fees and annual fees, to the maximum extent practicable, approximately 100 percent of its total budget authority for the FY, less the budget authority for excluded activities, including fee-relief activities identified by the Commission. These statutory mechanisms allow the NRC to address fee cap exceedances, in the unlikely event they occur, consistent with law.

The NRC disagrees that fixed fee caps will have the negative consequences identified in these comments and, in any event, views the benefits of fixed fee caps for licensees, applicants, and the NRC, as outweighing any negative consequences. The NRC disagrees with the claims in these comments that the fixed fee caps will cause the NRC staff to be reluctant to work on activities that might exceed a fixed fee cap, distort agency behavior, create tradeoffs dissuading positive engagement between the NRC staff and applicants, and provide an incentive for applicants to slow-walk engagement with the NRC staff. Instead, the NRC views the fixed fee caps as creating positive incentives for the NRC staff, as well as applicants and licensees. The fixed fee caps will incentivize the NRC staff to identify safety-significant issues early and push teams to be more efficient. Risk-informed methods will keep reviews focused on the most safety-significant issues. Establishing fixed fee caps therefore will push consistent timelines, tighter milestone control, increased use of dashboards and project controls, consistent review scopes, and repeatable risk-informed approaches. Applicants and licensees will be driven by an incentive to avoid applicant failure and support timely reviews. Also, as a benefit, the fixed fee caps will provide enhanced predictability regarding service fees associated with licensing and other activities requested by licensees and applicants. No changes

were made to the final rule as a result of these comments.

B. Exceedances of Fixed Fee Caps

Comment: Some commenters raised questions regarding what would happen if the NRC exceeded a fixed fee cap, including whether the NRC would continue the review, whether the review costs would be recovered through annual fees, and whether continuation of the review without fee recovery would violate statutory requirements.

Response: In response to these comments, the NRC has clarified in the preamble what would happen in the unlikely event of such an exceedance. However, the NRC disagrees that continuation of a review after an exceedance would violate statutory requirements.

In the preamble above, the NRC has made clear that the NRC is not planning to exceed the fixed fee caps for reasons not attributable to applicant failure, and that in the unlikely event of such an exceedance, the NRC will continue to work diligently to complete the licensing review as soon as practicable consistent with the NRC’s authorizing legislation, including the AEA, and NEIMA, as well as E.O. 14300. The NRC has put multiple systems and management controls in place to monitor resources and schedules throughout the NRC’s review to identify and mitigate any challenges to the fixed fee caps.

Consistent with section 5(a) of E.O. 14300, any exceedance of a fixed fee cap not attributable to applicant failure will not be borne by applicants or licensees as either service fees or annual fees. NEIMA requires the NRC to recover through service fees and annual fees, to the maximum extent practicable, approximately 100 percent of its total budget authority for the FY, less the budget authority for excluded activities, including fee-relief activities identified by the Commission. These statutory mechanisms allow the NRC to address fee cap exceedances, in the unlikely event they occur, consistent with law. No changes were made to the rule text as a result of these comments.

C. Fixed Deadlines

Comment: Some commenters raised concerns related to fixed deadlines, including why fee caps are being established before fixed deadlines have been established and whether the NRC would continue the review after the NRC exceeds the fixed deadline.

Response: The NRC disagrees with these comments. The NRC is not establishing fixed deadlines in this final rule and will address the E.O. 14300

policy to establish fixed deadlines for final decisions (including the 12- and 18-month periods cited in section 5(a) of E.O. 14300) in a future rulemaking. The NRC is not waiting to establish fixed fee caps until after fixed deadlines are established because there are benefits to implementing the fixed fee caps in this final rule. The fixed fee caps will provide cost predictability and drive increased efficiency and accountability in the NRC's licensing and other activities requested by applicants and licensees. Should fixed deadlines be established, the NRC would not assess 10 CFR part 170 fees beyond the fixed deadline, even if the fixed fee cap has not been reached, absent applicant failure, consistent with section 5(a) of E.O. 14300. In the unlikely event of such an exceedance, the NRC would continue to work diligently to complete the licensing review as soon as practicable consistent with the NRC's authorizing legislation, including the AEA, and NEIMA, as well as E.O. 14300. No changes to the final rule were made as a result of these comments.

D. Tailored Caps

Comment: One commenter supported tailored caps, acknowledging that it has long been recognized by industry that the scope and duration of a review are only well understood after the NRC issues an acceptance letter. Some commenters raised concerns about tailored caps, including how the NRC would establish tailored caps and be consistent in doing so, guidance being developed regarding establishment of tailored caps, risks associated with establishing a lower tailored cap, and factors that should be considered in establishing tailored caps.

Response: The NRC agrees, in part, and disagrees, in part, with these comments. The NRC agrees that the scope and duration of a review are only well understood after the NRC accepts a complete application for review. The NRC is establishing tailored caps because, depending on the complexity of the requested activity, it would be more appropriate to hold the NRC accountable to a tailored cap below the bounding categorical cap. In certain cases, due to the bounding nature of the categorical caps, categorical caps may be higher than the resources needed for a specific application and thus fail to provide the efficiency and accountability benefits that fixed fee caps are designed to offer.

Tailored caps will reflect the content and complexity of the specific application and will be provided to applicants as part of the NRC's established practice of communicating

schedule and resource estimates. The NRC is not able to determine if it could set a fixed fee cap lower than the categorical cap until it receives a specific complete application that can be accepted for review because the resources needed for the NRC to review and issue a final decision on a requested activity depend, in part, on the specific application submitted, as the complexity, completeness, and quality of an application can vary. Allowing for tailored caps will encourage applicants to engage early with the NRC and submit a complete, high-quality application. Several factors, such as effective pre-application engagement and prior demonstration of a facility under DOE or Department of War authorization, are expected to improve the efficiency of application reviews and will likely result in a lower tailored cap.

The NRC disagrees with the comments raising concerns about inconsistency, dispute, and underestimation risks associated with tailored caps. Although tailored caps by their nature will be unique to the particular application, the NRC will apply the same methodology for determining the fixed fee cap for a given application. The NRC has substantial experience applying a consistent methodology to estimate resources for licensing reviews and other applicant-requested activities because it has been communicating schedule and resource estimates for these activities for years. The fixed fee caps build off this established practice. In addition, the NRC is developing guidance on establishment and management of fixed fee caps, which will be issued before the fixed fee caps become effective on October 1, 2026, and will support consistent application of tailored caps. The NRC will consider various factors, including those raised in the comments, when considering establishment of a tailored cap. No changes were made to the final rule as a result of these comments.

E. Starting Point for Fixed Fee Caps

Comment: Some commenters requested that the starting point for the fixed fee caps be changed to when an application is submitted to the NRC because the first required step in the regulatory process is submittal of the application and that way, the fixed fee caps include the acceptance review.

Response: The NRC disagrees with the comments. Consistent with E.O. 14300, the starting point for the fixed fee cap is when a complete application for the requested activity has been accepted for review by the NRC because that is the

first required step in the regulatory process and the NRC is not able to determine if it can set a fixed fee cap lower than the categorical cap until it receives a complete application that can be accepted for review. Prior to that point, the NRC is not able to determine if it can set a fixed fee cap lower than the categorical cap because the resources needed for the NRC to review and issue a final decision on a requested activity depend, in part, on the specific application submitted, as the complexity, completeness, and quality of an application can vary. The NRC will be held accountable for efficiency, timeliness, and quality of acceptance reviews through multiple performance management mechanisms such as Annual Performance Plan performance indicators, internal tracking dashboards, and quarterly performance reviews. No changes were made to the final rule as a result of these comments.

F. Applicant Failure

Comment: One commenter requested clarification regarding whether all three criteria in the definition in § 170.3 needed to be met to have applicant failure. One commenter requested that applicant failure not be the sole basis for increasing fixed fee caps. One commenter raised concerns about what would happen if a fixed fee cap was exceeded due to applicant failure, noting that the only reasonable course of action seemed to be suspension, withdrawal, or denial. One commenter provided questions regarding when the guidance on applicant failure would be issued and whether it would be published for public comment. One commenter specifically noted that guidance on applicant failure would be useful to applicants, and some commenters requested examples of what would constitute applicant failure. Some commenters requested clarification regarding whether a government shutdown would constitute applicant failure.

Response: The NRC agrees, in part, and disagrees, in part, with these comments. The NRC agrees that all three criteria in the definition in § 170.3 need to be met to have applicant failure, and the NRC has added language in the preamble to make that explicit.

However, the NRC disagrees with the comments regarding applicant failure not being the sole basis for increasing a fixed fee cap, and suspension, withdrawal, or denial being the only reasonable course of action if a fixed fee cap is exceeded due to applicant failure. Applicant failure is the sole basis for increasing a fixed fee cap, consistent with the principles of fairness and

equity—ensuring that applicants are not charged additional fees unless their own actions or inactions are the cause of significant additional NRC review effort. Having applicant failure be the sole basis for increasing a fixed fee cap also provides greater cost predictability for applicants and licensees, as it is clear that fixed fee caps will not be increased unless applicant failure, which is within the reasonable control of a diligent applicant, applies. Applicant failure will not automatically result in withdrawal, suspension, or denial of an application; the NRC plans to continue reviews, even if there is applicant failure, unless the specific circumstances necessitate that the NRC suspend the review or deny the application (such as an explicit request from an applicant for the NRC to pause or delay the review). If applicant failure occurs, the NRC will notify the applicant and set the new fixed fee cap to the lowest practicable amount necessary to account for the applicant failure.

The NRC is developing guidance on establishment and management of fixed fee caps, which will be issued before the fixed fee caps become effective on October 1, 2026. As discussed in the FY 2026 proposed fee rule, this guidance will provide further examples of applicant failure and support consistent application of the definition of applicant failure.

The NRC notes that a government shutdown, absent other circumstances, would not meet the definition of applicant failure in § 170.3 because it is not within the reasonable control of a diligent applicant. If the NRC is unable to perform work on a requested activity as a result of a government shutdown, service fees would not be assessed during the government shutdown. If the NRC is able to perform work on the requested activity during a government shutdown, service fees would continue to be subject to the fixed fee cap. No changes were made to the rule text as a result of these comments.

G. Dispute Process for Fixed Fee Caps

Comment: Some commenters raised concerns about the dispute process for fixed fee caps because the NRC Form 529 requires submission of an NRC Form 527 as a prerequisite and the NRC Form 527 does not appear applicable to fixed fee cap disputes not associated with an invoice.

Response: The NRC agrees, in part, and disagrees, in part, with these comments. The NRC disagrees with the comment that the NRC's established processes for disputes of 10 CFR part 170 fees, including use of the NRC Form

529, are not applicable to disputes associated with fixed fee caps, and a separate process should be developed for disputing fixed fee caps. Building off these existing NRC processes will facilitate more efficient implementation of the fixed fee caps. The NRC agrees, however, that the NRC Form 529 should be clarified to better address fixed fee cap disputes, and the NRC Form 527 should not be a pre-condition for fixed fee cap disputes not associated with an invoice.

The NRC is updating the NRC Form 529 to coincide with the effective date of this final rule. The updated NRC Form 529 will include clarified instructions on how the form should be completed for fixed fee cap disputes not associated with an invoice. The updated NRC Form 529 will distinguish the pre-conditions for fixed fee cap disputes not associated with an invoice from those for disputes involving fees-for-service charges, and completion of an NRC Form 527 will not be listed as a pre-condition for fixed fee cap disputes not associated with an invoice. No changes were made to the final rule as a result of these comments.

H. Categories of Requested Activities Included in Table 1 in § 170.33

Comment: One commenter noted that, as an editorial matter, the word “traveler” should be added in two rows in table 1 in § 170.33 because “TSTF” is an organization and “traveler” is the name of the document that could be adopted: (1) “Adopting a Technical Specifications Task Force (TSTF) traveler using the Consolidated Line-Item Improvement Process,” and (2) “All Other TSTF travelers.” Some commenters requested the following footnote be removed from table 1 in § 170.33: “Consistent with the definition of requested activity of the Commission in section 3 of the Nuclear Energy Innovation and Modernization Act (42 U.S.C. 2215 note), this activity includes only topical reports submitted by licensees or applicants (*i.e.*, persons or entities that either hold a current license or have a license application under NRC review).” These commenters requested that the fixed fee caps apply to topical reports submitted by other entities, such as vendors and pre-applicants.

Response: The NRC agrees, in part, and disagrees, in part, with these comments. The NRC agrees that adding the word “traveler” provides a more accurate description of the activities and avoids potential confusion; therefore, the NRC incorporated the term “traveler” in the relevant rows in table 1 in § 170.33.

The NRC disagrees with the comments regarding topical reports and is retaining this footnote in table 1 in § 170.33. The fixed fee caps and table 1 in § 170.33 apply to only requested activities of the Commission that involve the issuance of a final safety evaluation, and NEIMA defines the term “requested activity of the Commission” as limited to activities “requested by a licensee or applicant.” Aligning the fixed fee caps with the scope of activities covered by the NEIMA milestone schedules and reporting requirements allows the agency to (1) build off these existing processes to efficiently implement fixed fee caps; (2) maintain a predictable universe of applicability; and (3) preserve the important distinction between voluntary pre-application engagement, which benefits from flexibility and has purposefully been excluded from the fixed fee caps in this final rule, and activities requested by licensees and applicants, which are subject to the fixed fee caps. Pre-application engagement leads to more effective resource planning, earlier identification of potential policy or technical issues, and improved application quality and review efficiency, ultimately leading to a lower tailored fee cap when a complete application is accepted for review. In the preamble above, the NRC has made clear that although fixed fee caps apply to only requested activities of the Commission that involve the issuance of a final safety evaluation, the NRC will continue to establish and communicate schedule and resource estimates for other activities, including topical reports submitted by vendors and pre-applicants, and will be held accountable for efficiency, timeliness, and quality of these reviews through multiple performance management mechanisms such as Annual Performance Plan performance indicators, internal tracking dashboards, and quarterly performance reviews.

I. Fixed Caps on Service Fees for Advanced Nuclear Reactor Applicants

Comment: One commenter requested that the NRC establish categorical caps using the Reduced Hourly Rate in table 1 in § 170.33 for exemption requests and topical reports submitted as part of qualifying application activities.

Response: The NRC disagrees with adding categorical caps using the Reduced Hourly Rate in table 1 in § 170.33 for exemption requests and topical reports. The fixed fee caps do not apply to pre-application activities, which are voluntary and occur before the first required step in the regulatory process; therefore, a topical report or

exemption request submitted by an advanced nuclear reactor pre-applicant before a qualifying application would not receive a fixed fee cap. Although fixed fee caps do not apply to pre-application activities, the NRC will continue to establish and communicate schedule and resource estimates and will be held accountable for efficiency, timeliness, and quality of these reviews through multiple performance management mechanisms. However, if a topical report or exemption request is submitted by an advanced nuclear reactor applicant as part of a qualifying application, it would be covered by the fixed fee cap associated with the qualifying application, which would use the Reduced Hourly Rate and be communicated in the NRC written communication on schedule and resources for the qualifying application. No changes to the final rule were made as a result of this comment.

J. Assumptions for Categorical Caps

Comment: Some commenters raised concerns about the assumptions and data used to establish the categorical caps as a general matter and for specific caps in table 1 in § 170.33; concerns were raised about the staff hours and contract costs used to develop categorical caps, discrepancies between categorical caps and resource estimates available on the NRC's public web page, historical data not aligning with efficiencies achieved in response to the ADVANCE Act and E.O. 14300, and activities where there is limited historical data. For example, some commenters questioned specific categorical caps as being too high, such as the categorical caps for "Code Reliefs"/"COL (under construction)—Part 52" and for "License Amendments"/"Operating—Parts 50 and 52"/"All Other TSTFs." In addition, some commenters raised concerns about categorical caps not distinguishing between different applications within a licensing pathway, such as a microreactor compared to a large LWR, and one commenter specifically noted that an applicant for a nuclear reactor approval under 10 CFR parts 50, 52, or 53 should be able to estimate the maximum cost of the NRC review prior to application submittal, regardless of reactor size. Some commenters raised concerns regarding the categorical caps discouraging certain licensing pathways because of the categorical caps established for various activities. For example, one commenter noted that the categorical cap for a COL not referencing an ESP is less than the categorical caps for an ESP followed by

a COL, but the amount of NRC review and service fees for both should be nearly identical due to efficiencies gained.

Response: The NRC agrees, in part, and disagrees, in part, with these comments. The NRC agrees with providing cost predictability to applicants under 10 CFR part 53, and in this final rule, the NRC incorporated new requested activities under 10 CFR part 53 in table 1 in § 170.33. The FY 2026 proposed fee rule specifically noted that "[t]able 1 would be updated to reflect any new requested activities that involve the issuance of a final safety evaluation, including any resulting from the 10 CFR part 53 rulemaking or other future rulemakings." The NRC is not establishing separate categorical caps for requested activities under 10 CFR part 53 because the NRC does not currently have the data necessary to support establishment of separate categorical caps for the new 10 CFR part 53 rule. The NRC will use tailored caps to address expected efficiencies under 10 CFR part 53 and may consider establishing separate categorical caps for requested activities under 10 CFR part 53 in a future fee rule after it has execution data gained from experience implementing the new 10 CFR part 53 rule.

The NRC disagrees with the other comments regarding the categorical caps. The NRC reviewed the specific categorical caps identified by commenters and confirmed that the categorical caps were derived consistent with the methodology described in the FY 2026 proposed fee rule and retained in this final rule. The categorical caps are based on historical, inflation-adjusted data for the range of activities included in each category; removal of outliers in the historical data (such as a review that did not involve a reasonably diligent applicant); efficiencies achieved; additional efficiencies resulting from E.O. 14300 and the ADVANCE Act not requiring rulemaking; alignment with the updated NEIMA milestone schedules; and current execution experience. Future updates to the categorical caps will reflect additional efficiencies that are realized as a result of implementation of E.O. 14300 and the ADVANCE Act—both from E.O. 14300 rulemakings and other actions taken by the NRC. For categories with limited historical data, the NRC used recent comparable information, such as execution data from recent activities or estimated resources data from recent applications accepted for review.

Regarding the comments requesting distinctions between different applications within the same licensing pathway (for example, microreactors compared with large LWRs), the NRC expects to set a lower tailored cap after considering factors such as technology type, application complexity, and the extent of pre-application engagement. With respect to differences in categorical caps across licensing pathways that involve multiple sequential application reviews, the NRC notes that the categorical cap for a single application (e.g., COL not referencing an ESP) will not equal the summation of each categorical cap for an application in a sequential application pathway (e.g., an ESP followed by a COL) for several reasons. The primary reason is that the categorical caps bound the range of resources needed for each category in table 1 in § 170.33. Due to the bounding nature of the categorical caps, categorical caps for separate, sequential applications account for possible changes from the prior approval that could affect the resources needed to review the subsequent sequential application. The NRC will set a lower tailored cap, if appropriate, after considering factors such as efficiencies gained in a sequential application pathway when the subsequent application falls squarely within the scope of a prior approval. In addition, there are administrative hours needed to set up, track, and complete each review, regardless of whether the application is in a sequential application pathway. Applicable administrative hours are accounted for in each categorical cap.

K. Updates for Categorical Caps

Comment: Some commenters raised concerns regarding the sentence in the preamble indicating that the NRC would "evaluate categorical caps biennially, consistent with the Chief Financial Officers Act of 1990." One commenter requested that the NRC establish and maintain a publicly accessible web page that provides the most current categorical fee caps.

Response: In response to these comments, the NRC has revised the preamble to clarify that the categorical caps in table 1 in § 170.33 will be updated annually to reflect any changes to the professional hourly rate or Reduced Hourly Rate. The NRC will also evaluate categorical caps biennially to closely review the NRC staff hours and contract costs used to establish the categorical caps. While one commenter suggested establishing a publicly accessible NRC web page containing the most current categorical caps, the categorical caps will be updated

annually in the fee rule and the CFR, and the electronic *Code of Federal Regulations* (eCFR; <https://www.ecfr.gov/>) serves as a continuously updated online version of the CFR. No changes to the rule text were made as a result of these comments.

L. Use of Unobligated Carryover To Reduce Fees

Comment: Several commenters requested the NRC to use available authority to apply unobligated carryover to reduce the FY 2026 annual fees.

Response: Each FY, the NRC follows the direction of Congress that accompanies the annual appropriations act. The explanatory statement associated with the FY 2026 enacted budget included direction for the NRC to use \$12.4 million of existing Integrated University Program or University Nuclear Leadership Program (UNLP) carryover balances to fund the UNLP in FY 2026. No additional Congressional direction was provided to use carryover to offset the budget and fees.

The NRC's ability to use carryover to offset fees is dependent on available amounts of carryover in the corresponding control point and Congressional action to direct the use of carryover with a corresponding reduction in current-year budget authority in the annual appropriations process. Under NEIMA, the NRC must recover, to the maximum extent practicable, approximately 100 percent of the total budget authority appropriated for the FY, less the budget authority for excluded activities. The NRC's discretionary use of carryover does not reduce the amount of current-year budget authority appropriated to the NRC. No changes were made to the final rule as a result of these comments.

M. Agency Support in the Professional Hourly Rate

Comment: One commenter requested that the NRC review the agency support estimates to confirm they accurately represent anticipated FTE because agency support, as it relates to the calculation of the professional hourly rate, is nearly flat between the FY 2025 final fee rule and the FY 2026 proposed fee rule, but there was a decrease in FTE at the NRC.

Response: The NRC confirmed that in FY 2026, the agency support costs, which include corporate support and the IG, are accurate. While there was a reduction in agency support in FY 2026 compared to FY 2025, this reduction is not linearly proportional, as there is a cost for the infrastructure that must be maintained. These infrastructure costs

include, for example, the cost for information management, information technology, security, facilities management, rent, utilities, financial management, acquisitions, human resources, and policy support. The NRC continues to pursue further efficiencies and improvements to its processes. No changes to the final rule were made as a result of this comment.

N. Generic Regulatory Work Recovered Through 10 CFR Part 171 Annual Fees

Comment: One commenter requested that the NRC provide greater transparency on 10 CFR part 171 annual fees. Some commenters requested that the NRC evaluate opportunities to improve efficiency in regulatory activities funded through 10 CFR part 171 annual fees, while recognizing the NRC's efforts to improve efficiency in activities billed under 10 CFR part 170.

Response: The NRC continues to look for ways to enhance transparency and efficiency. The work papers that support the fee rule show in detail how the NRC allocates the budgeted resources for each class of licensees and calculates the annual fees. The NRC has made enhancements to the work papers every year since FY 2019 and will continue to look for ways to improve the work papers to provide more transparency regarding annual fees. In addition, the CBJ includes language to indicate which product lines impact service fees versus annual fees. With respect to efficiency, the NRC continues to pursue further efficiencies and improvements to all NRC activities, including those recovered through 10 CFR part 171 annual fees. Future fee rules will reflect additional efficiencies that are realized as a result of implementation of E.O. 14300 and the ADVANCE Act—both from E.O. 14300 rulemakings and other actions taken by the NRC. There are no changes to the final rule as a result of these comments.

O. Fuel Facilities Fee Class

Comment: Several commenters expressed appreciation for the NRC's efforts to lower the FY 2026 annual fees for the fuel facilities fee class. One commenter requested that given the dynamic growth of this fee class, the NRC consider if the definitions in 10 CFR part 171 accurately reflect the fee classes of licensees, which dictate the effort factors, and make adjustments accordingly. This commenter stated that there is an inconsistency between the 10 CFR part 70 definitions for Category I, II, and III facilities; and the 10 CFR part 171 definitions of high and low enriched uranium facilities.

Response: The NRC confirmed that the existing definitions in 10 CFR part 171 accurately reflect the fuel facilities fee class of licensees. The NRC effort factors are based on the commensurate level of regulatory effort. The effort factors in the matrix represent non-billable, regulatory effort (e.g., rulemaking and guidance). In addition, the programmatic effort (expressed as a value in the matrix) reflects the safety and safeguards risk significance associated with the nuclear material and use/activity, and the commensurate generic regulatory program (i.e., scope, depth, and rigor). The NRC will continue to assess resource requirements and evaluate programmatic efficiencies for the fuel facilities fee class. No changes were made to the final rule as a result of these comments.

P. Reduced Hourly Rate

Comment: One commenter expressed appreciation for the Reduced Hourly Rate for advanced nuclear reactor applicants and pre-applicants. Another commenter requested clarification on whether the cost difference between the professional hourly rate and Reduced Hourly Rate is (1) included in excluded activities or (2) incorporated into the 10 CFR part 171 annual fee base and thus borne by existing licensees. The commenter urged the NRC to ensure that any unrecovered costs due to the Reduced Hourly Rate are not incorporated into the 10 CFR part 171 annual fee base.

Response: The NRC disagrees with the comment regarding unrecovered costs due to the Reduced Hourly Rate because the ADVANCE Act's Reduced Hourly Rate provisions state explicitly which costs are to be included in the Reduced Hourly Rate and which costs are to be included in the excluded activities associated with the Reduced Hourly Rate. Section 201 of the ADVANCE Act amended NEIMA to specify that the Reduced Hourly Rate is the FTE rate for mission-direct program salaries and benefits for the Nuclear Reactor Safety Program, divided by the productive hours assumption, for that FY, and does not include mission-direct program salaries and benefits for the Nuclear Materials and Waste Safety Program, mission-indirect program support for the Nuclear Reactor Safety Program and the Nuclear Materials and Waste Safety Program, and agency support. Section 201 of the ADVANCE Act also amended NEIMA to include the following as excluded activities: "[t]he total costs of mission-indirect program support and agency support that . . . may not be included in the hourly rate charged for

fees assessed and collected from advanced nuclear reactor applicants . . . [and] advanced nuclear reactor pre-applicants.” The FY 2026 proposed fee rule and this final rule were developed consistent with those statutory requirements. No changes were made to the final rule as a result of these comments.

V. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, as amended (RFA),⁴ the NRC has prepared a regulatory flexibility analysis related to this final rule. The regulatory flexibility analysis is available as indicated in the “Availability of Documents” section of this document.

VI. Regulatory Analysis

Under NEIMA, the NRC is required to recover, to the maximum extent practicable, approximately 100 percent of its annual budget for FY 2026, less the budget authority for excluded activities. The NRC assesses two types of fees to meet the requirements of NEIMA. First, service fees, established in 10 CFR part 170 under the authority of the IOAA and NEIMA, recover the NRC’s costs of providing specific benefits to identifiable recipients (such as licensing work, inspections, and special projects). Second, annual fees, established in 10 CFR part 171 under the authority of NEIMA, recover generic and other regulatory costs not otherwise recovered through 10 CFR part 170 fees.

With respect to 10 CFR part 170 service fees, this rule was developed under the IOAA and NEIMA and consistent with OMB Circular A–25. NEIMA requires the NRC to “assess and collect fees,” in accordance with the IOAA, “from any person who receives a service or thing of value from the [NRC] to cover the costs to the [NRC] of providing the service or thing of value.”

With respect to 10 CFR part 171 annual fees, this rule was developed under NEIMA. NEIMA requires the NRC to “establish by rule a schedule” of annual fees that “fairly and equitably” allocate the aggregate amount of annual fees among licensees and certificate holders. NEIMA also requires that annual fees, “to the maximum extent

practicable, shall be reasonably related to the cost of providing regulatory services.” Because 10 CFR part 170 service fees will not equal 100 percent of the agency’s total budget authority for the FY (less the budget authority for excluded activities), the NRC assesses 10 CFR part 171 annual fees to recover the remaining amount necessary to comply with NEIMA.⁵

In the annual fee rule, the NRC adjusts its fees to recover its annual budget authority to ensure that the NRC complies with the statutory requirements for cost recovery. Similarly, in this final rule, the NRC has made adjustments to recover its annual budget authority consistent with the statutory fee recovery requirement. For this final rule, the NRC did not identify any alternatives to the current statutorily required fee structure. Further, NEIMA requires the NRC to establish its fee schedule by rule and thus the NRC did not identify any alternatives to rulemaking. However, the NRC did consider several alternatives to alleviate the significant impact of annual fees on a substantial number of small entities, in accordance with the RFA. Those alternatives include:

1. Basing fees on the amount of radioactivity possessed by the licensee (e.g., number of sources).
2. Basing fees on the frequency of use of licensed radioactive material (e.g., volume of patients).
3. Basing fees on the NRC size standards for small entities.

Based on the expertise of the NRC staff, informed by previous reviews of these alternatives, the NRC continues to believe that a maximum fee for small entities is the most appropriate and

effective option for reducing the impact of fees on small entities.

The NRC also performed an analysis of the costs and benefits over FY 2026.⁶ Consistent with OMB Circular A–4, the fees charged by the NRC are considered transfer payments and therefore not part of the costs of this rulemaking.

OMB Circular A–4 directs agencies to report transfer payments from and to government agencies separately.⁷ The two primary government agencies assessed fees are DOE and NIST. The NRC assesses fees to DOE to recover costs related to regulating DOE’s Title I and Title II activities under UMTRCA as part of the uranium recovery facilities fee class. Additionally, the NRC assesses an annual fee to DOE based on the number of 10 CFR part 71 CoCs held by DOE as part of the transportation fee class. The NRC also assesses fees to DOE as part of the spent fuel storage/reactor decommissioning fee class; these costs were inadvertently not included in the Regulatory Analysis in tables XX and XXI in the FY 2025 final fee rule but have been added to tables XX and XXI in the Regulatory Analysis in the FY 2026 final fee rule. The NRC assesses fees to NIST as a member of the fuel facilities fee class for its license for possession and use of special nuclear material and as a member of the non-power production or utilization facilities fee class for its research reactor. The NRC also assesses fees to several Federal agencies for a variety of small materials licenses. The fees assessed to government agencies, including both 10 CFR parts 170 and 171 fees, are identified below.⁸

⁶ The NRC selected FY 2026 as the time horizon for this rule because, consistent with NEIMA, this rule amends the NRC’s fee regulations to allow the NRC to recover, to the maximum extent practicable, approximately 100 percent of its FY 2026 budget authority, minus the budget authority for excluded activities, by September 30, 2026 (the end of FY 2026).

⁷ Currently there are no State government agencies that hold an NRC license or are an NRC applicant and thus, no State government agencies are assessed fees under this rule.

⁸ The underlying data in Section VI, “Regulatory Analysis,” of this document have been updated to reflect finalized figures, replacing the preliminary data used in the proposed rule. Specifically, the number of licensees changed from 2,458 to 2,448, which resulted in adjustments to the undiscounted and discounted cost estimates. In addition, the figures in the last column (FY 2026 Final Rule) in tables XX and XXI were updated to reflect final figures. All of these updates are minor and non-substantive.

⁴ 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, Title II, 110 Stat. 847 (1996).

⁵ The assessment of annual fees by the NRC began in FY 1987 to meet the requirements of Public Law 99–272, the Consolidated Omnibus Budget Reconciliation Act of 1985, which required the NRC to recover 33 percent of its budget authority. Subsequent legislation required the NRC to recover an increasing percentage of its budget authority. See, e.g., Public Law 100–203, Omnibus Budget Reconciliation Act of 1987 (requiring that the NRC, for FYs 1988 and 1989, recover at least 45 percent of its budget authority in each fiscal year); Public Law 101–508, Omnibus Budget Reconciliation Act of 1990 (OBRA–90) (requiring that the NRC, for FYs 1991 through 1995, recover approximately 100 percent of its budget authority in each fiscal year, less excluded amounts); Public Law 106–377, Energy and Water Development Appropriations Act, 2001 (amending OBRA–90 to decrease the NRC’s fee recovery amount by 2 percent per fiscal year beginning in FY 2001, ending at 90 percent in FY 2005).

TABLE XX—FEES CHARGED TO GOVERNMENT AGENCIES
[Dollars in millions]⁹

	FY 2025 final rule	FY 2026 final Rule
DOE (Uranium Recovery)	\$0.361	\$0.215
DOE (Transportation)	2.576	2.147
DOE (Spent Fuel Storage/Reactor Decommissioning)	1.238	0.777
NIST (Fuel Facilities)	0.134	0.015
NIST (Non-Power Production or Utilization Facilities)	0.187	0.152
Other Agencies (Materials Users)	1.473	3.979
Total	5.969	7.285

After accounting for the fees assessed to government agencies, the “adjusted amount to be recovered through 10 CFR parts 170 and 171 fees” assessed to applicants and licensees was \$804.1 million in the FY 2025 final fee rule. This amount has been corrected to \$802.8 million in table XXI, “Fee

Totals,” of this document by adding the missing \$1.2 million in fees assessed to DOE as part of the spent fuel storage/reactor decommissioning fee class in the Regulatory Analysis to tables XX and XXI. After accounting for the fees assessed to government agencies, the “adjusted amount to be recovered

through 10 CFR parts 170 and 171 fees” assessed to applicants and licensees is \$811.5 million in the FY 2026 final fee rule, resulting in a difference of approximately \$7.3 million in FY 2026 compared to FY 2025. Table XXI shows this calculation.

TABLE XXI—FEE TOTALS
[Dollars in millions]⁹

	FY 2025 final rule	FY 2026 final rule
Adjusted amount to be recovered through 10 CFR parts 170 and 171 fees	\$808.8	\$818.8
Less government agency fees (see table XX)	– 6.0	– 7.3
Total	802.8	811.5

As indicated, both the amount of fees assessed to federal government agencies in FY 2026 (\$7.3 million) as well as the fees assessed to non-government licensees and applicants in FY 2026 (\$811.5 million) are considered transfer payments under OMB Circular A–4 and, therefore, not part of the costs of this rulemaking.

Therefore, the costs of this final rule constitute the resources for licensees to read the annual rule and resultant changes to their internal processes for payment. The NRC expects that this final rule will affect 2,448 licensees, each spending a maximum of 1 hour reading the rule and 1 hour updating their accounting software. For the purpose of this analysis, the NRC developed a labor rate of \$148, which includes only labor and material costs that are directly related to the implementation of the annual rule.¹⁰ The final rule results in a net cost to licensees of approximately \$727,000, undiscounted.¹¹ In addition, the Office

of Information and Regulatory Affairs (OIRA) requires agencies to report results as a perpetual stream once a rule is implemented, which in this case reflects annualized cost of about \$47,561, at a 7 percent discount rate.

Additionally, this final rule establishes fixed caps on service fees for requested activities of the Commission that involve the issuance of a final safety evaluation, consistent with NEIMA and E.O. 14300. The NRC will address the E.O. 14300 policy to establish fixed deadlines for final decisions in a separate rulemaking. Should fixed deadlines be established, the NRC would not assess 10 CFR part 170 fees beyond the fixed deadline, even if the fixed fee cap has not been reached, absent applicant failure.

To implement fixed fee caps, the NRC is establishing § 170.33, “Executive Order 14300 fixed fee caps,” and amending § 170.3, “Definitions,” and § 15.31, “Disputed debts.” The changes include a table of categorical caps for

requested activities of the Commission that involve the issuance of a final safety evaluation; a process for lower tailored caps based on the specific application; a definition of applicant failure, which is the sole basis for increasing the fixed fee cap; and procedures for fee cap disputes.

The NRC does not expect that the final rule will result in any behavioral changes related to market entry or exit among licensees on which the NRC assesses 10 CFR parts 170 and 171 fees. There is only a small increase in the adjusted amount to be recovered through 10 CFR parts 170 and 171 fees, and the way in which the NRC assesses these fees is well established. It is possible that the implementation of the fixed caps on service fees may induce current licensees to submit further licensing actions, or may increase the rate of market entry of new licensees as applicants.

⁹ Dollar amounts reported directly from fiscal years are nominal values.

¹⁰ The NRC used the BLS data tables to select appropriate hourly labor rates for the roles performing work necessary following issuance of the final rule, calculating a blended mean wage

based on the estimated proportion of work performed by each role from BLS, “May 2024 National Industry-Specific Occupational Employment and Wage Estimates” (BLS, 2025). This labor rate includes wages paid for the individuals performing the work plus the associated fringe benefit component of labor cost.

¹¹ For FY 2025, the rule affected 3,072 licensees under the same assumptions. Due to a calculation error, the correct cost should have been \$906,000 (3,072 times 2 hours times \$148), not \$453,000 as reported in the Regulatory Analysis included in the FY 2025 final fee rule.

VII. Backfitting and Issue Finality

The NRC has determined that the backfit and issue finality provisions in 10 CFR parts 50, 52, 53, 70, 72, and 76 do not apply to this final rule because these amendments do not require the modification of, or addition to, (1) systems, structures, components, or the design of a facility; (2) the design approval or manufacturing license for a facility; or (3) the procedures or organization required to design, construct, or operate a facility.

VIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31885).

IX. National Environmental Policy Act

The NRC has determined that this final rule is the type of action eligible for categorical exclusion because it meets criterion described in § 51.22(a)(3), “Amendments to parts . . . 15, . . . 170, or 171 of this chapter.” The agency action belongs to a category of actions that the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the actions within the category do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental impact statement nor environmental assessment has been prepared for this final rule.

X. Paperwork Reduction Act

This final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). Existing collections of information were approved by OMB, approval number 3150–0190.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XI. Executive Orders

The following are Executive orders that are related to this final rule:

A. Executive Order 12866: Regulatory Planning and Review (as Amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The OIRA has determined that this final rule is an economically significant regulatory action under section 3(f)(1) of E.O. 12866. Accordingly, the NRC submitted this final rule to OIRA for review. The NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(C) of E.O. 12866. More can be found in Section VI, of this document, “Regulatory Analysis.” Given that there is no change from previous fiscal years under this final rule in how the NRC assesses its 10 CFR parts 170 and 171 fees, the NRC considers the costs to licensees associated with this rule to be minor.

B. Executive Order 14154: Unleashing American Energy

The NRC has examined this final rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is a regulatory action as defined by E.O. 14192. This regulatory action generates \$47,561 in annualized costs at a 7 percent discount rate, over a perpetual time horizon. Details on the estimated costs of this final rule can be found in Section VI, of this document, “Regulatory Analysis,” which shows that the costs to licensees associated with this rule are minor.

XII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act of 1996 (5

U.S.C. 801–808). The OMB has found that it meets the criteria at 5 U.S.C. 804(2) and will submit the required report to Congress.

XIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending the licensing, inspection, and annual fees charged to its licensees and applicants, as necessary, to recover, to the maximum extent practicable, approximately 100 percent of its annual budget for FY 2026, less the budget authority for excluded activities, as required by NEIMA. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XIV. Availability of Guidance

The Small Business Regulatory Enforcement Fairness Act requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by 5 U.S.C. 604 to prepare a regulatory flexibility analysis. The NRC, in compliance with the law, prepared the “Small Entity Compliance Guide” for the FY 2025 fee rule. The compliance guide was developed when the NRC completed the small entity biennial review for FY 2025. The NRC plans to continue to use this compliance guide for FY 2026 and has relabeled the compliance guide to reflect the current FY. This compliance guide is available as indicated in the “Availability of Documents” section of this document.

XV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Documents	ADAMS accession No./FR citation/web link
Proposed rule, “Fee Schedules; Fee Recovery for Fiscal Year 2026,” dated March 12, 2026.	91 FR 12084.
Final rule, “Fee Schedules; Fee Recovery for Fiscal Year 2025,” dated June 24, 2025.	90 FR 26730.
FY 2025 Final Fee Rule Work Papers	ML25129A153.
Fiscal Year 2026 Final Rule Work Papers	ML26124A085.
OMB Circular A–25, “User Charges”	https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf .
SECY–05–0164, “Annual Fee Calculation Method,” dated September 15, 2005 ...	ML052580332.
NUREG–1100, Volume 41, “Congressional Budget Justification: Fiscal Year 2026” (June 2025).	ML25162A035.

Documents	ADAMS accession No./FR citation/web link
Final rule, "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2015," dated June 30, 2015.	80 FR 37432.
Final rule, "Variable Annual Fee Structure for Small Modular Reactors," dated May 24, 2016.	81 FR 32617.
Final Rule, "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2019," dated May 17, 2019.	84 FR 22331.
Final rule, "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2021," dated June 16, 2021.	86 FR 32146.
Final rule, "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2023," dated June 15, 2023.	88 FR 39120.
Final rule, "Revision of Fee Schedules; 100% Fee Recovery, FY 1999," dated June 10, 1999.	64 FR 31448.
Final rule, "Revision of Fee Schedules; Fee Recovery for FY 2002," dated June 24, 2002.	67 FR 42612.
Final rule, "Revision of Fee Schedules; Fee Recovery for FY 2006," dated May 30, 2006.	71 FR 30722.
Final rule, "Fee Schedules; Fee Recovery for Fiscal Year 2024," dated June 20, 2024.	89 FR 51789.
Comments on PR-15, 170 and 171—Fee Schedules; Fee Recovery for Fiscal Year 2026 (NRC-2023-0212).	ML26107A164.
Fiscal Year 2026 Regulatory Flexibility Analysis	ML26117A017.
Fiscal Year 2026 U.S. Nuclear Regulatory Commission Small Entity Compliance Guide.	ML25363A091.
Executive Order 12866, "Regulatory Planning and Review," October 4, 1993	58 FR 51735.
Executive Order 14154, "Unleashing American Energy," January 29, 2025	90 FR 8353.
Executive Order 14192, "Unleashing Prosperity Through Deregulation," February 6, 2025.	90 FR 9065.
Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," May 29, 2025.	90 FR 22587.
Presidential Memorandum, "Plain Language in Government Writing," dated June 10, 1998.	63 FR 31885.

List of Subjects

10 CFR Part 15

Administrative practice and procedure, Claims, Debt collection.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; 42 U.S.C. 2215; 31 U.S.C. 9701; and 5 U.S.C. 552 and 553, the NRC is making the following amendments to 10 CFR parts 15, 170, and 171:

PART 15—DEBT COLLECTION PROCEDURES

■ 1. The authority citation for part 15 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 186 (42 U.S.C. 2201, 2236); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 5 U.S.C. 5514; 26 U.S.C. 6402; 31 U.S.C. 3701, 3713, 3716, 3719, 3720A; 42 U.S.C. 664; 44 U.S.C. 3504 note; 31 CFR parts 900 through 904; 31 CFR part 285; E.O. 12146, 44 FR 42657, 3 CFR, 1979 Comp., p. 409; E.O. 12988, 61 FR 4729, 3 CFR, 1996 Comp., p. 157.

■ 2. In § 15.31, revise paragraph (a) to read as follows:

§ 15.31 Disputed debts.

(a) *Submitting a dispute.* (1) For any type of charges assessed by the NRC, a debtor may submit a dispute of debt within 45 days from the date of the initial demand letter. The debtor shall explain why the debt is incorrect in fact or in law and may support the explanation by affidavit, cancelled checks, or other relevant evidence. The dispute must be submitted to the Office of the Chief Financial Officer via the eBilling system, by email to FeeBillingInquiries.Resource@nrc.gov, or by mail to the Office of the Chief Financial Officer at: U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Chief Financial Officer. For debt disputes related to

charges for 10 CFR part 170 fees, the debtor must complete and submit an NRC Form 529 with the required information.

(2) For disputes associated with the Executive Order 14300 fixed fee cap, the debtor must complete and submit an NRC Form 529 with the required information within 45 days of the NRC written communication pertaining to the cap. The NRC Form 529 must be submitted to the Office of the Chief Financial Officer via the eBilling system, by email to FeeBillingInquiries.Resource@nrc.gov, or by mail to the Office of the Chief Financial Officer at: U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Chief Financial Officer.

* * * * *

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

■ 3. The authority citation for part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

■ 4. In § 170.3, add the definition for *Applicant failure* in alphabetical order to read as follows:

§ 170.3 Definitions.

* * * * *

Applicant failure means actions or inaction that—

- (1) Are within the reasonable control of a diligent applicant;
- (2) Are not due to actions or inaction of the Commission; and
- (3) Will cause substantial delays or require a significant increase in resources, including explicit requests by the applicant to the Commission to pause or delay review.

* * * * *

■ 5. In § 170.11, revise paragraph (d) to read as follows:

§ 170.11 Exemptions.

* * * * *

(d) All fee exemption requests must be submitted in writing to the Chief Financial Officer in accordance with § 170.5, and the Chief Financial Officer will grant or deny such requests in writing. Fee exemption requests submitted via email should be submitted to the NRC at cfofeeexemptionrequests.resource@nrc.gov.

■ 6. Revise and republish § 170.20 to read as follows:

§ 170.20 Average cost per professional staff-hour.

(a) Except as provided in paragraphs (b) and (c) of this section, fees for permits, licenses, amendments, renewals, special projects, 10 CFR part 55 re-qualification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 will be calculated using the professional staff-hour rate of \$337 per hour.

(b) For advanced nuclear reactor applicants:

(1) Fees under § 170.21 relating to the review of the submitted application for the advanced nuclear reactor applicant will be calculated using the reduced hourly rate of \$154 per hour.

(2) [Reserved]

(c) For advanced nuclear reactor pre-applicants:

(1) Fees under § 170.21 relating to the review of submitted materials as described in the licensing project plan will be calculated using the reduced hourly rate of \$154 per hour.

(2) This paragraph (c) shall cease to be effective on September 30, 2030.

■ 7. In § 170.21, in table 1, revise footnote 2 to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

Table 1 to § 170.21—Schedule of Facility Fees

* * * * *

² Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional hourly rate in effect when the service was provided. Effective October 1, 2025, the “full cost fees” described in the table 1 for advanced nuclear reactor applicants and advanced nuclear reactor pre-applicants will be assessed consistent with § 170.20(b) and (c).

* * * * *

■ 8. In § 170.31, revise table 1 to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

* * * * *

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees ¹	Fees ^{2,3}
1. Special nuclear material: ¹¹	
A. (1) Licenses for possession and use of U-235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium). ⁶ [Program Code(s): 21213]	Full Cost.
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel. ⁶ [Program Code(s): 21210].	Full Cost.
(2) All other special nuclear materials licenses not included in category 1.A.(1) which are licensed for fuel cycle activities. ⁶	
(a) Facilities with limited operations. ⁶ [Program Code(s): 21240, 21310, 21320]	Full Cost.
(b) Gas centrifuge enrichment demonstration facilities. ⁶ [Program Code(s): 21205]	Full Cost.
(c) Others, including hot cell facilities. ⁶ [Program Code(s): 21130, 21131, 21133]	Full Cost.
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI). ⁶ [Program Code(s): 23200].	Full Cost.
C. Licenses for possession and use of special nuclear material of less than a critical mass, as defined in § 70.4 of this chapter, in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers. ⁴ Application [Program Code(s): 22140].	\$1,500.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under category 1.A. ⁴ Application [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310].	\$3,100.
E. Licenses or certificates for construction and operation of a uranium enrichment facility. ⁶ [Program Code(s): 21200]	Full Cost.
F. Licenses for possession and use of special nuclear material greater than critical mass, as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities. ^{4,6} [Program Code(s): 22155].	Full Cost.
2. Source material: ¹¹	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal. ⁶ [Program Code(s): 11400].	Full Cost.
(2) Licenses for possession and use of source material in recovery operations such as milling, <i>in situ</i> recovery, heap-leaching, ore buying stations, ion-exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode. ⁶	
(a) Conventional and Heap Leach facilities. ⁶ [Program Code(s): 11100]	Full Cost.
(b) Basic <i>In Situ</i> Recovery facilities. ⁶ [Program Code(s): 11500]	Full Cost.
(c) Expanded <i>In Situ</i> Recovery facilities. ⁶ [Program Code(s): 11510]	Full Cost.
(d) <i>In Situ</i> Recovery Resin facilities. ⁶ [Program Code(s): 11550]	Full Cost.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees ¹	Fees ^{2,3}
(e) Resin Toll Milling facilities. ⁶ [Program Code(s): 11555]	Full Cost.
(f) Other facilities. ⁶ [Program Code(s): 11700]	Full Cost.
(3) Licenses that authorize the receipt of byproduct material, as defined in section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in category 2.A.(2) or category 2.A.(4). ⁶ [Program Code(s): 11600, 12000].	Full Cost.
(4) Licenses that authorize the receipt of byproduct material, as defined in section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in category 2.A.(2). ⁶ [Program Code(s): 12010].	Full Cost.
B. Licenses which authorize the possession, use, and/or installation of source material for shielding. ^{7,8} Application [Program Code(s): 11210].	\$1,500.
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. Application [Program Code(s): 11240].	\$7,200.
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter. Application [Program Code(s): 11230, 11231].	\$3,300.
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. Application [Program Code(s): 11710].	\$3,200.
F. All other source material licenses. Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810, 11820] ...	\$3,200.
3. Byproduct material: ¹¹	
A. Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. Application [Program Code(s): 03211, 03212, 03213].	\$15,800.
(1). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. Application [Program Code(s): 04010, 04012, 04014].	\$20,900.
(2). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. Application [Program Code(s): 04011, 04013, 04015].	\$26,200.
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. Application [Program Code(s): 03214, 03215, 22135, 22162].	\$4,300.
(1). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. Application [Program Code(s): 04110, 04112, 04114, 04116].	\$5,800.
(2). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. Application [Program Code(s): 04111, 04113, 04115, 04117].	\$7,200.
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 1–5. Application [Program Code(s): 02500, 02511, 02513].	\$6,300.
(1). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 6–20. Application [Program Code(s): 04210, 04212, 04214].	\$8,400.
(2). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: more than 20. Application [Program Code(s): 04211, 04213, 04215].	\$10,400.
D. [Reserved]	N/A.
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units). Application [Program Code(s): 03510, 03520].	\$3,900.
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Application [Program Code(s): 03511].	\$7,900.
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Application [Program Code(s): 03521].	\$75,100.
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter. The category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. Application [Program Code(s): 03254, 03255, 03257].	\$8,000.
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. Application [Program Code(s): 03250, 03251, 03253, 03256].	\$12,400.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees ¹	Fees ^{2,3}
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. Application [Program Code(s): 03240, 03241, 03243].	\$2,400.
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. Application [Program Code(s): 03242, 03244].	\$1,400.
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5. Application [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613].	\$6,600.
(1) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–20. Application [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622].	\$8,800.
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: more than 20. Application [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623].	\$11,000.
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution. Application [Program Code(s): 03620].	\$10,000.
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee category 3.P.; and	\$10,800.
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee categories 4.A., 4.B., and 4.C. ¹³ Application [Program Code(s): 03219, 03225, 03226].	
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: 1–5. Application [Program Code(s): 03310, 03320].	\$12,300.
(1) Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: 6–20. Application [Program Code(s): 04310, 04312].	\$16,300.
(2) Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: more than 20. Application [Program Code(s): 04311, 04313].	\$20,400.
P. All other specific byproduct material licenses, except those in categories 4.A. through 9.D. ⁹ Number of locations of use: 1–5. Application [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03130, 03140, 03220, 03221, 03222, 03800, 03810, 22130].	\$8,200.
(1) All other specific byproduct material licenses, except those in categories 4.A. through 9.D. ⁹ Number of locations of use: 6–20. Application [Program Code(s): 04410, 04412, 04414, 04416, 04418, 04420, 04422, 04424, 04426, 04428, 04430, 04432, 04434, 04436, 04438].	\$11,100.
(2) All other specific byproduct material licenses, except those in categories 4.A. through 9.D. ⁹ Number of locations of use: more than 20. Application [Program Code(s): 04411, 04413, 04415, 04417, 04419, 04421, 04423, 04425, 04427, 04429, 04431, 04433, 04435, 04437, 04439].	\$13,900.
Q. Registration of a device(s) generally licensed under part 31 of this chapter.	
Registration	\$900.
R. Possession of items or products containing radium-226 identified in § 31.12 of this chapter which exceed the number of items or limits specified in that section. ⁵	
1. Possession of quantities exceeding the number of items or limits in § 31.12(a)(4) or (5) of this chapter but less than or equal to 10 times the number of items or limits specified. Application [Program Code(s): 02700].	\$3,100.
2. Possession of quantities exceeding 10 times the number of items or limits specified in § 31.12(a)(4) or (5) of this chapter. Application [Program Code(s): 02710].	\$3,000.
S. Licenses for production of accelerator-produced radionuclides. Application [Program Code(s): 03210]	\$17,200.
4. Waste disposal and processing: ¹¹	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. Application [Program Code(s): 03231, 03233, 03236, 06100, 06101].	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. Application [Program Code(s): 03234].	\$8,400.
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. Application [Program Code(s): 03232].	\$6,100.
5. Well logging: ¹¹	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies. Application [Program Code(s): 03110, 03111, 03112].	\$5,600.
B. Licenses for possession and use of byproduct material for field flooding tracer studies. Licensing [Program Code(s): 03113].	Full Cost.
6. Nuclear laundries: ¹¹	

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees ¹	Fees ^{2,3}
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material. Application [Program Code(s): 03218].	\$26,800.
7. Medical licenses: ^{4,11}	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 1–5. Application [Program Code(s): 02300, 02310].	\$13,500.
(1). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 6–20. Application [Program Code(s): 04510, 04512].	\$17,900.
(2). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: more than 20. Application [Program Code(s): 04511, 04513].	\$22,400.
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 1–5. Application [Program Code(s): 02110].	\$10,500.
(1). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 6–20. Application [Program Code(s): 04710].	\$14,000.
(2). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: more than 20. Application [Program Code(s): 04711].	\$17,400.
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ¹⁰ Number of locations of use: 1–5. Application [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160].	\$10,400.
(1). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ¹⁰ Number of locations of use: 6–20. Application [Program Code(s): 04810, 04812, 04814, 04816, 04818, 04820, 04822, 04824, 04826, 04828].	\$15,300.
(2). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ¹⁰ Number of locations of use: more than 20. Application [Program Code(s): 04811, 04813, 04815, 04817, 04819, 04821, 04823, 04825, 04827, 04829].	\$19,100.
8. Civil defense: ¹¹	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities. Application [Program Code(s): 03710].	\$3,100.
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution. Application—each device.	\$21,000.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices. Application—each device.	\$10,900.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution. Application—each source.	\$6,400.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel. Application—each source.	\$1,300.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	Full Cost.
2. Other Casks	Full Cost.
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators.	
Application	\$4,700.
Inspections	Full Cost.
2. Users.	

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees ¹	Fees ^{2,3}
Application	\$4,700.
Inspections	Full Cost.
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices).	Full Cost.
11. Review of standardized spent fuel facilities	Full Cost.
12. Special projects:	
Including approvals, pre-application/licensing activities, and inspections. Application [Program Code: 25110]	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance	Full Cost.
B. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.
14. Decommissioning/Reclamation ¹¹	
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs). The transition to this fee category occurs when a licensee has permanently ceased principal activities. [Program Code(s): 03900, 11900, 21135, 21215, 21325, 22200].	Full Cost.
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, regardless of whether or not the sites have been previously licensed.	Full Cost.
15. Import and Export licenses: ¹²	
Licenses issued under part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, and the export only of heavy water, or nuclear grade graphite (fee categories 15.A. through 15.E.).	
A. Application for export or import of nuclear materials, including radioactive waste requiring Commission and Executive Branch review, for example, those actions under § 110.40(b) of this chapter. Application—new license, or amendment; or license exemption request.	N/A.
B. Application for export or import of nuclear material, including radioactive waste, requiring Executive Branch review, but not Commission review. This category includes applications for the export and import of radioactive waste and requires the NRC to consult with domestic host state authorities (i.e., Low-Level Radioactive Waste Compact Commission, the U.S. Environmental Protection Agency, etc.). Application—new license, or amendment; or license exemption request.	N/A.
C. Application for export of nuclear material, for example, routine reloads of low enriched uranium reactor fuel and/or natural uranium source material requiring the assistance of the Executive Branch to obtain foreign government assurances. Application—new license, or amendment; or license exemption request.	N/A.
D. Application for export or import of nuclear material not requiring Commission or Executive Branch review or obtaining foreign government assurances. Application—new license, or amendment; or license exemption request.	N/A.
E. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign government authorities. Minor amendment.	N/A.
Licenses issued under part 110 of this chapter for the import and export only of Category 1 and Category 2 quantities of radioactive material listed in appendix P to part 110 of this chapter (fee categories 15.F. through 15.R.).	
Category 1 (Appendix P, 10 CFR part 110) Exports:	
F. Application for export of appendix P Category 1 materials requiring Commission review (e.g., exceptional circumstance review under § 110.42(e)(4) of this chapter) and to obtain one government-to-government consent for this process. For additional consent see fee category 15.I. Application—new license, or amendment; or license exemption request.	N/A.
G. Application for export of appendix P Category 1 materials requiring Executive Branch review and to obtain one government-to-government consent for this process. For additional consents see fee category 15.I. Application—new license, or amendment; or license exemption request.	N/A.
H. Application for export of appendix P Category 1 materials and to obtain one government-to-government consent for this process. For additional consents see fee category 15.I. Application—new license, or amendment; or license exemption request.	N/A.
I. Requests for each additional government-to-government consent in support of an export license application or active export license. Application—new license, or amendment; or license exemption request.	N/A.
Category 2 (Appendix P, 10 CFR part 110) Exports:	
J. Application for export of appendix P Category 2 materials requiring Commission review (e.g., exceptional circumstance review under § 110.42(e)(4) of this chapter). Application—new license, or amendment; or license exemption request.	N/A.
K. Applications for export of appendix P Category 2 materials requiring Executive Branch review. Application—new license, or amendment; or license exemption request.	N/A.
L. Application for the export of Category 2 materials. Application—new license, or amendment; or license exemption request.	N/A.
M. [Reserved]	N/A.
N. [Reserved]	N/A.
O. [Reserved]	N/A.
P. [Reserved]	N/A.
Q. [Reserved]	N/A.
Minor Amendments (Category 1 and 2, appendix P, 10 CFR part 110, Export):	
R. Minor amendment of any active export license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign authorities.	
Minor amendment	N/A.
16. Reciprocity:	

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees ¹	Fees ^{2,3}
Agreement State licensees who conduct activities under the reciprocity provisions of § 150.20 of this chapter.	
Application	\$3,800.
17. MMLs of broad scope issued to Government agencies. Application [Program Code(s): 03614]	Full Cost.
18. Department of Energy.	
A. Certificates of Compliance. Evaluation of casks, packages, and shipping containers (including spent fuel, high-level waste, and other casks, and plutonium air packages).	Full Cost.
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities	Full Cost.

¹ *Types of fees*—Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession-only licenses; issuances of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(1) *Application and registration fees*. Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses, except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(i) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(ii) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee category 1.C. only.

(2) *Licensing fees*. Fees for reviews of applications for new licenses, renewals, and amendments to existing licenses, pre-application consultations and other documents submitted to the NRC for review, and project manager time for fee categories subject to full cost fees are due upon notification by the Commission in accordance with § 170.12(b).

(3) *Amendment fees*. Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to an export or import license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment, unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(4) *Inspection fees*. Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(5) *Generally licensed device registrations under 10 CFR 31.5*. Submittals of registration information must be accompanied by the prescribed fee.

² Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in fee categories 9.A. through 9.D.

³ Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended.

⁴ Licensees paying fees under categories 1.A., 1.B., and 1.E. are not subject to fees under categories 1.C., 1.D., and 1.F. for sealed sources authorized in the same license, except for an application that deals only with the sealed sources authorized by the license.

⁵ Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

⁶ Licensees subject to fees under fee categories 1.A., 1.B., 1.E., or 2.A. must pay the largest applicable fee and are not subject to additional fees listed in this table.

⁷ Licensees paying fees under 3.C., 3.C.1, or 3.C.2 are not subject to fees under 2.B. for possession and shielding authorized on the same license.

⁸ Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

⁹ Licensees paying fees under 3.N. are not subject to paying fees under 3.P., 3.P.1, or 3.P.2 for calibration or leak testing services authorized on the same license.

¹⁰ Licensees paying fees under 7.B., 7.B.1, or 7.B.2 are not subject to paying fees under 7.C., 7.C.1, or 7.C.2. for broad scope licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

¹¹ A materials license (or part of a materials license) that transitions to fee category 14.A is assessed full cost fees under this part but is not assessed an annual fee under 10 CFR part 171. If only part of a materials license is transitioned to fee category 14.A, the licensee may be charged annual fees (and any applicable fees under this part) for other activities authorized under the license that are not in decommissioning status.

¹² Because section 101 of the ADVANCE Act created an excluded activity for international nuclear export and innovation activities, import and export licensing actions will not incur fees.

¹³ Licensees paying fees under 4.A., 4.B., or 4.C. are not subject to paying fees under 3.N. licenses that authorize services for other licensees authorized on the same license.

■ 9. Add § 170.33 to read as follows:

§ 170.33 Executive Order 14300 fixed fee caps.

(a) Fees under §§ 170.21 and 170.31 will not exceed the Executive Order 14300 fixed fee cap, except as provided in paragraph (e) of this section. The activities for which the Executive Order 14300 fixed fee cap applies are only requested activities of the Commission that involve the issuance of a final safety evaluation, consistent with the

Nuclear Energy Innovation and Modernization Act (42 U.S.C. 2215 note) and section 5(a) of Executive Order 14300.

(b) For requested activities for which a complete application has been accepted for review by the Commission on or after October 1, 2026, the Executive Order 14300 fixed fee cap is the lesser of:

(1) The amount associated with the requested activity in table 1 to this section, in effect when a complete

application for the requested activity has been accepted for review by the Commission; or

(2) An amount that is lower, to the maximum extent practicable, than the amount in table 1 to this section and is determined by the Commission based on the specific application for the requested activity.

(c) For requested activities for which a complete application has been accepted for review by the Commission before October 1, 2026, the Executive

Order 14300 fixed fee cap is the lowest practicable amount determined by the Commission based on the specific application for the requested activity.

(d) The Commission will communicate the Executive Order 14300 fixed fee cap in the NRC written communication on schedule and resources for the requested activity.

(e) The Executive Order 14300 fixed fee cap will not be increased except in instances of applicant failure. If applicant failure applies, the Commission will provide a written communication informing the applicant of the new Executive Order 14300 fixed fee cap that applies to the requested activity. The new Executive Order

14300 fixed fee cap will be the lowest practicable amount determined by the Commission to account for the applicant failure.

(f) Consistent with § 170.51, any disputes associated with the Executive Order 14300 fixed fee cap must be submitted in accordance with § 15.31 of this chapter.

TABLE 1 TO § 170.33—FIXED CAPS ON SERVICE FEES

Activity	Type	Fixed caps on service fees ¹ (rounded)	Fixed caps on service fees for advanced nuclear reactor applicants ² (rounded)
Standard Design Approvals	Standard Design Approval (SDA) with no prior approvals—10 CFR part 52 or 53	\$32,656,000	\$16,552,000
	SDA referencing an approved Design Certification (DC) or SDA—10 CFR part 52 or 53	16,165,000	7,930,000
Design Certifications (including incorporation of approved design into 10 CFR part 52).	DC with no prior approvals—10 CFR parts 52 or 53	33,566,000	16,968,000
Licenses	DC referencing an approved DC or SDA—10 CFR part 52 or 53	16,825,000	8,096,000
	Combined License (COL) with no prior approvals—10 CFR part 52 or 53	30,145,000	14,590,000
	COL referencing only an approved DC—10 CFR part 52 or 53	21,046,000	10,432,000
	COL referencing only an Early Site Permit—10 CFR part 52 or 53	24,079,000	11,818,000
	COL referencing an Early Site Permit and an approved DC—10 CFR part 52 or 53	14,980,000	7,660,000
	Operating License—10 CFR parts 50 or 53	21,720,000	10,740,000
	Manufacturing License—10 CFR part 52 or 53	32,656,000	16,552,000
	Fuel Cycle Facilities—10 CFR parts 40 and 70	7,903,000	N/A
	Uranium Recovery—10 CFR part 40	3,574,000	N/A
Construction Permits	All Facilities—10 CFR part 50 or 53	18,334,000	10,007,000
Early Site Permits	All Facilities—10 CFR part 52 or 53	8,066,000	4,772,000
Limited Work Authorizations	All Facilities—10 CFR part 50 or 53	2,615,000	1,847,000
License Amendments (including power uprates) and DC Amendments.	Decommissioning—10 CFR parts 30, 40, 50, and 70	1,078,000	N/A
	Uranium Recovery—10 CFR part 40.		
	Expansions (e.g., new site)	1,664,000	N/A
	All Others	465,000	N/A
	Fuel Cycle Facilities—10 CFR parts 40 and 70	1,394,000	N/A
	Operating—10 CFR parts 50, 52, and 53.		
	Adopting a Technical Specifications Task Force (TSTF) traveler using the Consolidated Line-Item Improvement Process.	59,000	N/A
	All Other TSTF travelers	824,000	N/A
	Measurement Uncertainty Recapture Uprate (MUR) (non-bundled) ³ .	412,000	N/A
	Stretch Power Uprate (SPU) (non-bundled).	774,000	N/A
	SPU bundled with other related changes ⁴ .	1,111,000	N/A
	Extended Power Uprate (EPU) (non-bundled)	1,835,000	N/A
	EPU bundled with other related changes.	2,846,000	N/A
	Emergency and Exigent	185,000	N/A
	All Others	2,185,000	N/A
	Construction Permit—10 CFR parts 50 and 53	707,000	N/A
	Early Site Permit—10 CFR parts 52 and 53	707,000	N/A
	DC—10 CFR parts 52 and 53	9,061,000	N/A

TABLE 1 TO § 170.33—FIXED CAPS ON SERVICE FEES—Continued

Activity				
Restart Activities	COL (under construction)—10 CFR parts 52 and 53		707,000	N/A
	COL (construction not commenced)—10 CFR parts 52 and 53		707,000	N/A
	All Facilities—10 CFR part 50		3,109,000	N/A
	All Facilities—10 CFR parts 50, 52, 53, and 54		5,418,000	N/A
	Fuel Cycle Facilities—10 CFR parts 40 and 70		1,461,000	N/A
License Renewals	Uranium Recovery—10 CFR part 40		1,333,000	N/A
	New		636,000	N/A
Certificates of Compliance (CoC)	Transportation—10 CFR part 71.	Amendment	529,000	N/A
		Renewal	3,000	N/A
	Storage—10 CFR part 72	New	742,000	N/A
		Amendment or Renewal	901,000	N/A
Topical Reports ⁵	All Facilities—10 CFR parts 50, 52, and 53		3,196,000	N/A
Independent Spent Fuel Storage Installation (ISFSI).	Storage—10 CFR parts 50, 52, 53, and 72.	New	6,888,000	N/A
		Amendment or Renewal	514,000	N/A
Exemptions	All Parts of 10 CFR		336,000	N/A
Code Reliefs	COL (under construction)—10 CFR parts 52 and 53		770,000	N/A
	All Other Facilities—10 CFR parts 50, 52, and 53		403,000	N/A
	All Materials—10 CFR parts 30, 40, 70, and 72		169,000	N/A
License Transfers	All Facilities—10 CFR parts 50, 52, and 53		336,000	N/A

¹The fixed caps on service fees include professional staff hours multiplied by the appropriate professional hourly rate established in § 170.20(a), and contractual support services.

²The fixed caps on service fees for advanced nuclear reactor applicants include professional staff hours multiplied by the reduced hourly rate for advanced nuclear reactor applicants established in § 170.20(b), and contractual support services.

³The term “non-bundled,” as used in this table 1, refers to a license amendment request that includes a power uprate request and requests NRC approval for changes with a scope similar to requests approved by the Commission as of August 14, 2017.

⁴The term “bundled,” as used in this table 1, refers to a license amendment request that includes a power uprate request and requests NRC approval for changes that exceed the scope of requests approved by the Commission as of August 14, 2017, such as Maximum Extended Load Line Limit Analysis Plus; cycle extensions; fuel transitions, including accident tolerant fuel, and increased enrichment and high burnup fuel; and new accident and source term methodologies.

⁵Consistent with the definition of requested activity of the Commission in section 3 of the Nuclear Energy Innovation and Modernization Act (42 U.S.C. 2215 note), this activity includes only topical reports submitted by licensees or applicants (*i.e.*, persons or entities that either hold a current license or have a license application under NRC review).

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 10. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 44 U.S.C. 3504 note.

■ 11. In § 171.11, add paragraph (f) to read as follows:

§ 171.11 Exemptions.

* * * * *

(f) All fee exemption requests must be submitted in writing to the Chief Financial Officer in accordance with

§ 171.9, and the Chief Financial Officer will grant or deny such requests in writing. Fee exemption requests submitted via email should be submitted to the NRC at cfofeeexemptionrequests.resource@nrc.gov.

■ 12. In § 171.15, revise paragraphs (b)(1), (b)(2) introductory text, (c)(1), (c)(2) introductory text, (d)(1), and (e) to read as follows:

§ 171.15 Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses.

* * * * *

(b)(1) The FY 2026 annual fee for each operating power reactor that must be collected by September 30, 2026, is \$5,554,000.

(2) The FY 2026 annual fees are comprised of a base annual fee for power reactors licensed to operate, a base spent fuel storage/reactor decommissioning annual fee and

associated additional charges. The activities comprising the spent fuel storage/reactor decommissioning base annual fee are shown in paragraphs (c)(2)(i) and (ii) of this section. The activities comprising the FY 2026 base annual fee for operating power reactors are as follows:

* * * * *

(c)(1) The FY 2026 annual fee for each power reactor holding a 10 CFR part 50 or 53 operating license or combined license issued under 10 CFR part 52 or 53 that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 or 53 operating license, or a 10 CFR part 52 or 53 combined license, is \$325,000.

(2) The FY 2026 annual fee is comprised of a base spent fuel storage/reactor decommissioning annual fee

(which is also included in the operating power reactor annual fee shown in paragraph (b) of this section). The activities comprising the FY 2026 spent fuel storage/reactor decommissioning rebaselined annual fee are:

* * * * *

(d)(1) Each person holding an operating license for an SMR issued under 10 CFR part 50 or 53, or a combined license issued under 10 CFR part 52 or 53, that has provided notification to the NRC of the successful completion of startup testing, shall pay the annual fee for all licenses held for an SMR site. The annual fee will be determined using the cumulative licensed thermal power rating of all SMR units and the bundled unit concept, during the fiscal year in which the fee is due. Each fiscal year, the variable rate will be calculated based on October 1 of the fiscal year and updated, as appropriate, to determine the variable

fee for the current fiscal year. For a given site, the use of the bundled unit concept is independent of the number of SMR plants, the number of SMR licenses issued, or the sequencing of the SMR licenses that have been issued.

* * * * *

(e) The FY 2026 annual fee for licensees authorized to operate one or more non-power production or utilization facilities under a single 10 CFR part 50 license, unless the reactor is exempted from fees under § 171.11(b), is \$98,200.

■ 13. In § 171.16, revise paragraphs (b) introductory text, (c), and (d) to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

(b) The FY 2026 annual fee is comprised of a base annual fee and associated additional charges. The base FY 2026 annual fee is the sum of budgeted costs for the following activities:

* * * * *

(c) A licensee who is required to pay an annual fee under this section, in addition to 10 CFR part 72 licenses, may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in table 1 to this paragraph (c). Failure to file a small entity certification in a timely manner could result in the receipt of a delinquent invoice requesting the outstanding balance due and/or denial of any refund that might otherwise be due. The small entity fees are as follows:

TABLE 1 TO PARAGRAPH (C)

NRC small entity classification	Maximum annual fee per licensed category
Small businesses not engaged in manufacturing (Average gross receipts over the last 5 completed fiscal years):	
\$555,000 to \$8 million	\$5,800
Less than \$555,000	1,100
Small not-for-profit organizations (Annual gross receipts):	
\$555,000 to \$8 million	5,800
Less than \$555,000	1,100
Manufacturing entities that have an average of 500 employees or fewer:	
35 to 500 employees	5,800
Fewer than 35 employees	1,100
Small governmental jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 49,999	5,800
Fewer than 20,000	1,100
Educational institutions that are not State or publicly supported, and have 500 employees or fewer:	
35 to 500 employees	5,800
Fewer than 35 employees	1,100

(d) The FY 2026 annual fees for materials licensees and holders of certificates, registrations, or approvals

subject to fees under this section are shown in table 2 to this paragraph (d):

TABLE 2 TO PARAGRAPH (D)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY THE NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees ^{1 2 3}
1. Special nuclear material:	
A. (1) Licenses for possession and use of U-235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium). ¹⁵ [Program Code(s): 21213]	5,827,000
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel. ¹⁵ [Program Code(s): 21210]	1,975,000
(2) All other special nuclear materials licenses not included in category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations. ¹⁵ [Program Code(s): 21310, 21320]	1,628,000
(b) Gas centrifuge enrichment demonstration facility. ¹⁵ [Program Code(s): 21205]	⁵ N/A
(c) Others, including hot cell facility. ¹⁵ [Program Code(s): 21130, 21131, 21133]	⁵ N/A
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI). ^{11 15} [Program Code(s): 23200]	N/A

TABLE 2 TO PARAGRAPH (D)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY THE NRC—Continued
[See footnotes at end of table]

Category of materials licenses	Annual fees ^{1 2 3}
C. Licenses for possession and use of special nuclear material of less than a critical mass, as defined in § 70.4 of this chapter, in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers. [Program Code(s): 22140]	3,800
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under category 1.A. [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310]	9,200
E. Licenses or certificates for the operation of a uranium enrichment facility. ¹⁵ [Program Code(s): 21200]	2,539,000
F. Licenses for possession and use of special nuclear materials greater than critical mass, as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities. ⁴ [Program Code: 22155]	6,700
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal. ¹⁵ [Program Code: 11400]	1,237,000
(2) Licenses for possession and use of source material in recovery operations such as milling, <i>in situ</i> recovery, heap-leaching, ore buying stations, ion-exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
(a) Conventional and Heap Leach facilities. ¹⁵ [Program Code(s): 11100]	⁵ N/A
(b) Basic <i>In Situ</i> Recovery facilities. ¹⁵ [Program Code(s): 11500]	50,300
(c) Expanded <i>In Situ</i> Recovery facilities. ¹⁵ [Program Code(s): 11510]	⁵ N/A
(d) <i>In Situ</i> Recovery Resin facilities. ¹⁵ [Program Code(s): 11550]	⁵ N/A
(e) Resin Toll Milling facilities. ¹⁵ [Program Code(s): 11555]	⁵ N/A
(f) Other facilities. ^{6 15} [Program Code(s): 11700]	⁵ N/A
(3) Licenses that authorize the receipt of byproduct material, as defined in section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in category 2.A.(2) or category 2.A.(4). ¹⁵ [Program Code(s): 11600, 12000]	⁵ N/A
(4) Licenses that authorize the receipt of byproduct material, as defined in section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in category 2.A.(2). ¹⁵ [Program Code(s): 12010]	⁵ N/A
B. Licenses which authorize the possession, use, and/or installation of source material for shielding. ^{16, 17} [Program Code(s): 11210]	4,400
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. [Program Code: 11240]	16,100
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter. [Program Code(s): 11230, 11231]	8,100
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. [Program Code: 11710]	10,400
F. All other source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810, 11820]	12,800
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. [Program Code(s): 03211, 03212, 03213]	44,400
(1). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04010, 04012, 04014]	58,900
(2). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. [Program Code(s): 04011, 04013, 04015]	73,600
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. [Program Code(s): 03214, 03215, 22135, 22162]	15,000
(1). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04110, 04112, 04114, 04116]	20,000
(2). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. [Program Code(s): 04111, 04113, 04115, 04117]	24,900
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4) of this chapter. Number of locations of use: 1–5. [Program Code(s): 02500, 02511, 02513]	14,800
(1). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4) of this chapter. Number of locations of use: 6–20. [Program Code(s): 04210, 04212, 04214]	21,900

TABLE 2 TO PARAGRAPH (D)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY THE NRC—Continued
[See footnotes at end of table]

Category of materials licenses	Annual fees ^{1 2 3}
(2). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4) of this chapter. Number of locations of use: more than 20. [Program Code(s): 04211, 04213, 04215]	27,100
D. [Reserved]	⁵ N/A
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units). [Program Code(s): 03510, 03520]	14,400
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes. [Program Code(s): 03511]	14,400
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes. [Program Code(s): 03521]	120,300
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. [Program Code(s): 03254, 03255, 03257]	15,400
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. [Program Code(s): 03250, 03251, 03253, 03256]	21,000
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. [Program Code(s): 03240, 03241, 03243]	5,700
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. [Program Code(s): 03242, 03244]	4,300
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5. [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	20,500
(1) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622]	27,200
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: more than 20. [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623]	34,100
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution. [Program Code(s): 03620]	21,100
N. Licenses that authorize services for other licensees, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee category 3.P.; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee categories 4.A., 4.B., and 4.C. ²¹ [Program Code(s): 03219, 03225, 03226]	23,200
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: 1–5. [Program Code(s): 03310, 03320] ...	34,300
(1). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: 6–20. [Program Code(s): 04310, 04312]	45,800
(2). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: more than 20. [Program Code(s): 04311, 04313]	57,200
P. All other specific byproduct material licenses, except those in categories 4.A. through 9.D. ¹⁸ Number of locations of use: 1–5. [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03130, 03140, 03220, 03221, 03222, 03800, 03810, 22130]	16,700
(1). All other specific byproduct material licenses, except those in categories 4.A. through 9.D. ¹⁸ Number of locations of use: 6–20. [Program Code(s): 04410, 04412, 04414, 04416, 04418, 04420, 04422, 04424, 04426, 04428, 04430, 04432, 04434, 04436, 04438]	22,500
(2). All other specific byproduct material licenses, except those in categories 4.A. through 9.D. ¹⁸ Number of locations of use: more than 20. [Program Code(s): 04411, 04413, 04415, 04417, 04419, 04421, 04423, 04425, 04427, 04429, 04431, 04433, 04435, 04437, 04439]	28,200
Q. Registration of devices generally licensed under part 31 of this chapter	¹³ N/A

TABLE 2 TO PARAGRAPH (D)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY THE NRC—Continued
[See footnotes at end of table]

Category of materials licenses	Annual fees ^{1 2 3}
R. Possession of items or products containing radium-226 identified in § 31.12 of this chapter which exceed the number of items or limits specified in that section: ¹⁴	
(1). Possession of quantities exceeding the number of items or limits in § 31.12(a)(4) or (5) of this chapter but less than or equal to 10 times the number of items or limits specified. [Program Code(s): 02700]	9,800
(2). Possession of quantities exceeding 10 times the number of items or limits specified in § 31.12(a)(4) or (5) of this chapter. [Program Code(s): 02710]	10,400
S. Licenses for production of accelerator-produced radionuclides. [Program Code(s): 03210]	41,000
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. [Program Code(s): 03231, 03233, 03236, 06100, 06101]	36,400
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. [Program Code(s): 03234]	23,800
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. [Program Code(s): 03232]	14,000
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies. [Program Code(s): 03110, 03111, 03112]	19,200
B. Licenses for possession and use of byproduct material for field flooding tracer studies. [Program Code(s): 03113]	⁵ N/A
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material. [Program Code(s): 03218]	45,000
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: 1–5. [Program Code(s): 02300, 02310]	44,300
(1). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: 6–20. [Program Code(s): 04510, 04512]	58,900
(2). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: more than 20. [Program Code(s): 04511, 04513]	73,700
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: 1–5. [Program Code(s): 02110]	63,200
(1). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: 6–20. [Program Code(s): 04710]	84,200
(2). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: more than 20. [Program Code(s): 04711]	105,000
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17} Number of locations of use: 1–5. [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	23,300
(1). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17 19} Number of locations of use: 6–20. [Program Code(s): 04810, 04812, 04814, 04816, 04818, 04820, 04822, 04824, 04826, 04828]	33,000

TABLE 2 TO PARAGRAPH (D)—SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY THE NRC—Continued
[See footnotes at end of table]

Category of materials licenses	Annual fees ^{1 2 3}
(2). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. ^{9 17 19} Number of locations of use: more than 20. [Program Code(s): 04811, 04813, 04815, 04817, 04819, 04821, 04823, 04825, 04827, 04829]	42,300
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities. [Program Code(s): 03710]	9,800
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	28,500
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	14,800
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	8,700
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	1,800
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers	
1. Spent Fuel, High-Level Waste, and plutonium air packages.	⁶ N/A
2. Other Casks	⁶ N/A
B. Quality assurance program approvals issued under part 71 of this chapter	
1. Users and Fabricators	⁶ N/A
2. Users	⁶ N/A
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices)	⁶ N/A
11. Standardized spent fuel facilities	⁶ N/A
12. Special Projects. [Program Code(s): 25110]	⁶ N/A
13. A. Spent fuel storage cask Certificate of Compliance	⁶ N/A
B. General licenses for storage of spent fuel under § 72.210 of this chapter	¹² N/A
14. Decommissioning/Reclamation:	
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs). The transition to this fee category occurs when a licensee has permanently ceased principal activities. [Program Code(s): 03900, 11900, 21135, 21215, 21325, 22200]	^{7 20} N/A
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, whether or not the sites have been previously licensed.	⁷ N/A
15. Import and Export licenses	⁸ N/A
16. Reciprocity	⁸ N/A
17. MMLs of broad scope issued to Government agencies. ¹⁵ [Program Code(s): 03614]	535,000
18. Department of Energy:	
A. Certificates of Compliance	¹⁰ \$2,352,000
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities. [Program Code(s): 03237, 03238]	190,000

¹ Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession-only/storage licenses before October 1 of the current FY and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession-only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

² Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of part 30, 40, 70, 71, 72, or 76 of this chapter.

³ Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the FEDERAL REGISTER for notice and comment.

⁴ Other facilities include licenses for extraction of metals, heavy metals, and rare earths.

⁵ There are no existing NRC licenses in these fee categories. If the NRC issues a license for these categories, the Commission will consider establishing an annual fee for this type of license.

⁶ Standardized spent fuel facilities, 10 CFR parts 71 and 72 Certificates of Compliance and related Quality Assurance program approvals, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to users of the designs, certificates, and topical reports.

⁷ Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

⁸ No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license. Because section 101 of the ADVANCE Act created an excluded activity for international nuclear export and innovation activities, no annual fee is charged for import and export licenses.

⁹ Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses under fee categories 7.A., 7.A.1, 7.A.2, 7.B., 7.B.1, 7.B.2, 7.C., 7.C.1, or 7.C.2.

¹⁰ This includes Certificates of Compliance issued to DOE that are not funded from the Nuclear Waste Fund.

¹¹ See § 171.15(c).

¹² See § 171.15(c).

¹³ No annual fee is charged for this category because the cost of the general license registration program applicable to licenses in this category will be recovered through 10 CFR part 170 fees.

¹⁴ Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

¹⁵ Licensees subject to fees under categories 1.A., 1.B., 1.E., and 2.A., and licensees paying fees under fee category 17 must pay the largest applicable fee and are not subject to additional fees listed in this table.

¹⁶ Licensees paying fees under 3.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

¹⁷ Licensees paying fees under 7.A., 7.A.1, 7.A.2, 7.B., 7.B.1, 7.B.2, 7.C., 7.C.1, or 7.C.2 are not subject to fees under 2.B. for possession and shielding authorized on the same license.

¹⁸ Licensees paying fees under 3.N. are not subject to paying fees under 3.P., 3.P.1, or 3.P.2 for calibration or leak testing services authorized on the same license.

¹⁹ Licensees paying fees under 7.B., 7.B.1, or 7.B.2 are not subject to paying fees under 7.C., 7.C.1, or 7.C.2 for broad scope licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

²⁰ No annual fee is charged for a materials license (or part of a materials license) that has transitioned to this fee category because the decommissioning costs will be recovered through 10 CFR part 170 fees, but annual fees may be charged for other activities authorized under the license that are not in decommissioning status.

²¹ Licensees paying fees under 4.A., 4.B., or 4.C. are not subject to paying fees under 3.N. licenses that authorize services for other licensees authorized on the same license.

Dated: June 5, 2026.

For the Nuclear Regulatory Commission.

Christopher Carroll,
Chief Financial Officer.

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