DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 429

[CMS–4215–F]

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: Final rule.

SUMMARY: This rule finalizes and codifies the Medicare Drug Price Negotiation Program (''Negotiation Program'') and establishes certain new policies for the Negotiation Program and the Medicare Prescription Drug Benefit Program (''Part D Program'') as required by the Inflation Reduction Act of 2022. This final rule also finalizes a proposed policy for specific fixed combination drugs that are new formulations.

DATES:

Effective date: These regulations are effective on December 5, 2026.

Applicability date: These regulations are applicable to the Negotiation Program beginning with respect to initial price applicability year 2029 and to Part D Program coverage beginning January 1, 2029.

FOR FURTHER INFORMATION CONTACT: Elisabeth Daniel, *IRARebateandNegotiation@cms.hhs.gov,* or (667) 290–8793, for issues related to the Medicare Drug Price Negotiation Program.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule finalizes and codifies 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 final rule also finalizes and codifies 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'') as well as 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 are codifying policies established in final guidance for the Negotiation Program [1] in regulatory text. Specifically, we are codifying, 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.

In addition, we are codifying new policies for the Medicare Drug Price Negotiation Program as follows:

- Finalizing § 429.125(b)(4)(ii) regarding treatment of specific fixed combination drugs in our determinations of qualifying single source drugs. In this section, we are establishing a policy for specific fixed combination drugs that we determine are new formulations of existing drugs. Under this policy, 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), 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), 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), or antigen component(s) that are offered by the same NDA/BLA holder.
- Finalizing § 429.125(c)(3)(i), to clarify how CMS will 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.
- Finalizing § 429.130, to 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.
- Finalizing § 429.210(c), to provide additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity.
- Finalizing § 429.415(a)(2) and § 429.510(d)(2)(ii), to explain how CMS will calculate the 30-day equivalent supply for a selected drug or therapeutic alternative, respectively, payable under Part B that is typically administered one time (for example, some vaccines, gene therapies, and cancer therapies).
- Finalizing § 429.440 with modifications, to explain how CMS will implement the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030. We are modifying our proposed stepwise approach, at § 429.440(b)(4), for calculating a selected drug's ceiling in the event that certain ceiling amounts are below the Temporary Floor for Small Biotech Drugs.
- Finalizing §§ 429.605 and 429.610 with modifications, to 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.

Unless otherwise specified, CMS finalizes 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 final 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. In this final rule, unless otherwise specified, references hereinafter to ''the revised guidance for initial price applicability year 2026'' are to the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026 that was published by CMS on June 30, 2023. Additionally, in this final rule, unless otherwise specified, references

[1] The most recent final guidance published for the Negotiation Program 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, available at: *https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

hereinafter to ''the final guidance for initial price applicability year 2027'' are to the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 that was published by CMS on October 2, 2024.

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 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 final 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 finalizes 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 final rule. However, the definition of an eligible small biotech drug for purposes of the calculation of the Temporary Floor for Small Biotech Drugs on the maximum fair price for small biotech drugs under section 1194(d) of the Act is included in this final rule (as described in more detail in section II.E.2. of this final rule).

3. Summary of Costs and Benefits

We are finalizing new policies for the Negotiation Program as follows: a policy for specific fixed combination drugs that are 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 VI. of this final 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 final 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)(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 or payable under Part B or both for initial price applicability year 2028.[4] The Secretary will select up to 20 drugs covered under Part D or payable under Part B or both 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

[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.*

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 2028 [8] 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] In the final rule, we proposed to codify these requirements at parts 423 and 429 to title 42, chapter IV of the Code of Federal Regulations (CFR) to implement sections 11001 and 11002 of the IRA. The effective date of the finalized provisions is discussed in section I.A.5. of this final 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. Publication of the Proposed Rule and General, Out-of-Scope, and Within Scope Public Comments

1. Publication of the Proposed Rule

In response to the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program proposed rule (91 FR 36236 through 36368) (''proposed rule''), we received approximately 11,330 timely comment letters containing a variety of feedback and recommendations on the proposed rule and the information collection requests (ICRs) contained within the proposed rule.

2. General Comments

We received general comments on the Negotiation Program proposed rule. The following is a summary of the general comments we received and our responses.

Comment: Many commenters expressed general support for the Negotiation Program and the proposed policies.

Response: We thank commenters for their support.

Comment: Some commenters expressed general opposition to the Negotiation Program and the proposed policies.

Response: We appreciate the commenters for sharing their concern.

Comment: Some commenters noted that codifying policies of the Negotiation Program in regulation should not be an opportunity for CMS to expand the program requirements. A commenter urged CMS to assess whether proposed policies are consistent with statute, supported by reasoned decision making, and responsive to stakeholder comments as it implements the Negotiation Program.

Response: We appreciate this input and note that we have pursued implementation in accordance with the statutory requirements of the Negotiation Program. We appreciate the comments received from interested parties on the proposed rule. We read and responded to all significant comments received timely.

Comment: Many commenters expressed concern about the impact of the Negotiation Program on innovation and drug development, as well as concern about creating uncertainty in the pharmaceutical market. A few commenters recommended CMS continue to be transparent as it implements the Negotiation Program, and one of these commenters noted that CMS should adopt clear standards, consistent definitions, and predictable procedures across the Negotiation Program. A couple of commenters recommended CMS monitor and report on the impact of the Negotiation Program on patient access to prescription drugs.

Response: We thank these commenters for their input. Although the U.S. prescription drug market is the largest in the world—with a track record of fostering innovation—patients in the United States generally pay more for prescription drugs than anywhere else.[12] We believe the Negotiation Program will make prescription drugs more affordable for people with Medicare and the Medicare program—without restricting innovation and new product research and development.[13] [14] We also expect the Negotiation Program to encourage drug manufacturers to create business models to stay competitive, fostering the development of new treatments. Only drugs that have been approved by the Food and Drug Administration (FDA) for at least 7 years and only biological products that have been licensed by the FDA for at least 11 years are eligible for selection as part of the Negotiation Program, unless they are otherwise excluded in accordance with statute. With the implementation of the Negotiation Program, we believe prescription drugs will be more affordable, allowing more patients to purchase those prescription drugs and adhere to their medications. As a result, prescription drug sales likely will continue to grow and drug manufacturers will reap the rewards of more patients being able to afford their medications.

3. Out of Scope Comments

Many comments, including those related to implementation of policies and processes of maximum fair price (MFP) effectuation, such as operations of the Medicare Transaction Facilitator (''MTF''), were out of scope for purposes of this rulemaking.

4. Within Scope Comments

Summaries of the public comments within the scope of the proposed rule and our responses to those public comments are provided in the various sections of this final rule under the appropriate heading. Commenters included drug manufacturers and their trade associations, patient advocacy organizations, thought leaders, pharmacies and their trade associations, health plans, pharmacy benefit managers and their trade association,

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[5] See: *https://www.cms.gov/files/document/factsheet-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.*

[12] Assistant Secretary for Planning and Evaluation, ''International Prescription Drug Price Comparisons: Estimates Using 2022 Data,'' February 2024, see: *https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf.*

[13] Conti, Rena M., Richard G. Frank, and David M. Cutler, ''The Myth of the Free Market for Pharmaceuticals,'' *The New England Journal of Medicine,* vol. 390, no. 16, April 20, 2024.

[14] *Novo Nordisk et al.* v. *Becerra et al.,* brief amicus curiae of economists and scholars of health policy, Feb. 2, 2024, *https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/10/Novo-Nordisk_2024.02.02_Amicus-Brief-Economists-and-Health-Policy-Scholars.pdf.*

and individuals. A summary of the major issues and our responses follow.

D. Waiver of Delay in Effective Date

The Congressional Review Act (CRA) generally requires that the effective date of a major rule be 60 days after the rule is published in the **Federal Register**. 5 U.S.C. 801(a)(3)(A)(ii). The CRA allows an agency to issue a rule that would otherwise be subject to a 60-day delayed effective date requirement with an effective date at such time as the Federal agency promulgating the rule determines in circumstances where notice and public procedure are impractical, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)).

CMS is waiving the 60-day delay in the effective date for this rule to allow it to meet the statutory deadline of February 1 for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act), and avoid an infeasible scenario where CMS must wait until 60 days after the date the rule is published in the **Federal Register** to close the collection of Initial Delay Requests from Biosimilar Manufacturers (CMS–10844, OMB 0938–1452, Expiration 11/30/2028) as we are finalizing in § 429.110. To meet the statutory deadline of February 1 for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act), based on experience from initial price applicability years 2026, 2027, and 2028, CMS needs a minimum of approximately seven weeks to conduct the review process for Initial Delay Requests, as specified in section 1192(f) of the Act. The volume of Initial Delay Requests we receive varies by year, as well as the scope and complexity of review, since each application presents unique drug-specific considerations. Collecting and reviewing Initial Delay Requests in January 2027 without a waiver of the 60-day delay in the effective date would be infeasible for CMS to make determinations with respect to such requests, as CMS would have insufficient time to: (1) review such request(s); (2) request additional information and documents from the Biosimilar Manufacturer necessary to make determinations (if applicable); (3) allow a Biosimilar Manufacturer time to produce and submit to CMS the requested information (consistent with section 1192(f)(1)(B)(ii)(II) of the Act); and (4) review the additional information and documents submitted by Biosimilar Manufacturers to determine whether the selection of a negotiation-eligible drug that includes the reference product for the Biosimilar should be delayed, before the statutory deadline of February 1 for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act).

Review of an Initial Delay Request may require CMS to consider a substantial volume of technical information, and potentially request additional information from the Biosimilar Manufacturer, in order to make a determination. For example, in reviewing an Initial Delay Request pursuant to section 1192(f) of the Act, CMS must, among other actions, determine whether there is a high likelihood that the Biosimilar Manufacturer's Biosimilar will be licensed and marketed under section 351(k) of the Public Health Service Act before the date that is 2 years after the selected drug publication date with respect to such initial price applicability year for which a reference drug would be included on the selected drug list absent a successful Initial Delay Request (the High Likelihood Deadline). CMS must also, among other actions, determine that the Biosimilar Manufacturer and the Reference Manufacturer have not entered into an agreement that (1) requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request or (2) directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

As part of the Initial Delay Request, the Biosimilar Manufacturer must submit all agreements related to the Biosimilar filed with the Federal Trade Commission (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, and to the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure and 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.

In this example, CMS must review the aforementioned materials to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline and whether there are any agreements between the Biosimilar Manufacturer and Reference Manufacturer that would require the denial of the Initial Delay Request. If CMS began reviewing Initial Delay Requests in January 2027, CMS would have insufficient time for the following actions before the February 1 statutory publication deadline for the selected drug list. First, CMS must review the applicable agreements filed with the FTC or the Assistant Attorney General, any manufacturing schedule for the Biosimilar submitted to the FDA, and applicable disclosures pertaining to the marketing of the Biosimilar. Second, CMS may need to submit follow up requests to Biosimilar Manufacturers where, for example, the information and documents provided are insufficient for determining whether any agreement(s) violate the statutory requirements for granting the Initial Delay Requests, or where the information and documents provided do not establish clear and convincing evidence as required by statute that the Biosimilar will be marketed before the High Likelihood Deadline. Third, CMS would need to provide the Biosimilar Manufacturer with adequate time to produce and submit to CMS additional information and documents regarding the agreements and marketing of the Biosimilar before the High Likelihood Deadline. Fourth, CMS must review this additional information and documents provided by the Biosimilar Manufacturer to determine if the agreements violate the statutory requirements for granting the Initial Delay Request, and whether there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. These determinations must be made before the February 1 statutory publication deadline for the selected drug list.

In this example, CMS believes that completing these actions as part of the review of Initial Delay Requests to determine whether the selection of a negotiation-eligible drug should be delayed by one year before the February 1 statutory publication deadline for the selected drug list would be infeasible if CMS began reviewing Initial Delay Requests in January 2027.

In recognition of these timing requirements, such requests must be due by a date specified by CMS, which would be no later than the end of December of the calendar year prior to the selected drug publication date. A 60-day delay for completion of data collection, after the date of publication

in the **Federal Register**, would be in direct conflict with this provision.

Specifically, a 60-day delay in effective date following publication in the **Federal Register** would mean these actions would not begin until the effective date in early January 2027. This would prevent CMS from reviewing, following up, and granting Initial Delay Requests, if applicable, in accordance with section 1192(f) of the Act by the selected drug publication date for initial price applicability year 2029. Further, a 60-day delay would be inconsistent with our regulation as codified in § 429.110(f).

If CMS were to begin reviewing Initial Delay Requests 60 days after the publication of this Final Rule in the **Federal Register**, CMS would have a period of less than one month to review such requests, which is approximately half the minimum time that CMS believes is necessary, before the February 1 deadline for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act). As explained in the preceeding example, such a timeline is insufficient for CMS to review the Initial Delay Request and request follow ups, if necessary, allow Biosimilar Manufacturer(s) time to compile and submit additional information and documents, and for CMS to review such additional information and documents. Allowing CMS to request additional information and documents from the Biosimilar Manufacturer, if applicable (consistent with section 1192(f)(1)(B)(ii)(II) of the Act), and providing sufficient time for a manufacturer to respond to such requests, are key parts of the Initial Delay Request process, and could not be reasonably completed before the statutory deadline if CMS did not waive the 60-day delay in effective date. Therefore, this delay would interfere with the timely implementation of this statutorily authorized program. CMS finds good cause to waive the 60-day delay in effective date of the final rule, otherwise CMS will not be able to complete the Initial Delay Request process before the February 1, 2027 deadline for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act).

E. Severability of Provisions

Finally, CMS is clarifying and emphasizing its intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this 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 finalizes provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal.

II. Proposed Requirements for the Medicare Drug Price Negotiation Program and Analysis of and Responses to Public Comments

A. General Provisions

1. Basis and Scope (§ 429.10)

In proposed § 429.10, we proposed 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 proposed 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 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 policies related to requests for a biosimilar delay (proposed § 429.110) are distinct and severable from the policies related to the identification of qualifying single source drugs (proposed § 429.125). As another example, we intend that the 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 policies 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 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 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 § 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)).

We did not receive public comments on our proposals in this section.

Final Decision: We are finalizing § 429.10 as proposed.

2. Definitions (§ 429.20)

In the proposed rule, we proposed to 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 new definitions based on policies detailed in this final rule.

a. Additional Delay Request

We proposed 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 proposed 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 proposed 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 proposed 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 solicited 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to define ''Biologics License Application (BLA)'' as an application submitted under section 351 of the PHS Act.

j. Biosimilar Biological Product or Biosimilar

We proposed 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. We proposed to use the term ''biosimilar'' throughout part 429 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 proposed to define ''Biosimilar Delay Request'' as either an Initial Delay Request or an Additional Delay Request.

l. Biosimilar Manufacturer

We proposed 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 final rule.

m. BLA Holder

We proposed 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 proposed 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 final rule.

o. Combined Part B and Part D Amount

We proposed 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(s).

p. CPI–U

We proposed 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 proposed 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 proposed 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 proposed 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 proposed to define ''estimated renumeration 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 proposed to define ''extended-monopoly drug'' as having the meaning set forth in section 1194(c)(4) of the Act.

v. FDA-Approved Indication

We proposed 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 proposed to define ''fixed combination drug'' as having the meaning set forth in 21 CFR 300.50.

x. Generic Drug

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to define ''initial price applicability year'' as having the meaning set forth in section 1191(b)(1) of the Act.

ad. Knowingly

We proposed to define ''knowingly'' as having the meaning set forth in 42 CFR 1003.110.

ae. Long-Monopoly Drug

We proposed to define ''long-monopoly drug'' as having the meaning set forth in section 1194(c)(5) of the Act.

af. Manufacturer

We proposed to define ''manufacturer'' as having the meaning set forth in section 1191(c)(1) of the Act.

ag. Manufacturer Discount Program

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 final rule) for CMS' proposals for identifying drugs that meet this statutory definition.

am. Negotiation Period

We proposed 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 proposed 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 proposed to define ''New Drug Application (NDA)'' as an application submitted under section 505(b) of the FD&C Act.

ap. Off-Label Use

We proposed 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 proposed to define ''orphan drug designation'' as the meaning set forth in 21 CFR 316.3(b)(11).

ar. Outcomes

We proposed 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 proposed 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 proposed 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 proposed to define ''personally identifiable information (PII)'' as having the meaning set forth at 2 CFR 200.1.

av. Plasma-Derived Product

We proposed to define ''plasma-derived product'' as having the meaning set forth in section 1192(e)(3)(C) of the Act.

aw. Preliminary Price

We proposed 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 proposed to define ''price applicability period'' as having the meaning set forth in section 1191(b)(2) of the Act.

ay. Primary Manufacturer

We proposed 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 proposed to define ''private label distributor'' as having the meaning set forth in 21 CFR 207.1.

ba. Protected Health Information (PHI)

We proposed to define ''protected health information (PHI)'' as having the meaning set forth at 45 CFR 160.103.

bb. Qualifying Single Source Drug

We proposed 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 final 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 proposed 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 proposed 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 proposed to define ''Reference Manufacturer'' as the Primary Manufacturer of the Reference Drug that is named in a Biosimilar Delay Request.

bf. Reference Product

We proposed to define ''Reference Product'' as having the meaning set forth in section 1191(c)(4) of the Act.

bg. Relabeler

We proposed to define ''relabeler'' as having the meaning set forth in 21 CFR 207.1.

bh. Renegotiation-Eligible Drug

We proposed to define ''renegotiation-eligible drug'' as having the meaning set forth in section 1194(f)(2) of the Act.

bi. Repackager

We proposed to define ''repackager'' as having the meaning given the term ''repacker'' set forth in 21 CFR 207.1.

bj. Request To Terminate

We proposed 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), 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 proposed 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 proposed 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 proposed 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 proposed to define ''section 1194(e)(2) factors'' as the factors described in section 1194(e)(2) of the Act.

bo. Selected Drug

We proposed 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 final rule) for CMS' proposals for identifying drugs that meet this statutory definition.

bp. Selected Drug Publication Date

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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 proposed 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 proposed to define ''unit'' as having the meaning set forth in section 1191(c)(6) of the Act.

cd. Unmet Medical Need

We proposed 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 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.

ce. Wholesale Acquisition Cost (WAC) Unit Price

We proposed 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.

We received public comments on our proposed definitions. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that for the definition of ''off-label use'', CMS clarify that ''authoritative medical literature, and/or accepted standards of medical practice'' should be relevant to the Medicare population when it considers off-label use for the purpose of determining therapeutic alternatives. The commenter stated that clinical guidelines outside the United States would not be relevant and including such international guidelines could increase the administrative burden on the agency.

Response: We appreciate this commenter's suggestion to limit evidence related to off-label use to the Medicare population, and the commenter's statement that using clinical guidelines outside the United States would be irrelevant and increase administrative burden. As discussed in section II.F.3.d.1. of the proposed rule (91 FR 36292), we will consider information from studies with different study populations but intend to prioritize research and real-world evidence relating to Medicare populations, including individuals with disabilities, patients with end-stage renal disease, and Medicare-aged populations. Clinical practice guidelines developed outside the United States will not be categorically excluded from consideration or deemed irrelevant to the Medicare population solely on the basis of their country of origin. Rather, the relevance of any clinical practice guideline will be assessed, in part, based on the extent to which the guideline and its recommendations are reasonably applicable to the care delivery setting in which they are

intended to be implemented and the Medicare population. We refer the commenter to § 429.505 for additional information on how we evaluate evidence.

Comment: A commenter supported the broad definition of ''outcomes'' which includes aspects of a patient's life.

Response: We appreciate the commenter's support.

Comment: A commenter recommended that CMS clarify that research and development costs, as described under definitions relating to research and development costs in Appendix A of the Negotiation Program Guidance, should be applied in the rule. This commenter supported the exclusion of acquisition costs from consideration of research and development costs.

Response: We thank this commenter for their suggestion. Because the term ''Research and Development (R&D) Costs and Recoupment'' is defined in the information collections for Identification and Selection of Renegotiation-Eligible Drugs ICR Form (CMS–10844, OMB 0938–1443) and the Negotiation Data Elements ICR Form (CMS–10849, OMB 0938–1452), consistent with the general directive established in this final rule that data submissions must be reported to CMS in the form and manner specified by CMS, CMS declines to add a definition of ''Research and Development (R&D) Costs and Recoupment'' to § 429.20.

Comment: A commenter suggested that the definition of ''starting point'' should state the methodology for developing the starting point, rather than defining the term by referencing § 429.510.

Response: We appreciate this commenters' input. We believe the current definition of ''starting point'' appropriately indicates that the term refers to the numerical dollar amount used by CMS in developing an initial offer and that such dollar amount is determined per § 429.510(d) and 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). We do not believe repeating the process of determining the starting point outlined in § 429.510(d) is necessary.

Comment: A commenter recommended that CMS broaden the definition of ''unmet medical need'' to include public health needs and health outcomes important to patients, such as improvement in the safety profile of a drug, prevention of disease progression, improvement in quality of life, reduction in time off from work, and improvement in caregiver outcomes. The commenter also requested that CMS specify and publicly report the submitted data that CMS considers to be evidence an unmet medical need; and provide the public and Primary Manufacturers with detailed evidence on the factors considered in determining if a product meets or does not meet an unmet medical need and how this factor impacted the resulting MFP. A commenter suggested that ''unmet medical need'' be considered at the time of the launch of the product.

Response: Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, we note that the definition of ''unmet medical need'' is adopted from section 60.3.3.1 of the Negotiation Program Guidance, which was developed after consideration of public comments submitted for the revised guidance for initial price applicability year 2026 and with reference to section 1194(e)(2)(D) of the Act and FDA's ''Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics.'' Many of the considerations commenters raised, such as patient quality of life, are considered as part of other factors listed at section 1194(e)(2) of the Act. We will evaluate the extent to which a selected drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration, which aligns with CMS' approach to identifying indications for a selected drug, reviewing manufacturer costs and data, selecting a therapeutic alternative(s), and considering other negotiation factors.

Comment: A commenter recommended that CMS revise the definition of ''therapeutic advance'' to include representation of significant impact among a socially or economically vulnerable population, which is not evident among non-vulnerable populations; or patient-focused improvements in the symptoms or health outcomes associated with a disease (for example, reduction of symptoms, delayed progression of illness, ability to perform daily functions, improvements in adherence, quality of life); or improvements on a validated clinical outcome assessment for the disease state.

Response: We appreciate this commenter's suggestions. Consistent with the Negotiation Program Guidance, we will determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes for the selected drug compared to its therapeutic alternative(s) per the definition in this section of the final rule. We note that many of the other factors mentioned are considered during the development of the initial offer as outlined in § 429.510.

Comment: A commenter stated that CMS' proposed rule did not provide sufficient context regarding the potential expansion for the definition of ''authorized representative''. The commenter stated that, absent other entities, submissions or program contexts CMS has in mind, they cannot reasonably comment on whether an expanded definition is necessary or operable. The commenter recommended that CMS not finalize as proposed and instead identify the specific circumstances CMS intends the definition to cover in future rulemaking.

Response: We appreciate this commenter's suggestions. After further consideration of the intended application of the definition of ''Authorized Representative'' across Negotiation Program requirements and information collections, we believe that the proposed definition of ''Authorized Representative'', which was intended to be a general term, is more restrictive than intended given that it is limited to only individuals with the authority or capacity to legally bind a Primary Manufacturer and could be read as limited to use only in the context of the signing of a Negotiation Program Agreement. This may create issues for Biosimilar Manufacturers attempting to certify submissions in response to the Biosimilar Delay ICR Form (CMS–10844, OMB 0938–1443) or for Primary Manufacturers attempting to certify submissions such as the Negotiation Data Elements ICR Form (CMS–10849, OMB 0938–1452). Accordingly, we are making a clarifying change to the proposed definition of Authorized Representative by revising the defined term to ''Authorized Representative *of the Primary Manufacturer*'' and striking the reference ''*to the terms and conditions of the Negotiation Program Agreement*''. Additionally, we have added a definition of ''*Authorized Representative of the Biosimilar Manufacturer*'' under § 429.20 to provide specification on who may sign a Biosimilar Delay Request on behalf of a Biosimilar Manufacturer.

Comment: A few commenters opposed the definitions of ''Primary Manufacturer'' and ''Secondary Manufacturer'', stating that such definitions do not align with statute and may result in a Primary Manufacturer being held responsible, for example, for violations by or noncompliance of a Secondary Manufacturer.

Response: As discussed in CMS' response in Negotiation Program Guidance and the final guidance for initial price applicability year 2027, given that section 1193(a)(1) of the Act instructs CMS to negotiate with ''the manufacturer'' to arrive at the MFP for a given selected drug to which ''the manufacturer'' would provide access in accordance with the statute, and given that the term ''the manufacturer'' appears repeatedly throughout the statutory provisions establishing the Negotiation Program, the best statutory interpretation is to interpret the term ''manufacturer'' as a single entity for the negotiation process, responsible for negotiation of a single MFP for a given selected drug. Thus, in accordance with section 1193(a)(1) of the Act and other statutory references to ''the manufacturer,'' CMS will enter into a Negotiation Program Agreement with ''the manufacturer'' of a selected drug, where ''the manufacturer'' is the NDA/BLA holder. We adopted the designations and definitions of ''Primary Manufacturer'' and ''Secondary Manufacturer,'' respectively, to establish a process to negotiate the maximum fair price with ''the manufacturer'' to align with the meaning of the statutory language and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and MFP availability for the selected drug manufactured, marketed, controlled, or sold by the Secondary Manufacturer(s).

Final Decision: After consideration of public comments received, we are finalizing § 429.20 with modifications. We are making clarifying modifications to the term ''Authorized representative''. We are adding ''of the Primary Manufacturer'' to the term and removing ''to the terms and conditions of the Negotiation Program Agreement'' from the definition. We also are adding a definition for ''Authorized Representative of a Biosimilar Manufacturer''. The term as finalized in this rule is defined as ''an individual that has the authority or capacity to legally bind the Biosimilar Manufacturer and meets one of the following criteria:

- Chief Executive Officer of the Biosimilar Manufacturer
- Chief Financial Officer of the Biosimilar Manufacturer
- An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Biosimilar 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 definition''.

We are making additional non-substantive, technical modifications to other definitions. To the term, ''Combined Part B and Part D amount'', we are correcting a typographical error to a citation to ''§ 429.430''; to the term, ''FDA-approved indication'', we are adding ''other'' before ''FDA regulations as applicable''; to the term ''Initial Delay Period,'' we are replacing ''as proposed'' in paragraph (1) with ''as described'' to reflect that this a final regulation; to the term ''therapeutic advance'' at section II.A.2.bw. of the proposed rule, we are adding ''.'' after ''at such time of consideration''; to the term ''therapeutic alternative'' at proposed § 429.20, we are removing erroneous text ''For the purpose of developing the initial offer CMS considers therapeutic advance as of the date specified in § 429.505(d)(2)'', we are replacing ''unmet medical need'' with ''therapeutic advance'', and we are replacing ''addresses an unmet medical need'' with ''represents a therapeutic advance; to the term ''self-administered drug'', we are adding ''product'' after ''biological''; and to the definition of ''unmet medical need'', we are changing ''would'' to ''will''.

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 proposed to codify these limitations on review in proposed § 429.30.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern that the limitations on administrative and judicial review of precluded sections specified in section 1198 of the Act increase the need for CMS to act with restraint in finalizing its proposed policies related to those sections. Specifically, these commenters noted that such limitations increase the need for establishing objective regulatory standards and for ensuring methodological consistency with regards to certain policies precluded from administrative and judicial review.

Response: We appreciate these comments and reiterate that section 1198 of the Act establishes that there shall be no administrative or judicial review of the determinations described in that section. We believe the policies set forth and described in this final rule are consistent with the law and accomplish the aim of establishing objective regulatory standards and ensuring methodological consistency.

Final Decision: After consideration of public comments, we are finalizing § 429.30 as proposed.

B. Identification of Selected Drugs (§§ 429.100 through 429.135)

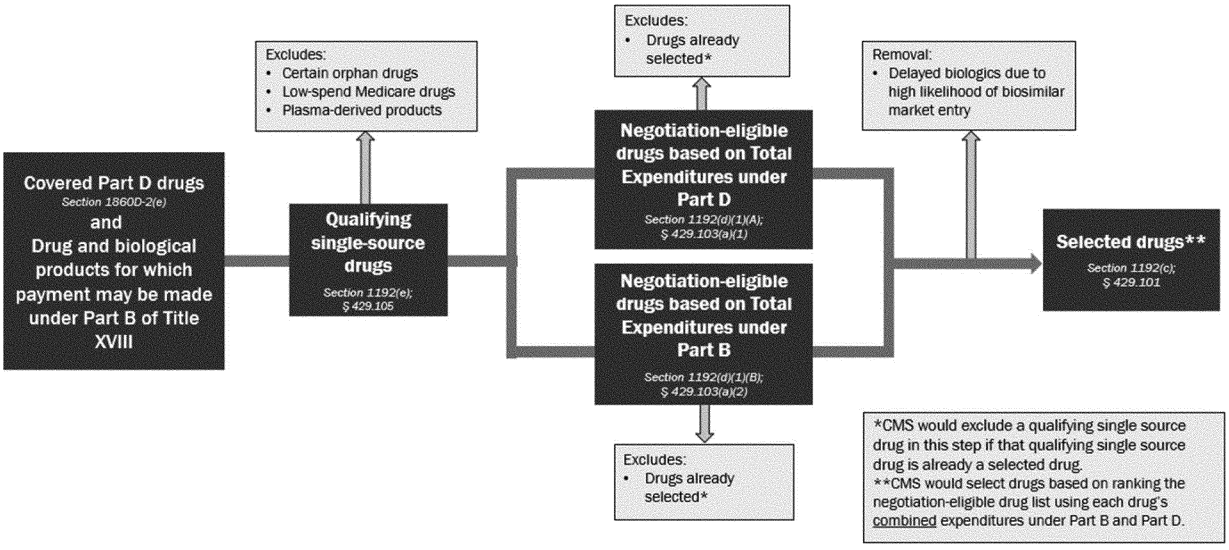
Section 1192 of the Act establishes the requirements governing the publication of the list of selected drugs for an initial price applicability year, the identification of selected drugs, ranking of negotiation-eligible drugs, and the identification of qualifying single source drugs. With respect to 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 proposed 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 proposed 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 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 proposed 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. As discussed in detail in section II.G.3. of this final rule, we may also select a drug or drugs for renegotiation based on criteria proposed in § 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 also proposed 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 proposed at § 429.100(a) to codify the requirement at section 1192(c)(1) of the Act that each drug included on the selected drug list [15] 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 final rule). We proposed 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 final

[15] 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.

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 proposed 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,[16] as applicable, identified as set forth in proposed § 429.125(b). For a potential qualifying single source drug identified under proposed § 429.125(b)(4)(i), we proposed to publish the shared active moiety/active ingredient identified under proposed § 429.125(b)(4)(i), plus any additional active moiety/active ingredient included in new formulations of such potential qualifying single source drug. We proposed 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 proposed 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 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 proposed 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 proposed 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 CMS [17] 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 proposed 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 proposed 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 final rule), we proposed 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 proposed 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 proposed in § 429.100(e) that a Primary Manufacturer has an ongoing obligation

[16] 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 proposed 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.

[17] See: *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

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).[18] 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 proposed 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 drug for a given initial price applicability year 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposal 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, stating that the list will improve public understanding of the drug selection process and help predict drugs that may be selected in the future, which would inform activities such as formulary planning and manufacturer preparations. A commenter supported reducing the published list of negotiation-eligible drugs to up to 30 negotiation-eligible drugs as a way to continue supporting transparency in the selection process while appropriately not overstating the predictive value of any single year's rankings. Some commenters supported CMS' efforts to provide transparency but urged CMS to return to the policy set forth in the Negotiation Program Guidance to publish a list of the up to 50 top negotiation-eligible drugs. These commenters stated that a more comprehensive list is critical for manufacturers to understand CMS' expenditure methodology and anticipate whether and when their products are likely to be selected, as well as for purchasers, researchers, and policymakers to better understand how the selection methodology operates, evaluate trends in Medicare drug spending, and identify drugs approaching the selection threshold. A commenter stated that, although the narrower list may offer sufficient transparency into the current initial price applicability year, visibility into drugs ranked #31 through #50 remains valuable to manufacturers assessing potential eligibility in the subsequent initial price applicability year. This commenter also stated that visibility into drugs ranked #31 through #50 is particularly important given CMS' inclusion of Medicare Advantage expenditures in the calculation of total expenditures under Part B: since MA expenditures are not included in CMS' published Part B spend data, anticipation of potential selection is challenging for manufacturers without the list of up to 50 top negotiation-eligible drugs. A commenter urged CMS to publish a list of drugs that were not considered qualifying single source drugs because they qualified for the orphan drug exclusion or the plasma-derived product exclusion and that, absent the exclusion, would have ranked among the 50 top negotiation-eligible drugs. A commenter recommended that CMS identify any drug falling within the top 20 drugs in total expenditures on a net basis but that is not a selected drug because it does not fall within the top 20 drugs in total expenditures on the gross basis used for selection.

Response: We thank the commenters for their support and suggestions. We agree with the commenter who stated that the list of up to 30 top drugs offers sufficient transparency into the current initial price applicability year and affirm that the purpose of the list of top negotiation-eligible drugs was, and is, to promote transparency into the drug selection process for the initial price applicability year for which the list of top negotiation-eligible drugs is published. As we stated in the proposed rule (91 FR 36245 through 36246), 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 drug for a given initial price applicability year are not static, and such list was not, and is not, intended to predict or replicate the selected drug list for future initial price applicability years. We recognize that the Part B Spending Dashboard [19] does not include Part B data for beneficiaries enrolled in MA. However, the absence of MA data from the Dashboard does not, in itself, provide a sufficient basis for publishing a list of up to 50 drugs with the highest Part B expenditures. As we have previously stated, such a list is not intended to predict or otherwise indicate which drugs may ultimately be selected for negotiation for future initial price applicability years.

We therefore disagree with the premise that an expanded list of up to 50 top negotiation-eligible drugs would provide greater benefit to interested parties as compared to the list of up to 30 top negotiation-eligible drugs, since

[18] See: *https://www.cms.gov/files/document/factsheet-medicare-top-50-negotiation-eligible-drug-list-ipay-2028.pdf.*

[19] See: *https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard.*

neither version of such list can or should be used to help manufacturers, researchers, or insurers predict drugs that may be selected in the future. We decline the suggestions to publish additional information such as the drugs that qualified for the orphan drug exclusion or plasma-derived product exclusion or information about drugs ranked using total expenditures on a net basis; such requests would be operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the selected drug publication date, and, in the case of the request for information about total expenditures on a net basis, irrelevant to the methodology CMS is statutorily required to use for purposes of drug selection.

Comment: A few commenters recommended that CMS take steps to increase transparency around the selected drug list. These commenters provided specific recommendations, including that CMS should publish a preliminary ''watch list'' prior to the selected drug publication date; provide advance notice to manufacturers of each drug appearing on the list of up to 30 top negotiation-eligible drugs; explain the methodology and data underlying the published rankings; and disclose material assumptions used to aggregate spending across dosage forms and strengths.

Response: We appreciate the suggestions. We believe that the publication of the selected drug list and the list of up to 30 top negotiation-eligible drugs provides sufficient transparency into the drug selection process. We believe that publishing a ''watch list'' or providing manufacturers with advance notice that their drug will be on the list of up to 30 top negotiation-eligible drugs prior to the selected drug publication date is operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by the selected drug publication date. We therefore decline to adopt these recommendations. In response to the recommendations that CMS explain the methodology and data underlying the published rankings and disclose material assumptions used to aggregate spending across dosage forms and strengths, we direct readers to §§ 429.120 and 429.125, respectively, which provide details on these processes.

Comment: A commenter supported CMS' proposal in § 429.100(e) to require Primary Manufacturers to notify CMS at least 30 calendar days prior to introducing new NDC–11s, stating that this requirement is essential for program oversight.

Response: We agree and thank this commenter for their support.

Final Decision: After consideration of public comments, we are finalizing § 429.100 as proposed.

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 proposed 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 proposed 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 final 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 final 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 proposed 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 final rule.

Finally, we proposed 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 the proposed rule, we proposed to modify this methodology. We proposed 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).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters supported CMS' proposal to evaluate total expenditures to the cent, rather than to the dollar as under prior policy, when determining 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). These commenters stated that the proposal is a practical regulatory improvement that improves accuracy in drug selection.

Response: We thank these commenters for their support.

Comment: A commenter stated that as the Negotiation Program expands and drug selection decisions impact an increasing number of supply chain entities, interested parties will require greater certainty regarding how CMS identifies and ranks negotiation-eligible drugs. This commenter recommended that CMS clearly define all datasets, variables, calculations, decision rules, and criteria used to determine eligibility, ranking, and selection, including how CMS will identify and evaluate drugs with the same total expenditures to the cent, but the commenter did not specify which aspects of these processes require further details in their view. This commenter also recommended that CMS evaluate the potential market effects of ranking negotiation-eligible drugs with the same total expenditures based on which drug has the earliest-approved FDA application, asserting that this methodology could inadvertently disadvantage products that have experienced follow-on competition from generics or biosimilars.

Response: We appreciate this commenter's input. We believe this final rule provides robust details regarding how we identify qualifying single source drugs (§ 429.125), calculate total expenditures (§ 429.120), rank and identify negotiation-eligible drugs (§ 429.115), and identify selected drugs (§ 429.105). For example, § 429.120(a) sets forth that we will use gross covered prescription drug costs for PDE records that meet the criteria described in § 429.120(a)(1) through (a)(5) to calculate total expenditures under Part D; likewise, § 429.120(b) sets forth that we will use total allowed charges on OM Part B claims that meet the criteria in § 429.120(b)(1)(i) through (b)(1)(vi), in addition to total allowed charges that would have been applicable under OM Part B for each MA encounter data record for Part B services that meet the criteria described in § 429.120(b)(2)(i) through (b)(2)(ix). To provide another example, § 429.125(b) describes the public sources—which include, but are not limited to RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file—that we use to identify the active moiety/active ingredient in a potential qualifying single source drug.

While we appreciate the recommendation to evaluate the potential market effects of ranking negotiation-eligible drugs with the same total expenditures to the cent based on which drug has the earliest-approved FDA application, we disagree with the premise that this methodology could disadvantage products with generic or biosimilar competition because a potential qualifying single source drug would not be a qualifying single source drug that could become a negotiation-eligible drug or selected drug if CMS determines that a generic drug is approved or a biosimilar is licensed for the potential qualifying single source drug, and such generic drug or biosimilar is subject to Bona Fide Marketing.

Final Decision: After consideration of public comments, we are finalizing § 429.105 as proposed.

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 at proposed a § 429.105 and section II.B.2. of this final 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 final 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 Dashboard [20] and the Medicare Part D

[20] Available at: *https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard*. Of note, this dashboard excludes MA data for Part B beneficiaries.

Drug Spending Dashboard,[21] 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 final rule, we also proposed 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 the 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 included 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) and (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 proposed 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 proposed 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 selected drug 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 final rule, and in proposed § 429.110(i) of the proposed rule includes the proposed requirements for the calculation of the rebate.

Consistent with section 1198(2) of the Act and proposed § 429.30, there would be 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.

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

[21] Available at: *https://data.cms.gov/tools/medicare-part-d-drug-spending-dashboard.*

§ 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 proposed 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 proposed § 429.110(c)(1)(i) require 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)(1)(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 1192(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 proposed 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 approved by FDA.
- CMS has identified clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline.

We proposed 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 proposed 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 United States 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 proposed 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 proposed 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 proposed 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 proposed 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 (SEC) 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 proposed at § 429.110(g)(1)(i)(B) to notify each Reference Manufacturer named in a successful Biosimilar Delay Request. We proposed 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 final 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 proposed 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 proposed 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 proposed 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) of the Act include requirements for an Additional Delay Request. We proposed 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 proposed 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 proposed 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 proposed 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) and (i))

As discussed previously, CMS proposed 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 proposed 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 proposed 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 section II.B.6.d. of this final

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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters suggested that CMS expand the Initial Delay Request submission window beyond 30 days so that Biosimilar Manufacturers have sufficient time to respond. A commenter recommended that CMS publish the opening and

closing dates of the submission window not less than 90 days before the window opens so that sponsors can sequence regulatory submissions around it. A commenter requested that CMS provide advance notice of a Reference Drug's potential or actual selection so that Biosimilar Manufacturers have reasonable advance notice to prepare a request for delay. A commenter requested CMS publish the number of Initial Delay Requests and Additional Delay Requests received and the number of requests granted, as well as a list of all Reference Drugs for the requests that were submitted.

Response: We thank the commenters for their suggestions. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, this final rule describes the timing for the submission of a request for a biosimilar delay in accordance with section 1192(f) of the Act (the ''Biosimilar Delay'') and is based on a set timeline in the statute and operational constraints related to the drug selection process. CMS must make a full determination and may not immediately delay the selection of a Reference Drug whilst making a complete determination of the requirements specified in section 1192(f) of the Act to determine the outcome of a request to delay the inclusion of a Reference Drug by one initial price applicability year (an ''Initial Delay Request''). Further, the deadline for an Initial Delay Request will be set as close to the selected drug publication date as is administratively feasible. We adopted this timeline under the authority granted in section 1192(f)(1)(B)(ii) of the Act to set the time, form, and manner of Biosimilar Delay requests, and have exercised this authority to establish a timeline (which is described in section II.B.3. of this final rule) that allows CMS to carefully review the Initial Delay Request documentation and, if applicable, to request follow-up information from the manufacturer of a biosimilar (the ''Biosimilar Manufacturer'') on its Initial Delay Request. The timeline ensures that we will have adequate time to review follow-up data and make a well-informed determination. These timing and operational constraints do not allow for any additional notice or to extend the submission period beyond 30 days.

In response to commenters' requests to publish data used to make determinations regarding the Reference Drug and to publish the list of all Reference Drugs for submitted Initial Delay Requests, we reiterate the response provided to similar comments in the Negotiation Program Guidance and the revised guidance for initial price applicability year 2026. Specifically, the submission of an Initial Delay Request does not guarantee that a Reference Drug would be a selected drug absent the Initial Delay Request, nor does it guarantee that the Initial Delay Request will be granted even if the Reference Drug would be a selected drug absent the Biosimilar Delay. CMS, therefore, will not publish a list of Biosimilar Manufacturers submitting an Initial Delay Request or CMS' determinations. However, as described in section II.B.3. of this final rule, we will notify each Biosimilar Manufacturer that submits an Initial Delay Request of CMS' determination regarding such request on or after the selected drug publication date for the initial price applicability year as described in § 429.110(g)(1)(i)(A). We will also notify each Reference Manufacturer named in a successful Initial Delay Request, as described in § 429.110(g)(1)(i)(B). Further, as described in § 429.110(g)(2), 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 set forth in § 429.100.

Comment: A couple of commenters asked CMS to allow submissions of requests as close as reasonably possible to the selected drug publication date for the initial price applicability year to ensure that decisions are informed by the most recent developments. A commenter requested that CMS maintain the end of December submission due date for the Initial Delay Request. A few commenters suggested that CMS accept supplemental late-breaking information that may impact CMS' determination. A commenter suggested CMS permit Biosimilar Manufacturers to submit amendments to address potential errors or omissions during CMS' consideration process. A couple of commenters requested that CMS create a dispute resolution or appeal process for CMS' determination that a Biosimilar does not qualify for the Biosimilar Delay.

Response: We thank commenters for this feedback. Consistent with our response to the comments immediately prior, and our response to similar comments in the Negotiation Program Guidance, the timing for submission of a request for a biosimilar delay is based upon the statute and operational constraints related to the drug selection process. We decline at this time to create a dispute resolution process for the Biosimilar Delay. The statutory deadlines for the Negotiation Program do not provide enough time to establish a dispute resolution process before the selected drug publication date. Additionally, we believe that the submission period allows manufacturers to provide the relevant data to support their application for the Biosimilar Delay and, following the close of the submission period, for CMS to request additional information or to address an error or omission as applicable, and we decline to use a dispute resolution process for a manufacturer to supplement a submission.

Comment: A commenter suggested CMS provide notice to the Reference Manufacturer of an Initial Delay Request or an Additional Delay Request, before a determination of whether the Initial Delay Request or Additional Delay Request will be granted. A couple of commenters suggested that CMS provide notice to Reference Manufacturers of unsuccessful Initial Delay Request or Additional Delay Request submissions. In the event that an Initial Delay Request or Additional Delay Request is not granted, a couple of commenters recommended that CMS provide the Biosimilar Manufacturer that requested the Initial Delay Request or Additional Delay Request rationale for why the Initial Delay Request or an Additional Delay Request was not granted.

Response: We thank this commenter for their input. Information regarding the timing for CMS to notify each Reference Manufacturer named in a successful Biosimilar Delay Request is discussed in section II.B.3.b. of the proposed rule (91 FR 36250) and in § 429.110(g)(1)(i)(B). Additionally, on this same page of the proposed rule, CMS stated we would not notify Reference Manufacturers named in unsuccessful Initial Delay Requests as an unsuccessful Initial Delay Request does not impact selection. Accordingly, notifying the Reference Manufacturer of an unsuccessful Initial Delay Request would generate more administrative burden for CMS and as such, we decline to adopt this suggestion in the final rule. As finalized at § 429.110(g)(1), we will provide a written notice to the Biosimilar Manufacturer regarding whether the request was successful or unsuccessful. If unsuccessful, we will specify the reason for the unsuccessful request.

Comment: A commenter requested that CMS clarify the date by which a Biologics License Application filed under section 351(k) of the PHS Act (hereinafter referred to as 351(k) application) must be accepted for review by the FDA to qualify for a

Biosimilar Delay, and suggested that CMS permit a Biosimilar Manufacturer to update its Initial Delay Request with changes to the 351(k) BLA filing status on any date on or before the January 31st prior to the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests a Biosimilar Delay. A commenter requested that CMS permit Biosimilar Manufacturers who have not yet filed 351(k) applications to submit Initial Delay Requests. A commenter supported CMS' proposal to identify a date by which the Biosimilar Manufacturer's BLA must be accepted for review by the FDA to be considered for the Initial Delay Requests. A few commenters requested that CMS permit Biosimilar Manufacturers who have filed 351(k) applications but have not yet had the application accepted by the FDA for review, to submit Initial Delay Requests, subject to acceptance of the application. A commenter recommended that Biosimilar Manufacturers be able to submit information accompanying the Initial Delay Request that indicates it is likely that the 351(k) application will be approved by the publication of the selected drug list for the applicable initial price applicability year. A commenter recommended that CMS permit Biosimilar Manufacturers to submit information as part of the Initial Delay Request demonstrating that the FDA is likely to approve the 351(k) application. A few commenters argued that CMS' proposed approach to determining the high likelihood standard is closer to requiring certainty of launch than high likelihood of launch within the biosimilar delay window, which is not aligned with statute. A commenter stated that CMS' proposal to determine whether there is a high likelihood that a Biosimilar will be licensed and marketed within the statutory timeframe by January of the calendar year of the selected drug publication date for the initial price applicability year for which the Reference Drug would be selected absent the Initial Delay Request is not the best reading of the statute but did not provide an alternative interpretation for consideration.

Response: We thank commenters for their feedback. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027 and the revised guidance for initial price applicability year 2026, we believe that section II.B.3. of the proposed rule aligns with the statutory language and do not find reason to allow for additional circumstances that would meet the licensure component of high likelihood determination. As stated in section 1192(f)(3)(A) of the Act, the Secretary must find that the BLA has been accepted for review or approved by the FDA. We also state that in section II.B.3. of the proposed rule that the Biosimilar Manufacturer must be operationally ready, and that the finding is made reasonably in advance of the selected drug publication date to allow CMS to finalize the selected drug list. As such, commenters' suggestions are either inconsistent with the statute requiring the BLA to have been accepted for review or approved by the FDA, or infeasible due to the timing required to release the selected drug list.

As stated in § 429.110(d)(1), we 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 CMS to review the information and finalize the selected drug list for the initial price applicability year. As discussed in the Negotiation Program proposed rule (91 FR 36249), this would enable CMS to use the most recent possible data to make a determination on the Initial Delay Request and before publication of the selected drug list for the initial price applicability year. Accordingly, we decline to specify a date by which a 351(k) application must be accepted by the FDA to qualify for a Delay in this forum.

As discussed in the Negotiation Program proposed rule (91 FR 36248), we believe that the best interpretation of section 1192(f)(1)(A) of the Act requires that the 351(k) application has been approved or accepted for review by the FDA by January 15 of the selection year. Additionally, as discussed in the Negotiation Program proposed rule (91 FR 36250), in accordance with section 1192(f)(3)(B) of the Act, we must use information from items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act submitted to us 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. We believe the requirements detailed in that section are the best read of the statute for ascertaining that there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. The statute requires clear and convincing evidence, and contrary to commenters' arguments, the requirements detailed in the section are intended to comply with this evidentiary standard. Commenters' alternative proposals did not satisfy this evidentiary standard, and as such, we decline to modify our proposed approach at this time.

Comment: A few commenters stated that CMS should request all information under its authority in section 1192(f)(1)(B)(ii)(II) of the Act that a Biosimilar Manufacturer deems relevant to determination of a high likelihood of marketing and offered suggestions on the types of supportive evidence that CMS should consider when evaluating whether a Biosimilar Manufacturer is likely to meet the High Likelihood Deadline. A couple of commenters stated that much of the information relevant to marketing of a Biosimilar is commercially sensitive and therefore may not be reflected in the types of information set forth in § 429.110(f)(1) and therefore requested that CMS permit Biosimilar Manufacturers to submit confidential business information as part of the Initial Delay Request process. A commenter requested that CMS establish protection for treatment of confidential commercial or financial information in the regulatory text, as well as the preamble.

Response: We thank commenters for their feedback. In response to commenters' suggestions to use any evidence as acceptable evidence under section 1192(f)(1)(B)(ii)(II) of the Act, we note that this provision applies only after we have first reviewed the information submitted in accordance with sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act and determine that additional information is needed from the Biosimilar Manufacturer. As discussed in the Negotiation Program proposed rule (91 FR 36247), we note that we will protect from disclosure information submitted in a Biosimilar Delay Request that is a trade secret or confidential commercial or financial information 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)). We decline at this time to amend the regulatory text regarding confidential information.

Comment: A few commenters recommended that CMS strike references to a precise launch date, stating that identifying a clearly specified launch date is not always possible, and that CMS should instead rely on other public facing statements from manufacturers indicating that they will be able to launch within the 2-year window. A commenter suggested that a Biosimilar Manufacturer should be

determined to have high likelihood of marketing the Biosimilar if either option is indicated: lack of agreements with the FTC or the Department of Justice (DOJ) prohibiting marketing of the drug; or public facing investor disclosures or manufacturing schedules indicating that marketing is set to commence within the 2-year timeframe. A couple of commenters recommended that CMS accept a ''Notice of First Commercial Marketing'', provided to the Reference Manufacturer by the Biosimilar Manufacturer at least 180 days prior to marketing of the Biosimilar, as documentation of meeting the high likelihood standard. A few commenters recommended CMS consider relevant court orders and litigation developments; litigation status and legal status; evidence of manufacturing and commercial readiness; public statements indicating readiness to launch to investors or the SEC accompanied by attestations from executives of the Biosimilar Manufacturer; other information submitted by interested parties. A commenter stated that the circumstances indicating high likelihood that CMS proposed should not represent the exclusive circumstances under which a high likelihood determination could be made. A couple of commenters supported CMS' proposal to consider disclosure about capital investment, revenue expectations, and actions consistent with the normal course of business and manufacturing schedules as part of Initial Delay Request evaluation.

Response: We thank commenters for their feedback. We appreciate commenters' concerns regarding the current items a Biosimilar Manufacturer can use to demonstrate clear and convincing evidence that that Biosimilar will be marketed before the High Likelihood Deadline. As stated previously in the Negotiation Program Guidance, CMS remains bound by the statutory constraints that the Biosimilar Manufacturer must provide ''clear and convincing evidence,'' to be found in the documentation specific in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act.[22] As discussed previously, we recognize that representatives of a manufacturer have fiduciary obligations as company representatives and legal disclosure requirements under the Securities Act of 1934 for a public traded company. We again decline to specify that statements of a fiduciary alone that the Biosimilar will be marketed and/or that there are no patent barriers demonstrate ''clear and convincing'' evidence that there is a high likelihood the Biosimilar will be marketed by the High Likelihood Deadline. We do not believe that this information alone is ''clear and convincing.'' Additionally, we disagree with commenters' suggestions that the statute permits CMS to consider an attestation as evidence separate from the specified documentation in the statute. We also disagree with the alternatives suggested by commenters for demonstrating clear and convincing evidence that the Biosimilar will be marketed by the High Likelihood Deadline because they do not account for the often complex and serial nature of patent litigation between reference product and biosimilar manufacturers prior to market entry of a biosimilar and/or whether there are patents related to the Reference Drug that could prevent the Biosimilar from being marketed before the High Likelihood Deadline.

As stated previously in the Negotiation Program Guidance, we identified examples of the type of information we may consider to be ''clear and convincing evidence'' in the documentation submitted by the Biosimilar Manufacturer including the documentation specified in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act to evaluate if the Biosimilar has a high likelihood of being marketed by the High Likelihood Deadline. As described at § 429.110(d)(2), 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. 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 proposed 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 USPTO's 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.

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

[22] Which includes: all agreements related to the Biosimilar filed with the Federal Trade Commission 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; 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 the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (for example, in filings with the SEC 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 biological product.

statements and demonstrates readiness to meet revenue expectations. As discussed in the proposed rule (91 FR 36250), we proposed these criteria because we believe they are indicative of operational readiness and should be available in the elements that we must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act. These examples are illustrative but alone may not always constitute ''clear and convincing evidence'' of a high likelihood of marketing.

Comment: A few commenters recommended that CMS consider the totality of circumstances when considering whether to grant an Initial Delay Request. A commenter recommended that CMS consider the following additional criteria when evaluating the high likelihood standard: the Biosimilar Manufacturer has not stated that it will not market the product prior to the end of the relevant period; the Biosimilar Manufacturer has not withdrawn its BLA; the Biosimilar Manufacturer is not in arrears for fees under section 744H of the FD&C Act; no manufacturing facility has ''official action indicated'' as a status; there are no clinical trial protocol amendments that would delay enrollment completion and marketing beyond the pause period. A commenter recommended that CMS consult with FDA on whether a Biosimilar is likely to meet the high likelihood threshold. A commenter requested additional transparency on how CMS evaluates the high likelihood standard.

Response: We thank commenters for their feedback. As previously stated in this section, we remain bound by the statutory constraints that the Biosimilar Manufacturer must provide ''clear and convincing evidence,'' to be found in the documentation specific in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act. The information suggested by commenters does not provide clear and convincing evidence that the patents relevant to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline, or that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline. As discussed previously, we will consider the totality of the circumstances in making a determination of whether there is a high likelihood that a Biosimilar will be licensed and marketed by the High Likelihood Deadline given the information and acceptable documentation provided as part of the Initial Delay Request. Additionally, we will not take the absence of negative information as suggested by commenters within the specified acceptable documentation as clear and convincing evidence of high likelihood that a Biosimilar will be licensed and marketed before the High Likelihood Deadline. We direct readers to the Negotiation Program proposed rule (91 FR 36249 and 36250) for more information on how CMS determines whether there is a high likelihood that a Biosimilar will be licensed and marketed before the High Likelihood Deadline as discussed in section 1192(f)(3)(B) of the Act. In the Negotiation Program proposed rule (91 FR 36250), we discussed examples of the circumstances under which the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, though clarified that the examples are not exhaustive of the information that might be included in the documentation required at section 1192(f)(3)(B) of the Act in a submission for a request for an Initial Delay Request necessary to determine ''clear and convincing evidence'' that the Biosimilar will be marketed before the High Likelihood Deadline. Finally, we believe we will have sufficient information submitted by the Biosimilar Manufacturer as part of the Initial Delay Request or Additional Delay Request to determine that there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline and declines at this time to implement a structural consultation with FDA regarding High Likelihood.

Comment: A few commenters requested that CMS remove or clarify the proposed requirement that Biosimilar Manufacturers not have pending litigation regarding patent infringement. A commenter recommended that CMS revise the standard to ''neither a court or PTAB has ruled that the Biosimilar Manufacturer has infringed on a patent'' and clarify that resolution of patent litigation be taken as clear and convincing evidence of that the Biosimilar will be marketed before the High Likelihood Deadline. A commenter supported the proposal to disqualify Initial Delay Request applications that indicate an agreement between the Reference Manufacturer and the Biosimilar Manufacturer exists to require the Biosimilar Manufacturer to submit a Biosimilar Delay Request, delay market entry, or restrict quantity sold. The commenter requested that CMS clarify what types of agreements between the biosimilar manufacturer and reference manufacturer are disqualifying and recommended clarifying that quantity limits and improper constraints restrict output, timing, or ability to compete, such as volume caps, deferring entry, or encourage substitution for an authorized biosimilar are disqualifying. The commenter requested that CMS clarify that settlements between the Biosimilar Manufacturer and the Reference Manufacturer not be automatically disqualifying, just because litigation is involved.

Response: We thank commenters for these suggestions. We refer readers to the Negotiation Program proposed rule (91 FR 36249) and proposed § 429.110(d)(2). We state 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 before the High Likelihood Deadline; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the United States 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 before the High Likelihood Deadline. In response to the commenter requesting that resolution of patent litigation be taken as sufficient clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, we note that other barriers may be present that could prevent the Biosimilar Manufacturer from being operationally ready by the High Likelihood deadline. Accordingly, we decline at this time to remove the requirement that Biosimilar Manufacturers not have pending litigation regarding patent infringement and decline at this time to revise the standard by which High Likelihood is determined.

Consistent with our response to similar comments in the Negotiation Program Guidance, the final guidance for initial price applicability year 2027, and the revised guidance for initial price applicability year 2026, we reiterate that section 1192(f)(2)(D)(iv) of the Act excludes certain Biosimilar Manufacturers from the Biosimilar Delay if CMS determines that the Biosimilar Manufacturer is the same as the Reference Manufacturer or that the Biosimilar Manufacturer has entered into any agreement with the Reference

Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay, or that restricts the quantity (either directly or indirectly) of the Biosimilar that may be sold in the United States over a specified period of time. We confirm that the existence of an agreement alone between a Biosimilar Manufacturer and a Reference Manufacturer does not disqualify the Biosimilar from being eligible for a delay. CMS will consider all information available at the time of the Biosimilar Manufacturer discloses the existence of an agreement between the Biosimilar Manufacturer and Reference Manufacturer to determine whether the agreement requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request or restricts the quantity (either directly or indirectly) of the Biosimilar that may be sold in the United States over a specified time consistent with the statute. At this time, we decline to provide specific details on what types of agreements would be considered disqualifying and refers readers to the characteristics of such agreements as described in section 1192(f)(2)(D)(iv) of the Act. We decline to provide specific details at this time to avoid inadvertently providing an inflexible or exhaustive list of agreements that could unintentionally leave out certain agreements that, as required by statute, would require denying the Biosimilar Delay Request.

Comment: A few commenters opposed the October deadline by which CMS proposes to require Biosimilar Manufacturers to demonstrate licensing and marketing during the Initial Delay Period or Second Delay Period, and recommended CMS evaluate at the end of the year instead. A couple of commenters recommended that CMS provide an initial determination of whether licensing and marketing have occurred in October, accompanied by a public notice, before making a final determination at the end of the year. A commenter suggested requiring ongoing updates from the Biosimilar Manufacturer regarding launch dates. A couple of commenters requested that CMS provide additional transparency on how a Biosimilar Manufacturer can demonstrate that it has made a significant amount of progress toward both licensure and marketing of the Biosimilar since the submission of the Initial Delay Request and provide additional clarity on timing of when a determination of licensure and marketing would be made.

Response: We appreciate these comments. In the Negotiation Program proposed rule (91 FR 36251), and in proposed § 429.110(g)(3), we proposed 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 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 successful Initial Delay Requests submitted with respect to initial price applicability year 2029 for example, we will 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 in fall 2027. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027, and in accordance with section 1192(f)(2)(B) of the Act, in specifying the end of October date, we considered the time needed for a Biosimilar Manufacturer to submit an Additional Delay Request and for CMS to review such a request prior to publication of 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. We will specify the notification date based on the comments received and operational considerations to allow for sufficient notice prior to the publication of the selected drug list for the initial price applicability year. Accordingly, we believe that a date no later than the end of November is an appropriate deadline by which to determine if a Biosimilar has been licensed or marketed. If a Biosimilar Manufacturer fails to demonstrate that the Biosimilar has been licensed or marketed by the end of November deadline following an Additional Delay Request, there are no additional steps that the Biosimilar Manufacturer may take. As such, we believe that a deadline for the Biosimilar Manufacturer to demonstrate licensure and marketing following an Additional Delay Request that is later than the deadline, for the Initial Request is appropriate.

In response to commenters requesting additional transparency on how CMS determines 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, as described in the Negotiation Program proposed rule (91 FR 36251) and 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 toward 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).

Specifically, we proposed 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 § 429.110(f)(1), including any follow-up documentation requests from CMS to the manufacturer described in § 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 § 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. Accordingly, we believe the approach described previously is both sufficiently transparent and permits holistic consideration of information that is relevant to determining that a significant amount of progress has been made. As such, we decline at this time to change this process.

Comment: A few commenters requested that CMS identify examples of situations under which a product would qualify for an Additional Delay Request. A few commenters recommended criteria under which CMS should grant an Additional Delay Request including: FDA approval of a BLA; BLA under review by FDA; complete response letter sent by the FDA, but BLA resubmitted; disclosures to investors or the SEC that the Biosimilar Manufacturer plans to market the product by the specified date; manufacturing schedules indicating that the Biosimilar Manufacturer is likely to market the product; agreements with FTC or DOJ that do not block the Biosimilar Manufacturer from marketing the product; and attestations by the Biosimilar Manufacturer that it plans to market the product by the applicable date.

Response: We thank these commenters for their suggestions. As described in the Negotiation Program proposed rule (91 FR 36251) and proposed at § 429.110(e)(1)(i) and (ii), Biosimilar Manufacturers of a Biosimilar that was identified in a successfully granted Initial Delay Request (consistent with proposed § 429.110(f)) are eligible to submit an Additional Delay Request if 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. Additionally, we would determine whether the requirements for the Initial Delay Request, as described in § 429.110(c)(1)(ii), remain met. If the requirements described at § 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 § 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, we are required to use certain types of information that may constitute ''clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress towards both such licensure and marketing of such biosimilar biological product''. As suggested by a commenter, we may consider agreements filed with the FTC, manufacturing schedules, and disclosures to investors. Other suggestions by the commenter do not fall under that scope, but could describe specific facts that are not themselves sources of evidence, but could be part of CMS' assessment if found in one of the sources of evidence. We decline to establish that any of the commenters' alternative criteria for granting Additional Delay Requests, by themselves, are sufficient for granting such requests, as this would be inconsistent with the statutory requirements for granting Additional Delay Requests. Further, these alternatives are inconsistent with CMS' holistic consideration when reevaluating whether there is a high likelihood that the Biosimilar will be licensed and marketed by the High Likelihood Deadline and whether, on the basis of clear and convincing evidence, the Biosimilar Manufacturer has made a significant amount of progress towards both licensure and marketing of the Biosimilar since the submission of the Initial Delay Request.

Comment: A commenter supported CMS' proposed rebates payable by the Reference Manufacturer of a drug that would have otherwise been selected when a Biosimilar fails to launch. A couple of commenters requested that CMS provide additional clarity on how it intends to operationalize administration and payment of retrospective rebates when a Biosimilar fails to launch, and whether prior failures to launch by the Biosimilar Manufacturer will factor into delay determinations. A commenter requested that CMS not make failure to market rebates punitive. A commenter recommended that CMS establish an automatic post-delay audit framework if a manufacturer is granted an Initial Delay Request or Additional Delay Request and require the payment of rebates and refer the matter to the FTC for antitrust review if the Biosimilar Manufacturer fails to engage in Bona Fide Marketing. A commenter requested that CMS clarify how it will treat rebate liability for concurrent Initial Delay Requests when one Biosimilar Manufacturer launches and the other does not.

Response: We thank commenters for their support. We refer readers to § 429.110(i) for additional information on how we intend to operationalize administration and payment of rebates when CMS determines that a Biosimilar has not been licensed and marketed during the applicable period. As stated in proposed § 429.110(h)(1)(ii), we 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, 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.3 of this final 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. As stated in the Negotiation Program proposed rule (91 FR 36252) and as described in § 429.110(h)(2)(i), 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 two 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. The question regarding concurrent Initial Delay Request submissions is addressed accordingly; if at least one Biosimilar from an Initial Delay Request or a different Biosimilar biological product is licensed and marketed, the Reference Drug would no longer meet the criteria to be a selected drug and would be excluded from the selected drug list for the initial price applicability year that follows 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.

Where no MFP is agreed upon because the Reference Drug no longer met the criteria to be a selected drug for an applicable list, the Reference Manufacturer would not be subject to rebates for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the delay.

To clarify how the rebate owed by the Reference Manufacturer for the initial price applicability year for which an Initial Delay Request was granted will be calculated, we refer readers to section II.B.3.c. of this final rule and reiterate that this rebate is not owed by the Biosimilar Manufacturer that submits an 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 § 429.110(i)(1), if (1) CMS delayed the selection and negotiation of a Reference Drug for one or two 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, as described in § 429.110(i)(4) 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 would be calculated as follows:

- In accordance with section 1192(f)(4)(B)(i) of the Act and as described in § 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 § 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 § 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 described in § 429.110(i)(4)(iii) and the rebate amount for units covered under Part D as described in § 429.110(i)(4)(ii).

As discussed previously in this section, CMS is bound by statute for calculation of rebate amounts. We also refer commenters to § 429.130 for further discussion on the approach to how we will evaluate Bona Fide Marketing.

Final Decision: After consideration of public comments received, we are finalizing § 429.110 as proposed, with the following non-substantive technical modifications. For clarity, at § 429.110(i)(5), we are replacing the cross-reference to ''(h)(2)'' with ''(h)(2)(i)'' to more precisely describe the paragraph we intended to cross-reference. Additionally, to address a drafting error and align with section II.B.3.b. of the proposed rule (91 FR 36249), at § 429.110(d)(2)(i)(C), we are adding ''and is not contingent on the outcome of pending litigation''. The paragraph now states: 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 and is not contingent on the outcome of pending litigation.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 described 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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.[23] 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 final 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 proposed 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 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 final 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters shared feedback on CMS' proposed approach to identifying negotiation-eligible drugs. A few commenters opposed CMS' proposal, in particular the proposal to combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs, as proposed in § 429.105(a). A couple of commenters suggested that nothing in statute permits CMS to combine total expenditures under Part B and Part D when evaluating or selecting drugs for negotiation. A commenter supported CMS' proposal to combine total expenditures when ranking and selecting negotiation-eligible drugs.

Response: We thank these commenters for their feedback and appreciate the support from the commenter. Consistent with our response to similar comments in the Negotiation Program Guidance, we disagree with the commenters who stated that the proposal to combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs is inconsistent with statute. Section 1192(b)(1)(A) of the Act requires that CMS rank negotiation-eligible drugs ''according to the total expenditures for such drugs under parts B and D of title XVIII.'' Such statutory language directs CMS to combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs.

Final Decision: After consideration of public comments received, we are finalizing § 429.115 as proposed.

5. Calculation of Total Expenditures (§ 429.120)

As described in sections II.B.2., II.B.4., and II.B.6.c.2. of the proposed rule, we proposed 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 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 proposed to codify the definition of total expenditures in section 1191(c)(5) of the Act at § 429.20, and we proposed 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 proposed 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; [24] (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.[25]

[23] 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.

[24] A PDE record is considered final action based on the final action indicator for the claim and claim line.

[25] 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 Medicare drug exclusion (proposed § 429.125(e)(2)) and to identify negotiation-eligible drugs and selected drugs (proposed §§ 429.115 and 429.105). We proposed 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

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b. Calculation of Total Expenditures Under Part B

At § 429.120(b), we proposed 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 OM Part B claims data (inclusive of beneficiary coinsurance and Medicare payment) and a comparable amount calculated using 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 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 final rule, we reiterate and expand upon the discussion in the Negotiation Program Guidance.

More than half (54 percent [26]) 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 final rule we proposed 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] 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[ed]'' 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 proposed 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.

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.

[26] 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/*.

Accordingly, we proposed 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; [27] (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 proposed 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; [28] (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.[29] 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. Then, we would 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))).

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 proposed to use the apportionment 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters strongly supported this proposal at § 429.120(b), explaining that, because over half of Medicare enrollees are enrolled in MA plans, and overall use of prescription drugs is similar amongst fee-for-service and MA enrollees, CMS would exclude roughly half of total spending on drugs payable under Medicare Part B by only using Part B claims data. In these commenters' views, an approach that would calculate total expenditures under Part B of Title XVIII of the Act using only Part B claims data would skew the negotiation-eligible drug list toward drugs covered under Part D and away from drugs payable under Part B.

A few commenters opposed the proposal to include MA expenditures in the calculation of total expenditures under Part B, stating that statute prohibits this approach. A commenter stated that CMS did not identify legal authority that supports its decision to categorize MA expenditures as Part B expenditures in the Negotiation Program Guidance or the Negotiation Program proposed rule. A few commenters stated that the statute permits CMS to consider only payments made ''under Part B'' and not payments made under MA plans, which is Part C of the Medicare statute. A commenter stated that by referring to ''total expenditures for drugs payable under Part B'', as opposed to total expenditures under Part B, CMS improperly conflates coverage and payment. A commenter disagreed with our explanations in the Negotiation Program proposed rule for why we believe MA expenditures ought to be included in ''total expenditures under part B of title XVIII'' for purposes of the Negotiation Program. First, they disagreed with our read of section 1852(a)(1) of the Act, which requires MA plans to offer the same benefits as those in Part B fee-for-service, stating that the payments for these drugs are financed under a different mechanism under Part C as compared to Part B. Second, they asserted that the inclusion of ''an individual who is enrolled in an MA plan under part C'' in the definition of a ''maximum fair price eligible individual'' at section 1191(c)(2)(B) of the Act has no bearing on the type of expenditures that should be included when identifying negotiation-eligible drugs. Third, they stated that the exclusion in section 1191(c)(5) of the Act of expenditures for a drug or biological product that are bundled or packaged extends to MA expenditures since CMS makes capitated payments to MA plans on a per member per month basis.

[27] An OM Part B claim is considered final action based on the final action indicator for the claim and claim line.

[28] 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.

[29] See: *https://www.cms.gov/medicare/coding-billing/ncci-medicare.*

Response: We thank the commenters for the support and feedback. We reiterate our statement in the Negotiation Program Guidance and the proposed rule (91 FR 36254) that the statute is best read as permitting the inclusion of MA expenditures for drugs payable under Part B and administered to MA enrollees in total expenditures under Part B. We agree with commenters that contended that, by excluding such data, a significant portion of spending on drugs payable under Part B would be excluded because of the number of enrollees in MA plans.[30]

We disagree with the commenters that contended that the statute does not permit CMS to include MA expenditures in the calculation of total expenditures under Part B, as well as with the claim that we did not identify statutory authority justifying the inclusion of MA expenditures. In both the Negotiation Program Guidance and proposed rule (91 FR 36254 through 36255), we provided robust discussion of our statutory authority for including MA expenditures in ''total expenditures under part B of title XVIII'' for purposes of the Negotiation Program, including as follows: (1) section 1852(a)(1) of the Act requires MA plans to provide to enrollees the ''benefits under the original [M]edicare [Fee-For-Service] program''; (2) including MA expenditures in the calculation of total expenditures under Part B is consistent with the statutory approach reflected in the definition at section 1191(c)(2)(B) the Act of a ''maximum fair price eligible individual'', which considers ''individual[s] enrolled in an MA plan'' to be ''include[ed]'' 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; and (3) section 1191(c)(5) of the Act's definition of total expenditures under Part B does not exclude MA expenditures, despite explicitly specifying that expenditures where payment for the drug is bundled with payment for another Part B service are excluded from such definition.

Additionally, we disagree with the commenter's position that the exclusion in section 1191(c)(5) of the Act of expenditures for a drug or biological product that are bundled or packaged extends to MA expenditures. MA expenditures do not constitute bundled payments or packaged payments under this provision. CMS pays MA organizations a capitated, risk-adjusted amount per enrollee each month, in accordance with Part C of title XVIII of the Act, including section 1853 of the Act, as further specified in 42 CFR 422, subpart G. This per-enrollee payment covers the full scope of a beneficiary's Medicare-covered services for that period, regardless of the beneficiary's actual utilization. By contrast, we interpret the reference to bundled payment for purposes of section 1191(c)(5) of the Act to refer to reimbursements of a single, predetermined amount for a defined clinical episode of care, such as a surgical procedure bundled under a prospective payment system. Likewise, we interpret the reference to packaged payment in such section to refer to single payments that cover multiple related ancillary items or services, such as drugs and biologicals that function as supplies to a primary procedure. Because MA expenditures reflect per-enrollee capitation rather than episode-based reimbursement or a packaged payment, the exclusion stated in section 1191(c)(5) of the Act does not apply to MA expenditures.

We refer readers to the discussion in the proposed rule, and the discussion earlier in this section of the final rule, for further discussion of each of these points.

Comment: A few commenters supported the methodology CMS proposed at § 429.120(b)(2) for calculating MA expenditures using MA encounter data. A couple of these commenters recommended that CMS continue to refine this methodology to ensure MA expenditures are fully and accurately accounted for and noted that the methodology is only as good as the data underlying it; in their view, MA encounter data is often incomplete and inconsistent, which is likely to lead to CMS underestimating MA expenditures for certain drugs. A commenter recommended that CMS pair codification of § 429.120(b) with (1) concrete steps to improve MA encounter data completeness and accuracy and (2) increased transparency into how CMS validates MA encounter data.

A few commenters stated that CMS' proposed methodology to estimate MA expenditures by identifying MA units from encounter data and then determining what Medicare would have paid under FFS is a poor proxy for expenditures on drugs payable under Part B and paid for by MA plans, stating that it is inappropriate to assume that MA plans' expenditures for drugs payable under Part B will equal or average the Part B FFS limits and fails to satisfy statute's instruction to determine ''expenditures under Part B''. These commenters stated that, in other contexts such as the Part B Drug Inflation Rebate Program, CMS has declined to measure MA utilization due to significant operational complexities and recommended that CMS do the same here. These commenters also raised concerns that CMS faces significant delays in accessing complete and final MA encounter data and asserted that, if Congress had intended CMS to use MA expenditures, it would have given CMS more time to account for the data lag for MA units by permitting a larger gap between the selected drug publication date and the end of the 12-month period over which expenditures must be measured. A commenter stated that MA encounter data does not necessarily indicate which drug was administered, for example, where a drug is assigned to a nonspecific HCPCS code or multiple drugs are assigned to a single HCPCS code. A commenter stated that the data lag and imprecision of MA encounter data make it harder for interested parties to identify which drugs are most likely to be selected.

Response: We appreciate the feedback and suggestions. As we noted in the Negotiation Program Guidance and the proposed rule (91 FR 36255), 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. We will monitor this approach and make refinements as needed in the future. We note that the Part B Drug Inflation Rebate Program is governed by separate statutory provisions, and its timelines and uses of data, including how MA encounter data would be used in that Program, differ significantly from that in the Negotiation Program. The operational complexity of incorporating MA encounter data into the Part B Drug Inflation Rebate Program reflects the distinct purposes that the use of that data would serve within that Program; our proposal to incorporate MA encounter data into our measurement of total expenditures under Part B for Negotiation Purposes reflects the

[30] Data through March 2026 shows that MA enrollment has risen to 55 percent of eligible Medicare beneficiaries. Meredith Freed et al., ''Medicare Advantage in 2026: Enrollment Update and Key Trends,'' KFF (June 5, 2026). *https://www.kff.org/medicare/medicare-advantage-enrollment-update-and-key-trends/.*

statutory authority and purposes of this Program. We therefore disagree that the operational constraints we have identified within the Part B Drug Inflation Rebate Program mean that we must also exclude MA expenditure data from the calculation of total expenditures under Part B in the Negotiation Program. We also disagree with the concerns that data lags will prohibit our use of Part B encounter data. In recent internal analysis, we observed that 55 percent of MA encounter data are currently submitted by MA organizations within 30 days and 85 percent of MA encounter data are currently submitted within 60 days of the claim from date. We agree with the commenter that stated that MA encounter data does not always indicate which drug was administered in cases where a qualifying single source drug is assigned to a HCPCS code with other products, though we note that this is also the case for Medicare Part B claims. We refer this commenter to our apportionment methodology set forth in § 429.120(b)(3). We also note that, typically, ''single source drugs and biologicals'' as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes.

Comment: A commenter recommended that, when determining Part B expenditures that would have been applicable for MA enrollees, CMS should account for the reduced payment amounts that CMS would make for 340B drugs if the 340B payment policy in the CY 2027 Hospital Outpatient Prospective Payment System Proposed Rule is finalized.

Response: We thank the commenter for their input but note the comment is related to the *Payment Adjustment for 340B-Acquired Drugs Based on Results of the Medicare OPPS Drug Acquisition Cost Survey* proposed in the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center payment system proposed rule (91 FR 41737). CMS will consider any future changes to Medicare payment policies when they are effective.

Final Decision: After consideration of public comments, we are finalizing § 429.120 as proposed.

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 proposed 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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.[31] 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 proposed 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 proposed that we may further investigate whether such NDA(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 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)[32] 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 proposed 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 proposed 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 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.[33] 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 proposed 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 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 name represents a genuine difference in active moiety/active ingredient.

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

[31] 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 final 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.

[32] See: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-and*.

[33] See 21 CFR 314.3(b) (defining the terms ''active ingredient'' and ''active moiety'').

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 Act [34] 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: CMS received many comments on its reading of the statute to aggregate all dosage forms and strengths of a drug with the same active moiety and the same holder of a NDA or of a biological product with the same active ingredient and the same holder of a BLA, for the purposes of identifying potential qualifying single source drugs as proposed at § 429.125(b). Many commenters disagreed with CMS' approach to identifying a qualifying single source drug and asserted that the proposal at § 429.125(b) contradicts the statute and stated that they do not believe that CMS has the statutory authority to aggregate qualifying single source drugs across multiple NDAs/BLAs. These commenters claimed that the statute defines a qualifying single source drug in reference to a distinct NDA or BLA, and some of these commenters stated that it would be reasonable and appropriate that such a definition would align with the FDA's approval and licensure processes under section 505(c) of the FD&C Act or section 351(a) of PHS Act. A few commenters claimed that the statute defines a qualifying single source drug by reference to the definition of a ''covered Part D drug'' at section 1860D–2(e) of the Act, which in turn cross-references the definition of a ''covered outpatient drug'' at section 1927(k)(2) of the Act. The commenter asserted that, under section 1927(k)(2) of the Act, whether a single source drug is a distinct ''covered outpatient drug'' is based on whether the product is approved pursuant to a distinct NDA or BLA, and the only exception to this rule is for line extensions. A few commenters asserted that the reference to ''payment under Part B'' in section 1192(e)(1) of the Act requires CMS to identify a qualifying single source drug exclusively by reference to how the CMS identifies the drug for payment purposes and asserted that CMS has long interpreted section 1847A of the Act as identifying distinct single source drugs payable under Part B by reference to whether they have distinct NDAs or BLAs. Some commenters stated that CMS' failure to limit the identification of a potential qualifying single source drug to products approved or licensed under a distinct NDA/BLA will be detrimental to future innovation and patient access to medications and limit manufacturers from researching follow-on innovations such as extended release formulations and new indications, including indications for rare diseases.

Response: We thank these commenters for their input. As discussed in responses to similar comments in the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027, and the Negotiation Program Guidance, section 1192(d)(3)(B) of the Act directs CMS to ''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 or package size or package type of the drug'' for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug. Identifying potential qualifying single source drugs on the basis of active moiety, active ingredient, or antigen component, as applicable, permits us to effectuate these statutory directives. We use ''active ingredient'' and ''active moiety'' (or, for vaccines for infectious disease(s), ''antigen component'') as markers for active substances that remain constant across changes in strength, dosage form, or release mechanism. These terms also comport with the ordinary meaning of ''drug''. See, for example, Drug, Black's Law Dictionary (12th ed. 2024) (''A substance intended for use in diagnosis, cure, treatment, or prevention of disease.''); Drug, Merriam-Webster's Collegiate Dictionary (12th ed. 2025) (''[A] substance used as a medication or in the preparation of medication''). We adopted this approach in guidance for initial price applicability years 2026, 2027 and 2028, and this final rule to ensure that a new dosage form, strength, or new formulation of a drug with the same ''active ingredient'', ''active moiety'', or ''antigen component'', but that received a new FDA approval or licensure, would not avoid or delay eligibility for negotiation contrary to these statutory provisions. Indeed, complying with the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths and new formulations has the effect of reducing manufacturer incentives to engage in ''product hopping,'' as well as counteracting the effects of existing ''product hopping'' on the Negotiation Program. Ensuring that drug and biological products are not inappropriately excluded from, or delayed from inclusion in, the Negotiation Program based on modest or minor modifications is consistent with the purpose of the statute, which is to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures ''to compute and apply the maximum fair price 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.'' In addition, section 1194(e)(1)(D) of the Act instructs CMS, for purposes of the negotiation process discussed in further detail in subpart F of this final 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. The aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act are clear and are designed to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries in accordance with statute. Because different dosage forms and strengths, as well as different formulations, containing the same active moiety/active ingredient may be approved or licensed under multiple NDAs or BLAs, the suggestion from commenters to define a qualifying single

[34] 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.

source drug in reference to a distinct NDA or BLA is inconsistent with sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act. Contrary to the views of some commenters, sections 1192(d)(3)(B) and 1196(a)(2) of the Act require the aggregation of data across dosage forms and strengths of the drug, including new formulations of the drug, and not based on the specific formulation or package size or package type of the drug, thereby necessarily establishing that the statutory selection and negotiation procedures apply more broadly than to a distinct NDA or BLA.

For these same reasons, we disagree that the references in section 1192(e)(1) of the Act to the definition of a ''covered Part D drug'' and to payment which ''may be made under part B'' require CMS to identify a qualifying single source drug with respect to a distinct NDA or BLA. This language in section 1192(e)(1) of the Act sets forth one of multiple statutory criteria that CMS must use to identify qualifying single sources drugs. Specifically, section 1192(e)(1) of the Act requires that a qualifying single source drug that is a drug as set forth in section 1192(e)(1)(A) of the Act or that is a biological product as set forth in section 1192(e)(1)(B) of the Act must be ''a covered part D drug (as defined in section 1860D–2(e))'' or ''a drug or biological product for which payment may be made under part B of title XVIII'' or both. Were we to accept the commenters' view that this statutory language requires CMS to identify a qualifying single source drug with respect to a distinct NDA or BLA, we would fail to give full effect to the aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act. Under our understanding of the statutory language, section 1192(e) of the Act, including its references to a ''covered Part D drug'' and to payment which ''may be made under part B'', sets forth the qualifying conditions for drug and biological products; these qualifying conditions do not supersede nor conflict with—and, to the contrary, must be read in concert with—the aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act. Unlike the views offered by some commenters, our understanding of the statutory language gives 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 applying an interpretation of the statute that follows the statutory criteria for the identification of a qualifying single source drug under section 1192(e) of the Act and, consistent with sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act, gives effect to the statutory policy that a drug that may be selected for negotiation includes multiple dosage forms and strengths and formulations of that drug.

Comment: A commenter expressed appreciation for CMS' consistent approach to the identification of potential qualifying single source drugs. This commenter stated that section 1192(d)(3)(B) of the Act clarifies the intent of policymakers to apply negotiated prices across dosage forms and strengths of a selected drug, which the commenter asserted necessitates the approach CMS proposes in the rule for identifying potential qualifying single source drugs. This commenter stated that the approach proposed by CMS will prevent gaming and abuse of the Negotiation Program that may occur if manufacturers were able to prevent a high-revenue product from qualifying for negotiation through product hopping and obtaining new NDAs and BLAs, effectively resetting the clock on the statutory 7- and 11-year periods before a drug or biological product may qualify for selection.

Response: We thank the commenter for the support. We agree that the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths, as described in the proposed rule, is expected to reduce incentives for pharmaceutical manufacturers to engage in ''product hopping.'' This ensures that the Negotiation Program selects drugs for negotiation that have high total expenditures under Part B and Part D of the Medicare program regardless of variations like differences in formulation or packaging.

Comment: A commenter requested that CMS provide greater transparency regarding its methodologies for identifying the active moiety/active ingredient in a potential qualifying single source drug, stating that public sources cited by CMS (such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Bases of Strength file) aggregate and display FDA information, as well as other data, for secondary purposes, such as clinical terminology standardization, drug information directories, and labeling repositories, and the classifications in these sources do not necessarily track the regulatory distinctions that are determinative for FDA's active moiety/active ingredient identification. The commenter recommended that CMS use NDA and BLA approvals, approved labeling, and Orange Book and Purple Book data, as the primary and binding sources for identifying active moieties/active ingredients, with supplementary databases such as RxNorm, OpenFDA, FDALabel, and DailyMed used only to confirm, and never to override, those records. The commenter requested that CMS publish an analytic plan describing what information from each public source will be used and how CMS will reconcile differences that may arise between the sources, stating that without a defined hierarchy specifying which sources will be used in the event of conflict, manufacturers will have insufficient information about how CMS will treat their products. The commenter also requested that any FDA consultation undertaken to resolve a naming or classification question should be disclosed to the affected manufacturer, with a defined opportunity for the manufacturer to respond, and the consultation—including the information provided to FDA, the FDA division consulted, and FDA's response—should be documented in the administrative record.

Response: We appreciate the input. We maintain that manufacturers have sufficient notice of the information we use to identify active moieties/active ingredients, as described in this final rule. Because information on active moiety/active ingredient names are not always standardized across systems, we believe that using a combination of public sources, including those cited by CMS (for example, FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file, OpenFDA, FDALabel, RxNorm, and DailyMed), in addition to FDA consultation, as applicable, is the best way to accurately identify active moieties/active ingredients. We consider the body of information across sources together, which we believe produces a more accurate and complete identification than relying on any one source alone. This holistic, non-hierarchical approach preserves our ability to incorporate FDA feedback to ensure accurate identification of the active moiety/active ingredient consistent with the statute. Where these sources conflict or CMS seeks additional clarity, we may consult FDA. We recognize that some fields within these sources are not fully standardized because the sources themselves draw on multiple, non-uniform inputs. To that end, CMS incorporates RxNorm to provide normalized names and unique identifiers for medicines and drugs, consistent with RxNorm's stated goal to

provide such normalization.[35] Further, RxNorm incorporates FDA's approved labeling information in the form of FDA SPL. FDA's SPL is a published standard used by FDA for processing and managing labeling and labeling changes. In response to the request that CMS use NDA and BLA approvals, FDA approved labeling, and Orange Book and Purple Book data, we reiterate that our proposal referred to FDA and FDA-derived sources such as FDALabel, DailyMed, and OpenFDA. Further, in addition to FDA's SPL, OpenFDA incorporates many other FDA sources such as Orange Book, Drugs@FDA and the NDC Directory. Lastly, FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file is an FDA publication. Therefore, we believe our proposal already incorporates the sources suggested by the commenter and do not believe it is necessary to add these additional FDA sources to the non-exhaustive list of sources already identified. In response to the request that CMS publish an analytic plan, we believe this final rule provides sufficient detail on how CMS identifies active moieties/active ingredients. Our approach is holistic and sensitive to drug-specific details rather than a rigid assessment of data fields. In response to the request that CMS disclose any FDA consultation to the affected manufacturer, we note that section 1192(e) of the Act sets forth the requirements for the identification of qualifying single source drugs and does not require nor contemplate that CMS disclose such consultations to manufacturers.

Comment: A commenter requested that CMS exclude Part B vaccines from the Negotiation Program and clarify that influenza vaccines do not meet the qualifying single source drug definition due to annual changes in antigen component composition.

Response: We note that nothing in the statute indicates that CMS should categorically exclude such vaccines from being potential qualifying single source drugs nor from the Negotiation Program more broadly. We refer this commenter to our proposals for vaccines for infectious disease(s) at § 429.125(b)(3) and 429.125(c)(2)(i), which account for changes to the antigen component(s) in such vaccines.

Comment: A few commenters supported and recommended that CMS finalize the proposal at § 429.125(b)(3) to identify a potential qualifying single source drug for a vaccine for infectious disease(s) on the basis of such vaccines' antigen component on such vaccines' labeling. A couple of these commenters stated that this approach is consistent with the statute and vaccine science and will support public health goals. One of these commenters stated that this policy reflects the statute's product-specific design and asserted that same statutory logic supports applying the 7- and 11-year periods to each drug product or biological product based on the approval or licensure of its own NDA, BLA, or supplement.

Response: We appreciate the support and feedback. To the commenter who stated that § 429.125(b)(3) supports applying the 7- and 11-year periods to each drug product or biological product based on the approval or licensure of its own NDA, BLA, or supplement, we note that vaccines for infectious disease(s), as we stated in the proposed rule (91 FR 36257, 36261), are more appropriately assessed using their antigen component due to the evolving nature of pathogen strains over time. Some manufacturers of vaccines for infectious disease(s) update the antigen component(s) of their products through supplemental BLAs. In such cases, we would consider the vaccine for infectious disease(s) approved through the supplemental BLA to be a separate potential qualifying single source drug under § 429.125(b)(3) from the product that FDA initially licensed because these products do not have the same antigen component. It is therefore appropriate to use the earliest date of licensure for the earliest-approved FDA application (whether that is a BLA or supplemental BLA) belonging to the BLA holder and that contains the antigen component used to identify that unique potential qualifying single source drug, as we proposed at § 429.125(c)(2)(i), for purposes of identifying the starting date from which to measure the 11-year period described in § 429.125(c)(2). In contrast, it would not be appropriate to use the approval date of a supplemental NDA or BLA with the same active moiety/active ingredient for purposes of identifying the starting date from which to measure the 7- or 11-year periods for drugs and biological products that are not vaccines for infectious diseases because the approval of such a supplemental NDA or BLA would not result in a new potential qualifying single source drug.

Final Decision: After consideration of public comments, we are finalizing § 429.125(a) and (b) as proposed, but with a technical modification to § 429.125(b)(4) to improve organizational clarity that is discussed in the next section of this final rule. We direct readers to the discussion in section II.B.6.a.1. of this final rule for our consideration of public comments received on the policy proposed at § 429.125(b)(4)(i) as well as our summary of the aforementioned technical modification to § 429.125(b)(4).

(1) Fixed Combination Drugs

At proposed § 429.125(b)(4), for the purpose of identifying potential qualifying single source drugs and subject to the proposed policy for specific fixed combination drugs that are new formulations proposed at § 429.125(b)(4)(i) to clarify our treatment of new formulations, we proposed 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

[35] See: *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html#how-is-rxnorm-produced.*

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 previous 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 the 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.

In the Negotiation Program proposed rule (91 FR 36258), we stated that, since publishing the Negotiation Program Guidance, we have continued to consider program integrity risks posed by certain fixed combination drugs. Specifically, we stated that we were 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 product, 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 product. 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, we explained that we were 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).

We explained that, in this scenario, we were 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 product 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.[36]

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 product 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(a), we would calculate the combined total expenditures under Part B and Part D separately for the original product and the new formulation. We stated our belief 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 product 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 product, 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. We explained that this dynamic presents program integrity risks because evaluating the time since approval or licensure separately for the original product 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 product 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

[36] Other provisions of the Act further support our policy to aggregate across NDA/BLAs when identifying the dosage forms and strengths and new formulations that constitute a qualifying single source drug. This policy is described in section II.B.6.a. of this final rule. For purposes of our discussion of fixed combination drugs in this section II.B.6.a.1. of the final rule, we focus on the most relevant provisions for purposes of our proposed policy, which are the instructions at sections 1192(d)(3)(B) and 1196(a)(2) of the Act to aggregate across dosage forms and strengths and new formulations.

for high expenditure, single source drugs and biological products.

Second, if the original product 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. We explained that 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 product 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 proposed at § 429.125(b)(4)(i) a policy for specific fixed combination drugs that are new formulations: 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.[37]

We proposed the policy at § 429.125(b)(4)(i) because the program integrity concerns this policy would address relate primarily to biological products 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 integrity concerns raised by fixed combination drugs that are new formulations have not yet impacted drug selection but may soon do so as more drugs with significant total expenditures under Part B become qualifying single source drugs and negotiation-eligible drugs. We stated that we did 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 proposed 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.

The proposal incorporated previous 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 stated that we understood 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 stated that we understood the importance of developing criteria that allow the proposed policy for specific fixed combination drugs that are new formulations to be operationalized in a consistent and objective manner over a large set of active moieties/active ingredients/antigen components. We stated our belief that the terminology proposed at § 429.125(b)(4)(i) would achieve both these goals.

First, we stated our belief that the criteria proposed at § 429.125(b)(4)(i) can be operationalized in a consistent and objective manner using public sources. Specifically, we proposed 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 final 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 stated that we may also consult with FDA, as appropriate. We solicited comments on recommended approaches to inform CMS identification of active moiety(ies)/active ingredient(s)/antigen component(s) that enable an alternative 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, we stated that focusing on active moieties/active ingredients/antigen components that enable an alternative route of administration would reduce the number of products qualifying for the proposed policy for specific fixed combination drugs that are new formulations 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 stated our belief that

[37] 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.

the terminology proposed at § 429.125(b)(4)(i) would currently only impact biological products licensed under BLAs.

We explained that, 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. Identifying 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 purpose of implementing the Negotiation Program.

We noted that we also considered comments on how a modification to CMS' fixed combination drug policy would potentially impact pharmaceutical innovation. Although a few of the previous 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 agreed with this latter argument and noted further our belief that the policy proposed at § 429.125(b)(4)(i) would effectuate sections 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 reiterated 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 directed readers to proposed § 429.510(e) and section II.F.3.d.1. of the Negotiation Program proposed rule for discussion of CMS' approach to adjusting the starting point for an initial offer based on section 1194(e)(2) factors, which include factors related to clinical benefit as compared to therapeutic alternatives.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the policy for specific fixed combination drugs that are new formulations proposed at § 429.125(b)(4)(i) and recommended finalizing. Many commenters agreed with CMS that the proposed policy is important for addressing a program integrity risk in which manufacturers may develop minor reformulations of existing drugs to 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. A few commenters remarked that the inclusion of a component that enables a different route of administration, including the addition of hyaluronidase to enable subcutaneous administration, largely represents a repackaging of the existing product and should not transform the existing drug into a new one for purposes of Medicare pricing. Some commenters stated that the proposal at § 429.125(b)(4)(i) is appropriately tailored to address this scenario. A commenter stated that the proposal appropriately balances program integrity concerns while preserving the existing framework for other fixed combination drugs, which will appropriately balance the goals of reducing Medicare drug costs and encouraging biosimilar competition. A commenter stated that the proposal is consistent with existing CMS policy, such as Medicaid line extension rules, establishing that minor product modifications should not allow manufacturers to avoid the consequences of competition or price regulation. A few commenters stated that the proposal is consistent with the statutory mandate at sections 1192(d)(3)(B) and 1196(a)(2) of the Act to aggregate data across dosage forms and strengths of a drug, including new formulations.

Response: We thank the commenters for their support.

Comment: Many commenters recommended that CMS withdraw the proposed policy for specific fixed combination drugs that are new formulations and instead treat a product approved under a distinct NDA/BLA, including a fixed combination drug, as a unique qualifying single source drug. Many of these commenters stated that the modification to CMS' fixed combination drug policy would contradict statute because, in their view, statute requires CMS to identify qualifying single source drugs in reference to a distinct NDA or BLA, and FDA approves or licenses fixed combination products separately from products with a single active moiety/active ingredient. In their view, CMS' existing aggregation framework already contradicts statute, and the commenters contended that the proposed policy worsens that asserted contradiction. Many commenters stated that the proposal would result in premature negotiation-eligibility for products that would qualify for the criteria proposed at § 429.125(b)(4)(i) because 7- or 11-years, as applicable, would not have elapsed between that product's own approval or licensure and the selected drug publication date.

Some commenters disagreed with CMS' statement in the proposed rule (91 FR 36258) that certain fixed combination drugs that are new formulations may be appropriately understood as different formulations of the same drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act; these commenters asserted instead that these statutory provisions are fully satisfied by aggregating expenditures and applying the MFP across the dosage forms and strengths (including new formulations such as an extended-release formulation) that are marketed under a qualifying single source drug's unique NDA or BLA. A few commenters stated that the fixed combination drug policy is unmoored from statute because statute says nothing about route of administration as a basis for determining whether products should be aggregated into the same qualifying single source drug. A couple of commenters stated that, if Congress intended CMS to aggregate fixed combination drug products with products containing only a subset of their active moieties/active ingredients, it would have done so expressly as it did for line extensions under the Medicaid Drug Rebate Program and Part D Drug Inflation Rebate Program.

Response: We appreciate the commenters' feedback. In response to the commenters that asserted that the statute requires CMS to identify qualifying single source drugs in reference to a distinct NDA or BLA, we direct readers to our response to

comments on this topic in section II.B.6.a. of this final rule. In response to comments stating that the proposal at § 429.125(b)(4)(i) would result in premature negotiation-eligibility for products that qualify for the proposal, we refer readers to our discussion in section B.6.b. of the proposed rule (91 FR 36261) and this final rule describing how CMS identifies the date of approval or licensure, as applicable, for a potential qualifying single source drug with more than one FDA application, including a fixed combination drug that qualifies for the policy proposed at § 429.125(b)(4)(i).

We disagree with the commenters who stated that a fixed combination drug described in proposed § 429.125(b)(4)(i) should not be aggregated under the same qualifying single source drug pursuant to section 1192(d)(3)(B) and 1196(a)(2) of the Act and that route of administration should not be used as a component of qualifying single source drug identification. The proposed policy is consistent with the statutory directives. Section 1196(a)(2) of the Act requires that CMS establish ''procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of the drug.'' Likewise, section 1192(d)(3)(B) of the Act requires CMS to 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'' (emphasis added). The terms ''including'' and ''such as'' in section 1192(d)(3)(B) of the Act make clear that the extended release example is illustrative, not exhaustive. That example, however, illustrates how our proposed policy is consistent with these statutory aggregation directives. With respect to extended release formulations, these directives reflect the understanding that such formulations are new formulations of the same underlying drug, albeit ones that are delivered through a modified release mechanism. Here too, fixed combination drugs in which an additional active moiety, active ingredient, or antigen component enables an alternative route of administration for its co-administered active moiety(ies), active ingredient(s), or antigen component(s) is likewise best understood as part of the same underlying drug as the product with only the co-administered active moiety(ies), active ingredient(s), or antigen component(s), albeit with an alternative route of administration enabled by the additional active moiety, active ingredient, or antigen component. Just as CMS may aggregate extended release formulations under our statutory directives—even though FDA may approve or license those formulations under a separate NDA or BLA from the original formulation—CMS may also consider a fixed combination drug as part of the same qualifying single source drug as the product with the co-administered active moiety(s), active ingredient(s), or antigen component(s), even if FDA approves or licenses the fixed combination drug under a separate NDA or BLA. Finally, including a fixed combination drug described in proposed § 429.125(b)(4)(i) with the original product in the same potential qualifying single source drug, pursuant to sections 1192(d)(3)(B) and 1196(a)(2) of the Act, is consistent with commonly held and plain language understandings of what constitutes the same underlying drug, as evidenced, at least in part, by how the pharmaceutical and financial industries generally view these products. For example, manufacturers commonly market products that meet the criteria of the proposed policy, including formulations of a drug with hyaluronidase, under the same branding as the original, non-hyaluronidase formulation. Similarly, filings (for example, filings with the SEC) pertaining to the marketing of the fixed combination drug and the original formulation commonly refer to and calculate the products' sales and contributions to revenue in the collective. Accordingly, we believe the proposed policy reflects the best understanding of the statutory aggregation directives. Similarly, we disagree with the commenters analogizing to the Medicaid Drug Rebate Program and Part D Drug Inflation Rebate Program line extension provisions to argue that the policy is not authorized under the statute. For the same reasons previously discussed, we believe the proposed policy accords with the best reading of the statutory aggregation provisions, and the lack of even more granular statutory language singling out these types of drugs does not undermine that conclusion.

Comment: A few commenters stated that the proposed modification for fixed combination drugs would violate the holding of *Loper Bright* because, in their view, CMS does not apply the single, best meaning of statute. These commenters stated that CMS is interpreting statute differently beginning in initial price applicability year 2029 than it did in prior initial price applicability years, as well as interpreting the same statutory text differently depending on the category of drug or biological product. A few commenters asserted that the proposed modification is arbitrary and capricious because it singles out products with an additional active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration without providing sufficient statutory, scientific, and regulatory basis for doing so. A few commenters asserted that CMS does not adequately explain its rationale for aggregating products that contain an additional active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration, while continuing to treat as separate products that add a new active moiety, active ingredient, or antigen component that does not create a new formulation and enable an alternative route of administration. One of these commenters stated that CMS did not identify evidence demonstrating that products that contain an additional active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration present a greater program integrity risk than other fixed combination drug products that would be aggregated as a unique qualifying single source drug under the general policy proposed at § 429.125(b)(4).

Response: We appreciate the commenters' perspectives. However, we disagree that the policy proposed at § 429.125(b)(4)(i) would not apply the best meaning of the statute or that it applies an inconsistent interpretation of the statute. Our proposal reflects our consistent interpretation of the statutory provisions requiring aggregation across dosage forms and strengths, inclusive of new formulations. Generally, and as relevant here, we have applied these statutory directives by identifying qualifying single source drugs as all dosage forms and strengths, including new formulations, with shared active moiety(ies), active ingredient(s), or antigen component(s). Our proposed § 429.125(b)(4)(i) continues to identify qualifying single source drugs on the basis of shared active moiety(ies), active ingredient(s), or antigen component(s), consistent with this interpretation of the statutory aggregation directives. Proposed § 429.125(b)(4)(i) marks a specific application of this interpretation to products with multiple active moieties, active ingredients, or antigen components as compared to prior policy. While prior policy always treated each unique combination of

active moieties, active ingredients, or antigen components as distinct potential qualifying single source drugs, proposed § 429.125(b)(4)(i) reflects our determination that for a narrow, limited set of products—that for which the addition of a distinct active moiety, active ingredient, or antigen component enables an alternative route of administration, as compared to a product without such additional active moiety, active ingredient, or antigen component but with otherwise shared active moiety(ies), active ingredient(s), or antigen component(s)—the new product would most appropriately be understood as a new formulation of the original product under section 1192(d)(3)(B) and 1196(a)(2) of the Act. For the reasons discussed in our proposed rule and in this final rule, including in the previous comment response, we believe our interpretation of this statute, and the application thereof represented by this proposed policy, reflects the best reading of the relevant statutory provisions. We disagree with the contention that we interpret the same statutory text differently depending on the category of drug or biological product; rather, the general fixed combination drug policy proposed at § 429.125(b)(4) and the proposed policy for new formulations at § 429.125(b)(4)(i) apply the same interpretation of sections 1192(d)(3)(B) and 1196(a)(2) of the Act to different categories of fixed combination drugs, only one of which fits the statutory description of a new formulation of the same drug. We also note that the proposed policy applies equally to all fixed combination drugs that meet the criteria set forth at proposed § 429.125(b)(4)(i), and likewise, the general fixed combination drug policy applies equally to all fixed combination drugs that do not meet these criteria.

We disagree with commenters who argued that proposed § 429.125(b)(4)(i) demonstrates that CMS is interpreting statute differently beginning in initial price applicability year 2029 than it did in prior initial price applicability years. As previously explained, proposed § 429.125(b)(4)(i) is consistent with our longstanding interpretation of the statutory aggregation directives. Rather, our proposed application of this interpretation with respect to products meeting the criteria at proposed § 429.125(b)(4)(i) is reflective of concerns that our prior policy, if applied to these products, could produce results that are inconsistent with our interpretation and create program integrity risks. We have long heard concerns from interested parties that, under the general fixed combination drug policy, certain fixed combination drugs could pose program integrity risks to the Negotiation Program. In comments on the initial guidance for initial price applicability year 2026 [38] and draft guidance for initial price applicability year 2027 and MFP effectuation for 2026 and 2027,[39] interested parties raised concerns that the general fixed combination drug policy creates program integrity risks in which CMS would treat an original formulation and a fixed combination drug that is a new formulation as separate qualifying single source drugs, which could result in certain drugs not being selected, being selected later than statutorily required, or avoiding application of the MFP if utilization shifts to the fixed combination drug product that is a new formulation of the original formulation. Those guidance documents established policy for initial price applicability years 2026 and 2027 in which we selected drugs based on total expenditures under Part D. Because the fixed combination drug program integrity risks primarily relate to biological products that are more likely payable under Part B, we did not believe it necessary for the implementation of the statute to establish a policy for specific fixed combination drugs that are new formulations at that time. In accordance with section 1192(a) of the Act, CMS was required to select drugs based on total expenditures under Part B and Part D beginning in initial price applicability year 2028. Therefore, when establishing policy for initial price applicability year 2028, we took the opportunity to solicit comments on our treatment of fixed combination drugs since initial price applicability year 2028 was the first initial price applicability year in which we identified and selected drugs based on total expenditures under Part B. Given the complexity of the issue, we deemed it prudent to take more time to evaluate policy options and stated our intent to address this program integrity risk in rulemaking beginning in initial price applicability year 2029. As we noted in the proposed rule (91 FR 36259), the program 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 therefore believe it necessary at this point to address the program integrity risk posed by certain fixed combination drugs in this rule. The proposed policy thus does not represent an inconsistent interpretation of statute across initial price applicability years but rather an updated policy applying the statute's aggregation requirements in response to the identification of a specific program integrity risk, input from interested parties, and the aggregation issues raised, largely, by the incorporation of total expenditures under Part B into the drug selection process beginning in initial price applicability year 2028.

Finally, commenters asserted that CMS did not adequately explain its rationale for aggregating fixed combination drugs that include an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration in accordance with proposed § 429.125(b)(4)(i). We disagree and refer readers to the robust discussion in the proposed rule (91 FR 36258 through 36259) of our program integrity concerns related to certain fixed combination drugs, which the proposal at § 429.125(b)(4)(i) specifically and narrowly targets. We also refer readers to our response to comments earlier in this section explaining why fixed combination drugs described in proposed § 429.125(b)(4)(i) are reasonably understood as new formulations comparable to extended-release formulations. Finally, we refer readers to comments summarized earlier in this section, which agreed that the inclusion of a component that enables a different route of administration, including the addition of hyaluronidase to enable subcutaneous administration, largely represents a repackaging of the existing product and should not be considered as a separate qualifying single source drug under the Negotiation Program.

Comment: Some commenters disagreed with CMS' statement in the proposed rule that the criteria proposed at § 429.125(b)(4)(i) can be operationalized in a consistent and objective manner using public sources. A few commenters asserted that the public sources cited by CMS in the proposed rule—such as RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file—do not address how CMS will determine whether an added ingredient creates a new formulation or enables an alternative route of administration. Some commenters stated that CMS does

[38] *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.*

[39] *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

not have the expertise to determine whether an active moiety, active ingredient, or antigen component creates a new formulation or enables an alternative route of administration, and that such expertise sits at FDA instead. A couple of commenters stated that CMS effectively acknowledges that it lacks a framework for determining whether an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration via its solicitation for comments on approaches to inform CMS' identification of such components. A commenter supported CMS' proposed approach to operationalizing proposed § 429.125(b)(4)(i), stating that the approach is a practical and administrable way to address program integrity risks.

Response: We appreciate the feedback. We agree with the commenter that stated that our approach to operationalizing proposed § 429.125(b)(4)(i) is practicable and administrable, and we disagree with commenters' concerns about the potential for inconsistent operationalization of proposed § 429.125(b)(4)(i). As we stated in the proposed rule (91 FR 36259), our proposal incorporated feedback from previous 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,'' which we used to articulate the nature of the issue underlying our concern. In the proposed rule, we proposed to identify fixed combination drugs that qualify for the policy identified at § 429.125(b)(4)(i) using criteria that are available in public sources. To provide additional transparency, we take this opportunity to provide further information about how CMS will use these public sources in a consistent and objective manner.

We will identify the active moieties, active ingredients, or antigen components in a fixed combination drug consistent with how we identify active moieties, active ingredients, and antigen components generally under § 429.125(b) for purposes of identifying potential qualifying single source drugs. Specifically, and as described in section II.B.6.a. of the proposed rule, we will 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), and antigen component(s) of drugs, biological products, and vaccines for infectious disease(s), as applicable. We will identify any fixed combination drug that shares one or more active moiety, active ingredient, or antigen component with another drug, biological product, or vaccine for infectious disease(s), as applicable, with the same NDA/BLA holder. Consistent with section II.B.6.a.1. of the proposed rule, we will use public sources such as, but not limited to, Orange Book, Purple Book, Drugs@FDA, and DailyMed to identify the route(s) of administration for 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 such fixed combination drug. To provide further information on additional public sources we may use, as requested by commenters, we affirm in this final rule that we may also use public sources including, but not limited to, FDA SPL resources such as FDALabel to identify the route(s) of administration.

Then we will identify active ingredients, active moieties, and antigen components, as applicable, that, when co-administered with one or more other active moiety(ies), active ingredient(s), or antigen component(s), enable an alternative route of administration for such co-administered active moiety(ies), active ingredient(s), or antigen component(s). Our determination that a fixed combination drug contains a CMS-identified route-enabling active ingredient, active moiety, or antigen component that meets the criteria proposed at § 429.125(b)(4)(i) is a product-specific evaluation, which may include consideration of whether the original product and the fixed combination drug have different routes of administration and whether the information or descriptions within product labeling for such product indicate that the additional active moiety, active ingredient, or antigen component enables the alternative route of administration. We may also consult with FDA, as appropriate, about the information contained in these public sources. We will consider this information holistically to determine whether the fixed combination drug is best understood under sections 1192(d)(3)(B) and 1196(a)(2) of the Act and proposed § 429.125(b)(4)(i) as a new formulation of 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 such fixed combination drug, and therefore should be aggregated into the same qualifying single source drug as 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 believe this determination falls squarely within CMS' expertise and aligns with the directives at sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

Comment: Some commenters opposed finalizing the proposed policy for specific fixed combination drugs that are new formulations but made the following recommendations about how CMS should operationalize the policy were it to be finalized. A few commenters recommended that the determination as to whether a fixed combination drug qualifies for the proposed policy should be made in consultation with FDA, the patient community, and using product-specific evidence that the additional component exists solely to enable a different route of administration. A commenter recommended that any such input from the public should be narrow and time-limited so that it does not delay the drug selection process or convert CMS' identification of qualifying single source drugs into a broader adjudicatory proceeding. A commenter asked that the burden of demonstrating that a product is not subject to proposed § 429.125(b)(4)(i) should sit with CMS and manufacturers, not with patients. A couple of commenters urged CMS to apply the proposed policy prospectively only to products approved or licensed after the effective date of the final rule. A few commenters stated that CMS should give affected manufacturers, patients, caregivers, and clinicians advance notice that CMS intends to apply proposed § 429.125(b)(4)(i) to a product and create an appeals process. A commenter asked CMS to clarify how aggregation under proposed § 429.125(b)(4)(i) would operate if the two products carry different FDA-approved indications, and how CMS would treat a product under the proposed policy if the additional active moiety, active ingredient, or antigen component is separately licensed and marketed. A commenter recommended that when CMS determines that a product qualifies for the proposed policy, CMS should publish the relevant NDA or BLA, NDC and HCPCS mapping, shared and added components, route of administration, and FDA sources supporting its conclusion.

Response: We appreciate the suggestions. We refer readers to our

immediate previous response and to the discussion in section II.B.6.a.1. of this final rule for details on how CMS intends to operationalize proposed § 429.125(b)(4)(i). There, we detail the public sources and processes we will use to implement the proposed policy. We affirm that we will use product-specific information to implement the proposed policy and may consult with FDA about information contained in the public sources described previously. We also take this opportunity to clarify for these commenters that nothing in the text of proposed § 429.125(b)(4)(i) suggests that the additional active moiety, active ingredient, or antigen component must exist *solely* to enable an alternative route of administration; rather, the regulatory text states that the additional component ''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)''.

We affirm that CMS' implementation of the proposal at § 429.125(b)(4)(i) will not modify the timing of the drug selection process nor require interested parties to demonstrate that a product does or does not qualify for the proposed policy. While we appreciate the suggestions, we decline to create an advance notice or appeals process or to consult interested parties such as patients. Section 1192(e) of the Act sets forth the requirements for the identification of qualifying single source drugs and does not require nor contemplate engagement with patients or with manufacturers via an advance notice or appeals process. Additionally, an advance notice or appeals process and patient consultation is operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by the selected drug publication date. We also decline to apply the proposed policy prospectively only to products approved or licensed after the effective date of the final rule due to the program integrity risks that currently marketed fixed combination drugs that are new formulations pose to the Negotiation Program. Further, prospective-only application of the proposed policy would be inconsistent with the statutory directives at sections 1192(d)(3)(B) and 1196(a)(2) of the Act. In response to the commenter's requested clarifications, we affirm that FDA-approved indications are not considered for purposes of aggregation in the drug selection process, and we reiterate that a qualifying single source drug can include dosage forms and strengths and formulations approved or licensed under different NDA/BLAs. In response to the commenter's suggestion that we publish certain information for products that qualify for the proposed policy, we refer readers to our discussion in section II.B.1. of this final rule and § 429.100, which affirms that, for a selected drug identified under proposed § 429.125(b)(4)(i), we will publish the shared active moiety(ies), active ingredient(s), or antigen component(s) identified under proposed § 429.125(b)(4)(i), plus any additional active moiety, active ingredient, or antigen component included in new formulations of such selected drug. Additionally, for all selected drugs, including those identified under proposed § 429.125(b)(4)(i), we will publish the NDC–11s CMS identifies in accordance with § 429.100(c)(1) and the corresponding NDC–9s and HCPCS codes (as applicable). We decline to publish the routes of administration and NDA(s)/BLA(s) because this information is publicly available. We also decline to publish FDA sources supporting our conclusion that a fixed combination drug is a new formulation because we believe this final rule provides sufficient detail on our operationalization process, including public sources that we may consult.

Comment: Some commenters expressed views on whether proposed § 429.125(b)(4)(i) appropriately targets drug and biological products that pose true program integrity risks to the Negotiation Program. A few commenters supported the proposed policy but stated that CMS should modify the proposal to broaden the scope of products that the provision would target, or at minimum retain flexibility to broaden the proposal in the future based on new fact patterns. These commenters expressed concern that, under the language at proposed § 429.125(b)(4)(i), manufacturers could still avoid or delay selection and application of the MFP by adding an active moiety, active ingredient, or antigen component to an existing qualifying single source drug to create a new formulation that is not different from the original product in a clinically meaningful way but does not meet the proposed § 429.125(b)(4)(i) criteria because: (1) the additional active moiety, active ingredient, or antigen component leaves the route of administration unchanged for the new formulation; or (2) the additional active moiety, active ingredient, or antigen component is not the sole enabler of the alternative route of administration (for example, because the change in route of administration may also depend on factors such as excipients, device design, or stabilizers). To address the first scenario, a couple of commenters recommended that CMS evaluate whether a fixed combination drug is a new formulation using the clinically meaningful difference standard that CMS used to articulate its program integrity concerns related to fixed combination drugs in the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. To address the second scenario, a commenter recommended that CMS modify the text of proposed § 429.125(b)(4)(i) to require that the relevant active moiety, active ingredient, or antigen component ''creates a new formulation and *helps to* enable an alternative route of administration . . .'', and another commenter recommended that CMS define ''enables'' to mean that the added component materially enables or materially facilitates the alternative route of administration for the shared component. In contrast, some commenters expressed concern that the proposal at § 429.125(b)(4)(i) would impact more products than would be appropriate but did not provide specific examples. Similar to the prior commenters, these commenters recommended that CMS consider whether the added active moiety, active ingredient, or antigen component creates a clinically meaningful different product from the original product, but in contrast to the prior commenters' view, they believed that fewer drugs would qualify for the proposal at § 429.125(b)(4)(i) if CMS were to employ a clinically meaningful difference standard.

Response: We appreciate the support and suggestions. We acknowledge the concern that manufacturers could still avoid or delay selection, or if selected, avoid application of the MFP, by including an active moiety, active ingredient, or antigen component in an existing qualifying single source drug that may be considered to result in a new formulation but does not meet the criteria proposed at § 429.125(b)(4)(i). With respect to the first scenario, in which a manufacturer includes an active moiety, active ingredient, or antigen component in an existing qualifying single source drug to create a new formulation that leaves the route of administration unchanged, we acknowledge that the proposed policy would not reach such a product. As we explained previously and in the

proposed rule (91 FR 36259), the proposed policy addresses the specific program integrity concern of which we are currently aware. We acknowledge commenters' concern that broader criteria—such as language in the Negotiation Program Guidance citing active moieties/active ingredients not biologically active against the disease state(s) for which the drug is indicated—could more comprehensively address program integrity risks across a wider range of product modification strategies. As noted in the proposed rule (91 FR 36260), we considered this approach. Commenters did not provide examples of fixed combination drugs that would not qualify for proposed § 429.125(b)(4)(i) but, they believe, should qualify. We continue to believe proposed § 429.125(b)(4)(i) is appropriately tailored to the program integrity risks with the general fixed combination drug 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 will continue to monitor the Negotiation Program for evidence of program integrity risks that are in tension with sections 1192(d)(3)(B) and 1196(a)(2) of the Act and which pose program integrity risks beyond those addressed by proposed § 429.125(b)(4)(i), and we may consider additional modifications to our fixed combination drug policy in the future.

With respect to the second scenario, in which the change in route of administration depends not only on the additional active moiety, active ingredient, or antigen component but also on other product features such as excipients, device design, injection volume, concentration, or stabilizers, we take this opportunity to clarify that the additional active moiety, active ingredient, or antigen component need not be the sole enabler of the alternative route of administration in order for a product to qualify for proposed § 429.125(b)(4)(i). A product may qualify for the proposed policy if the added component creates a new formulation and enables the alternative route of administration for the co-administered active moiety, active ingredient, or antigen component, even if other product features also contribute to making the alternative route possible. We believe this reading is consistent with proposed § 429.125(b)(4)(i) and addresses the concern raised by these commenters. Requiring the additional component to be the sole enabler of the alternative route of administration would be inconsistent with the purpose of the proposed policy and could allow manufacturers to avoid aggregation by arguing that the alternative route of administration also depended on other product features. We believe the existing regulatory text, as clarified herein, is sufficiently clear, and we do not believe a modification to the regulatory text or definition of ''enables'' is necessary at this time.

In response to the commenters who expressed concern that the scope of products that would be impacted by the proposal at § 429.125(b)(4)(i) is too broad, we respectfully disagree. We note that commenters generally understood the scope of the products affected by proposed § 429.125(b)(4)(i) to be fixed combination drug products that contain hyaluronidase, or a hyaluronidase variant, which aligns with our general expectation of the scope of this policy and the example provided in section VI.C.1. of the Negotiation Program proposed rule. As we previously stated, proposed § 429.125(b)(4)(i) narrowly addresses the program integrity risks with the general fixed combination drug policy and responds to previously received input summarized in the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027, and the Negotiation Program Guidance in which interested parties raised concerns about such program integrity risks.

Comment: Many commenters opposed the proposal at § 429.125(b)(4)(i) because, in their view, it conflicts with FDA's regulatory framework. Many commenters explained that FDA evaluates fixed combination drugs as distinct medicines and requires separate applications, clinical trials, and demonstrations of safety and effectiveness, and therefore, CMS should not disregard FDA's determination that a fixed combination drug constitutes a separate drug. A few commenters raised concerns that overriding FDA's determinations would introduce substantial uncertainty and send conflicting messages to interested parties by subjecting products to different standards within different parts of the federal government. Some commenters appeared to interpret the proposal at § 429.125(b)(4)(i) to mean that CMS would be determining the clinical efficacy of an additional active moiety, active ingredient, or antigen component and stated that it would be incorrect for CMS to assume that the additional component added to enable an alternative route of administration lacks meaningful clinical activity or value, and moreover, that the scientific expertise to make such a determination lies with FDA, not CMS. A commenter pointed to CMS' decisions in the calendar year (CY) 2021 Physician Fee Schedule (PFS) final rule and CY 2022 PFS final rule to not finalize proposals involving clinical evaluation of drugs approved under section 505(b)(2) of the FD&C Act as evidence that CMS has conceded that it does not have the scientific expertise to make such determinations. Some commenters asserted that CMS' continued reliance on 21 CFR 300.50 undermines the logic of the proposal at § 429.125(b)(4)(i), explaining that, in their view, CMS incorporates FDA's definition of a fixed combination drug at 21 CFR 300.50 but disregards FDA's judgements embedded within that definition regarding an active ingredient's contribution to the product's overall safety and effectiveness.

Response: We appreciate the input but disagree with the commenters' suggestion that CMS' treatment of fixed combination drugs when identifying qualifying single source drugs for purposes of the Negotiation Program must, in every instance, align with how FDA treats fixed combination drugs for purposes of 21 CFR 300.50. The proposal at § 429.125(b)(4)(i) does not disregard, diminish, or otherwise impact FDA's judgments embedded within 21 CFR 300.50 regarding an active moiety's, active ingredient's, or antigen component's contribution to a fixed combination drug's safety and efficacy: nothing in the policy proposed at § 429.125(b)(4)(i) suggests that an active moiety, active ingredient, or antigen component may not contribute to the safety and efficacy of a fixed combination drug in accordance with FDA's determination at 21 CFR 300.50. As we noted previously, the proposed policy is solely for the purpose of the Negotiation Program and identifies a specific, narrow category of fixed combination drugs—those in which the inclusion of an active moiety, active ingredient, or antigen component enables an alternative route of administration and creates a new formulation for the co-administered active moiety(ies), active ingredient(s), or antigen component(s)—that are appropriately understood as new formulations of the same drug under

sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

To the commenters who appeared to interpret proposed § 429.125(b)(4)(i) to mean that CMS would be determining the clinical efficacy of the additional active moiety, active ingredient, or antigen component included in a fixed combination drug, we reiterate that a fixed combination drug would meet the criteria in proposed § 429.125(b)(4)(i) if such additional component enables an alternative route of administration and creates a new formulation for the co-administered active moiety(ies), active ingredient(s), or antigen component(s). That is, the policy proposed at § 429.125(b)(4)(i) does not include an evaluation of the clinical efficacy of such additional component. For this same reason, we disagree with the suggestion that our proposal to define a fixed combination drug as having the meaning set forth in 21 CFR 300.50 undermines the logic of the proposed policy. The proposed policy does not contradict 21 CFR 300.50 but rather narrowly modifies how we will treat certain fixed combination drugs for purposes of achieving the Negotiation Program's statutory requirements. Similarly, we disagree with the commenter's suggestion that CMS' decisions with respect to payment policies for drugs approved under section 505(b)(2) of the FD&C Act undermine the proposed policy. The discussion in the PFS rulemakings to which the commenter referred addressed distinct statutory schemes and did not relate to the type of determinations we proposed here.

Comment: A commenter raised concerns that combining distinct formulations, such as a new formulation that is a fixed combination drug and an original formulation, under the same qualifying single source drug could increase the MFP. This commenter recommended that CMS ensure the MFP reflects the value of each product individually and should avoid an approach under which the added value of a new formulation increases the MFP for the original formulation.

Response: Sections 1192(d)(3)(B) and 1196(a)(2) of the Act direct CMS to identify a qualifying single source drug, and to negotiate a single MFP for that drug, inclusive of its dosage forms, strengths, and formulations. The proposal at § 429.125(b)(4)(i) gives full effect to these statutory directives. We decline to adopt this suggestion as it would be in conflict with the directive at section 1196(a)(2) of the Act to 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. We direct readers to our discussion of the application of the MFP across dosage forms and strengths in section II.H.1. of this final rule and at § 429.700.

Comment: A commenter raised objections to CMS' implementation of policies related to the identification and selection of fixed combination drugs in prior initial price applicability years. A commenter stated that that largest untapped savings for American patients do not lie in redefining what counts as a drug but rather in pharmaceutical benefit manager reform.

Response: These comments are out of scope for this final rule.

Comment: Many commenters stated that fixed combination drugs that are subcutaneous formulations of injectable drugs offer meaningful clinical value, including reduced infusion times, improved adherence, better tolerability, reduced caregiver burden, patient preference for subcutaneous administration, and the benefits and convenience of administering drugs at home or in more accessible practice sites. These commenters stated that CMS' proposal would discount those benefits. Many commenters highlighted that subcutaneous formulations offer benefits to and improve health equity access for underserved patient populations or patients that reside in rural geographic areas where barriers to health care resources may exist, noting that CMS' proposal could result in these patients losing access to beneficial treatment options. A few commenters noted the benefits of subcutaneous formulations, specifically the use of long-acting injectables, for patients with mental health conditions and the providers that serve those communities. Many commenters noted the clinical distinctiveness of subcutaneous products as compared to products that are administered via infusion, stating that a shared active ingredient alone is an incomplete measure of clinical equivalence, noting the differences in bioavailability, safety profiles, differences in tolerability, and dosing and monitoring requirements among products that share an active ingredient. Some commenters recommended that CMS preserve separate qualifying single source drug treatment for products that provide genuine improvements in safety, effectiveness, tolerability, adherence, or delivery, and develop transparent and objective criteria to distinguish genuine clinical innovation from efforts primarily to avoid negotiation eligibility. Some commenters stated that patient choice and individualized care are afforded by the existence of multiple formulations, which allow patients and providers to select the option best suited to individual circumstances, mobility, comorbidities, and access constraints. These commenters recommended that CMS incorporate long-term patient access into its final policy rather than applying an aggregation standard that sacrifices future treatment options for short-term expenditure reductions.

Response: We thank commenters for their input on the clinical value of fixed combination drugs that are subcutaneous formulations of injectable drugs and the benefits those formulations may offer to patients. We acknowledge the concerns commenters raised about the clinical value of subcutaneous formulations and the potential consequences of this policy for patients. Our determination that a fixed combination drug meeting the criteria at proposed § 429.125(b)(4)(i) is not a distinct qualifying single source drug rests on the statutory aggregation requirements at sections 1192(d)(3)(B) and 1196(a)(2) of the Act, not on an assessment of the clinical characteristics of any particular route of administration. The Negotiation Program is designed to address high-expenditure, single source drugs that lack generic or biosimilar competition. If we were to apply the general fixed combination drug policy to a fixed combination drug that includes 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), and such fixed combination drug has the same NDA/BLA holder as another drug or biological product containing those same co-administered active moiety(ies), active ingredient(s), or antigen component(s), the fixed combination drug would be treated as a distinct qualifying single source drug, resetting the negotiation eligibility clock of that formulation. That outcome would create a significant program integrity risk inconsistent with the statutory purpose of the IRA. The proposal at § 429.125(b)(4)(i) addresses a discrete and well-defined category of products. It reaches only those products whose distinction from the original drug is an added active moiety, active ingredient, or antigen component that creates a new formulation and enables a different route of administration. It does not apply to other types of fixed combination drugs that contain active moieties, active ingredients, or antigen

components that do not meet such criteria and which continue to retain their status as distinct qualifying single source drugs, where applicable, under proposed § 429.125(b)(4). Regarding commenters' concerns about clinical distinctiveness, we note that clinical differences across formulations do not on their own provide a basis for separate qualifying single source drug treatment under the statute. As discussed earlier, sections 1192(d)(3)(B) and 1196(a)(2) of the Act direct CMS to aggregate across dosage forms, strengths, and new formulations of a drug. These aggregation requirements operate notwithstanding the clinical differences that may exist between different dosage forms and strengths and formulations. For example, an extended release formulation may offer real benefits over an immediate-release formulation in dosing frequency and adherence, yet the statute directs CMS to consider it within the scope of the same drug. The same logic applies to the exception proposed at § 429.125(b)(4)(i). Differences in bioavailability, tolerability, or patient population between a subcutaneous and an intravenous formulation do not, by themselves, take a product outside the statute's aggregation directives. This does not mean we discount those differences. Rather, it means they are weighed at a different point in the statutory framework. Section 1194(e)(2) of the Act and § 429.505(d)(3)(iii) ensures we consider comparative clinical effectiveness to therapeutic alternatives outside the selected drug, not between formulations aggregated within the same selected drug, in the course of the negotiation process rather than in selecting drugs under section 1192 of the Act. The clinical value a subcutaneous formulation offers remains part of that selected drug's overall profile; however, it is accounted for when we assess the drug's benefits relative to competing therapeutic alternatives under section 1194(e)(2) of the Act and through other categories of information we consider under section 1194(e)(1) of the Act.

We also disagree that proposed § 429.125(b)(4)(i) sacrifices future treatment options in favor of short-term expenditure reductions. The policy does not restrict the development, approval, or marketing of new formulations, including subcutaneous formulations; it determines only whether such a formulation is aggregated with other products under the same qualifying single source drug or as a separate one for purposes of the Negotiation Program. We further note that patients and providers retain the ability to choose among available formulations of a qualifying single source drug or selected drug, as applicable, consistent with individual clinical circumstances, as discussed previously, regardless of whether those formulations are aggregated under the same qualifying single source drug or selected drug, as applicable.

Regarding commenters' concerns about health equity and access for rural and underserved patients, we share the goal of ensuring that Medicare beneficiaries have access to clinically appropriate treatment options. Consistent with section 1196(a)(2) of the Act and as discussed in II.H.1. of this final rule and at § 429.700, the MFP applies to the qualifying single source drug as a whole, including all dosage forms and strengths. We do not anticipate that this policy will steer patients away from subcutaneous formulations. The policy is intended to ensure that the Negotiation Program can reach high-expenditure drugs regardless of whether a manufacturer has introduced a new formulation with an alternative route of administration. The policy affects only the identification of qualifying single source drugs for purposes of the Negotiation Program. It does not alter FDA approval or licensure status, formulary requirements, or prescribing authority. We also considered but decline to adopt commenters' recommendation that we preserve separate qualifying single source drug treatment for products that provide genuine improvements in safety, effectiveness, tolerability, adherence, or delivery. The policy described at proposed § 429.125(b)(4)(i) covers a limited scope of fixed combination drugs where the additional active moiety, active ingredient, or antigen component serves to create a new formulation and enable an alternative route of administration.

Comment: Many commenters stated the proposed fixed combination drug policy would disincentivize future investments in post-approval innovations of drug products due to the potential for reduced expected returns on separately patented, independently developed products, and as a result would chill long term research and development planning, with some of these commenters recommending that CMS establish a more transparent and predictable regulatory framework to allow manufacturers to develop future investment roadmaps. Many commenters noted the technical and regulatory complexity of developing subcutaneous formulations of drugs, including the requirements to establish separate clinical programs, pharmacokinetic evaluations, manufacturing practices and full FDA review of new to market formulations and stated that CMS' proposal discounts those investments and the resulting patient benefits. Many commenters stated that this proposal would have chilling effects beyond subcutaneous product development and could result in discouraged development in areas such as pediatric formulations, rare disease therapies, inhaled anti-infectives and other delivery and adherence improvements to formulations of drug products, and they stated that legitimate innovation in those areas would be penalized. A few commenters stated that the proposal would negatively impact the U.S. intellectual property and innovation ecosystem by stripping economic value and practical benefits from separately patented delivery improvements. Some commenters questioned whether CMS' approach to fixed combination drugs is clear enough to offset the potential chilling effect on pharmaceutical investment and believed manufacturers would need a more predictable regulatory and investment framework to develop future roadmaps. Some commenters stated that the proposal does not appropriately distinguish between evasive product development and true innovative product development and recommended that CMS develop objective, transparent criteria to make that distinction rather than applying a blanket aggregation standard. A commenter stated that the proposal would discourage the development and availability of both intravenous and subcutaneous formulations, leaving patients with fewer treatment choices. A commenter suggested that the sequential development of intravenous products first and subcutaneous products to follow is rational and beneficial to patients, and CMS' proposal would penalize this development pathway without distinguishing it from evasive reformulation strategies. A commenter stated the proposal risks eroding U.S. biopharmaceutical leadership, shifting research and development investment away from the United States. Some commenters stated that the economic impacts of the proposed § 429.125(b)(4)(i) would reduce the time to recover distinct research and development costs including the post-development costs for a subcutaneous product's development, such as clinical trials, manufacturing, and FDA review, because newer therapies would inherit the older product's negotiation timeline and could be subject to price negotiation

as soon as they enter the market. Some commenters noted that developing subcutaneous formulations requires significant post-approval investment, including in separate clinical programs, pharmacokinetic evaluations, manufacturing, and FDA evaluation, and stated that the proposal would indirectly penalize that investment and signal to the industry that patient-centered improvements to existing drugs will not be appropriately valued. Many commenters noted that the policy would disproportionately harm small biotechnology companies, start-ups, and delivery-technology platform companies whose business models depend on innovations related to combination therapy innovation and that the proposal could foreclose continued development of those patient-centric innovations. Some commenters stated that the uncertainty created by the proposal could have a chilling effect on long-term planning because manufacturers cannot rationally commit resources to develop a product that may collapse into an earlier product's negotiation framework and recommended that CMS distinguish genuine delivery innovation from evasive reformulation and establish a more transparent and predictable framework for manufacturers to assess their investment decisions in advance.

Response: We thank commenters for their input and have carefully considered these comments in developing this final rule. The scope of the policy proposed at § 429.125(b)(4)(i) is limited to fixed combination drugs that differ from the original drug 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), such as the addition of hyaluronidase to enable subcutaneous administration of an existing intravenous product. It does not apply to other types of fixed combination drugs that contain active moieties, active ingredients, or antigen components that do not meet such criteria. Notably, commenters did not identify specific examples of fixed combination drugs that would qualify for proposed § 429.125(b)(4)(i), but should not, supporting CMS' analyses that the modification we proposed at § 429.125(b)(4)(i) is appropriately tailored to the program integrity risks it is designed to address. Its application is limited to fixed combination drugs that differ from the original drug 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). It does not apply to other types of fixed combination drugs that contain active moieties, active ingredients, or antigen components that do not meet such criteria, which remain eligible, where applicable, for separate qualifying single source drug treatment under proposed § 429.125(b)(4). Regarding the question of the potential chilling effects beyond subcutaneous product development, we note that the policy applies only to the narrow category of fixed combination drugs described under proposed § 429.125(b)(4)(i). Regarding commenters' concerns about the impact of the policy on the U.S. intellectual property and innovation ecosystem, we note that the policy intends to effectuate the statutory requirements of the Negotiation Program, which is designed to address high-expenditure, single source drugs that lack generic or biosimilar competition. The statute establishes a predictable framework under which certain drugs become eligible for selection based on total expenditure under Part B and Part D and the length of time they have been on the market without facing generic or biosimilar competition. Treating a new formulation as a distinct qualifying single source drug with a new negotiation eligibility clock would be in tension with sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

We also note that some commenters' projections of reduced innovation are highly dependent on assumptions regarding manufacturer, investor, and market responses whose magnitude and direction are inherently uncertain. These same uncertainties apply to commenters' predictions regarding the specific effect of proposed § 429.125(b)(4)(i) on the development of subcutaneous and other alternative formulations. Researchers have found no association between drug prices and R&D investment levels, noting that treatment costs reflect what the market will bear rather than the cost of R&D.[40] Recent empirical evidence further demonstrates that R&D spending, biotech equity investment, and business development activity all increased in the 6 quarters following IRA enactment compared to the 6 quarters prior, suggesting the biopharmaceutical industry has remained robust and continued investing in innovation despite the IRA's prospective effect on future drug prices.[41] This evidence undercuts the premise that the proposed policy will meaningfully depress investment in drug innovation, specifically given that the industry has continued to invest robustly even as broader IRA drug pricing provisions have been implemented. Commenters' analyses of potential impacts on innovation may not fully account for the range of ways in which manufacturers may adapt to changing market conditions, including by continuing to pursue alternative route of administration innovation for reasons independent of Negotiation Program timing, such as competitive differentiation, patient demand, and anticipated generic or biosimilar entry. Regarding the commenter who stated that the sequential development of intravenous products first and subcutaneous products to follow is rational and beneficial to patients, as discussed previously, projections of the policy's impact on manufacturers' investment and formulation sequencing decisions are inherently uncertain, and the proposed policy will be only one of many factors manufacturers consider in such decisions. We further reiterate that the proposed policy would apply only where the fixed combination drug differs from the original drug because of 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).

Regarding commenters' concerns about the disproportionate impact of the policy on small biotechnology companies, start-ups, and delivery-technology platform companies, consistent with proposed § 429.440, we note that the Negotiation Program proposed rule (91 FR 36281–36285) and this final rule include a Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030. That provision establishes a temporary floor for the MFP for eligible small biotech drugs, providing additional protection for qualifying smaller manufacturers. On the question of investment uncertainty and the recommendation that we distinguish

[40] O. Wouters, L. Berenbrok, M. He, Y. Li, & I. Hernandez. Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018. *JAMA Network Open.* 5(9) (2022). doi:10.1001/jamanetworkopen.2022.18623.

[41] Dao S, Ledley FD. Sustaining pharmaceutical innovation after the Inflation Reduction Act: trends in R&D spending, equity investment, and business development. *Drug Discovery Today.* 2025. PMID: 40482994.

genuine delivery innovation from evasive reformulation and establish a more transparent and predictable framework, the proposed policy at § 429.125(b)(4)(i) itself provides clear and defined criteria for qualifying single source drug aggregation purposes.

Comment: A few commenters stated that CMS' program integrity concerns are speculative and that CMS provided no evidence that manufacturers are developing fixed combination drug products to avoid the Negotiation Program. These commenters stated that CMS did not have a sufficient basis or justification to deviate from the established interpretation that all fixed combination drugs are distinct qualifying single source drugs and recommended that CMS retain the established interpretation. Some commenters noted that hyaluronidase-based subcutaneous formulations have been on market since before the IRA was enacted and that CMS' suggestion that these new formulations are being developed to avoid selection in the Negotiation Program or application of the MFP is not supported by evidence. A few commenters noted real-world product development examples to illustrate that products were not developed to circumvent the Negotiation Program, highlighting the clinical validation, years of formulation work, and significant investment required for subcutaneous product development, stating that CMS' proposal would sweep in products developed years before the IRA and that represent legitimate innovation. A commenter noted that if CMS believes program integrity concerns exist, the appropriate remedy is to bring that concern to Congress rather than altering how CMS identifies qualifying single source drugs.

Response: We thank commenters for their input. We disagree that our program integrity concerns are speculative. The use of reformulation strategies to extend market exclusivity and delay competition is well documented in peer-reviewed literature [42] and reflects broader industry dynamics that are not unique to any single manufacturer.[43] Further, we stated in the Negotiation Program Guidance that we intended to address this specific program integrity risk associated with fixed combination drugs that are new formulations in rulemaking. We also disagree that the pre-IRA market history of hyaluronidase-based subcutaneous formulations undermines the program integrity rationale for this policy. The program integrity risk identified by CMS does not depend on when a particular formulation was developed or approved, or on any manufacturer's intent in developing it. A program integrity risk can arise where a generally applicable policy does not fully capture the nuances of specific situations, not only from intentional fraud, abuse, or bad conduct. Absent the proposal at § 429.125(b)(4)(i), a product that CMS has determined constitutes a new formulation of an existing drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act would not be aggregated with that existing drug for purposes of identifying a qualifying single source drug and applying the MFP. As discussed in the proposed rule (91 FR 36260), the program 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. CMS is addressing that vulnerability through the proposed policy for specific fixed combination drugs that are new formulations to ensure that these formulations are properly aggregated and selected consistent with the statute so that the Negotiation Program achieves its intended statutory aims. Regarding the commenter who stated that the appropriate remedy for program integrity concerns is Congressional action, we disagree that Congressional action is the sole recourse to address our program integrity concerns. The policy proposed at § 429.125(b)(4)(i) is based on and consistent with the statutory directives at sections 1192(d)(3)(B) and 1196(a)(2) of the Act. It does not alter CMS' general framework for identifying qualifying single source drugs but rather is applicable only to a discrete type of product that CMS has determined constitutes a new formulation under the statute's aggregation provisions and that would otherwise be treated as a separate qualifying single source drug under the general fixed combination drug policy.

Comment: A few commenters stated that CMS should evaluate the total cost of treatment associated with a therapy, not acquisition price alone, noting that subcutaneous formulations can reduce facility administration expenses, staffing, monitoring, transportation costs, and caregiver burden. These commenters recommended that CMS assess total treatment costs, healthcare resource use, and long-term market effects before adopting classifications that discourage resource-saving improvements. A few commenters stated that by implementing proposed § 429.125(b)(4)(i), CMS would undermine its intended savings goals because the additional costs and burden associated with the administration of intravenous products—including facility fees, nursing time, and monitoring costs—would offset any acquisition price reduction achieved through negotiation. Some commenters suggested that the proposed policy would discourage more convenient treatment options and create more reliance on infusion centers and other resource-intensive care sites.

A few commenters believed that, if finalized, the proposal would set precedents affecting other Medicare reimbursement contexts, specifically the actions of Medicare Administrative Contractors (MACs) and coverage decisions related to intravenous and subcutaneous formulations. These commenters recommended that CMS codify in regulatory text that aggregation under § 429.125(b)(4)(i) is solely for purposes of the Negotiation Program and creates no presumption regarding clinical interchangeability, coverage, or preferred route of administration in any other Medicare policy context. A commenter raised concerns that a broader qualifying single source drug definition might cause Part D plans to place selected drugs on less favorable formulary tiers or impose utilization management restrictions and requested that CMS issue explicit guidance to Part D plans prohibiting utilization management restrictions on selected drugs solely on the basis of route of administration.

Response: We thank commenters for their feedback. On the question of total treatment costs and the potential for the policy to undermine our savings goals, we note that the Negotiation Program selects drugs based on total expenditures under Part B and Part D, which represent a significant and direct cost to Medicare and its beneficiaries. We recognize that site-of-care costs, facility fees, nursing time, and monitoring costs are relevant considerations in the broader assessment of treatment value. Regarding commenters' concerns about infusion capacity and the potential for the policy to discourage more convenient treatment options and the potential to steer patients toward higher-cost infusion settings, the policy

[42] See: Jones, G. H., Carrier, M. A., Silver, R. T., & Kantarjian, H. (2016). Strategies that delay or prevent the timely availability of affordable generic drugs in the United States. *Blood, 127*(11), 1398–1402.

[43] See: Horrow, C., Gabriele, S., Tu, S. S., Sarpatwari, A., & Kesselheim, A. S. (2024). Patent portfolios protecting 10 top-selling prescription drugs. JAMA Internal Medicine, 184(7), 737–744.

proposed at § 429.125(b)(4)(i) does not restrict the availability of subcutaneous or intravenous formulations. Prescribers and patients retain the ability to select from available formulations best suited to individual clinical circumstances, mobility, comorbidities and access constraints. Regarding commenters' concerns that the policy would set precedents affecting other Medicare reimbursement contexts, specifically the actions of MACs and coverage decisions related to intravenous and subcutaneous formulations, the policy proposed at § 429.125(b)(4)(i) reflects the Negotiation Program's statutory directives regarding aggregation and applies solely for purposes of the Negotiation Program. Regarding the commenter who recommended that we issue explicit guidance to Part D plans prohibiting utilization management restrictions on selected drugs solely on the basis of route of administration, consistent with our policies proposed at § 423.120(b)(2)(vii) and (viii), Part D plan sponsors are required to include each Part D drug that is a selected drug with an MFP in effect on their formularies, inclusive of 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). We refer readers to section III.A. of the Negotiation Program proposed rule and this final rule for further discussion of CMS' use of 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.

Comment: Some commenters recommended that CMS examine the full range of impacts of the proposed policy—including effects on patients, infusion providers, access, competitive market forces, Medicare spending, and future innovation—before finalizing any policy change. A few commenters stated that an exclusive focus on immediate negotiation expenditures would overlook treatments that were delayed, narrowed, or never developed and recommended that CMS evaluate the dynamic effects of delayed or never-pursued treatments and recognize that program performance should be measured through patient-centered outcomes and long-term innovation, not solely through immediate reductions in Medicare expenditures. A few commenters recommended that CMS monitor the impact of the proposed policy and commit to reconsidering the policy if evidence after implementation shows reduced development of meaningful improvements, fewer treatment choices, or disproportionate access effects. A commenter recommended that CMS address program integrity concerns through objective, individualized, and evidence-based review rather than categorical aggregation.

Response: We thank commenters for their recommendations. We share commenters' interest in ensuring that the Negotiation Program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries. The proposed policy was developed with the input of comments from patients, clinicians, healthcare providers, manufacturers, and other interested parties. The comments we received reflect the breadth and depth of that engagement. We have carefully considered all of that input in developing this final rule. We appreciate commenters' recommendation that we monitor the impacts of the policy and commit to reconsidering it if implementation evidence shows reduced development of meaningful improvements, fewer treatment choices, or disproportionate access effects. We will assess the real-world impacts as the policy described at proposed § 429.125(b)(4)(i) is implemented, including program integrity risks, and we will remain engaged with patients, clinicians, and other affected communities as we consider future rulemaking. Regarding the commenter who recommended that we address program integrity concerns through objective, individualized, and evidence-based review, not categorical aggregation, the policy proposed at § 429.125(b)(4)(i) is only applicable where a fixed combination drug differs from a drug or biological product with the same NDA/BLA holder 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). For all other fixed combination drugs not subject to the policy proposed at § 429.125(b)(4)(i), we reiterate that, where applicable, we continue to treat it as a distinct qualifying single source drug under the policy proposed at § 429.125(b)(4).

Comment: A few commenters recommended that CMS engage patients, clinicians, healthcare providers, and innovators in further evaluating the clinical, economic, and patient-centered impacts of the proposed change before adopting a final policy, stating that the agency cannot adequately assess the real-world consequences of reshaping the pricing framework governing subcutaneous therapies without meaningful input from the communities most directly affected. A commenter stated that some of the most meaningful effects of a formulation change may not be captured by product labeling or administrative data and that patient and clinician input should be indispensable before finalizing the proposal. A commenter asked CMS to explore further with the wider patient community and subject matter experts the degree to which application of an MFP on a qualifying single source drug that includes a fixed combination drug constitutes a deterrent for investment and research into novel indications.

Response: We thank commenters for their input, and we share commenters' commitment to ensuring that Medicare beneficiaries have access to clinically appropriate treatment options and that the real-world consequences of our policies are fully understood. The policy proposed at § 429.125(b)(4)(i) was developed through a notice-and-comment rulemaking process that provided patients, clinicians, healthcare providers, manufacturers, and other interested parties a meaningful opportunity to submit input on the proposed change. We have carefully considered all of that input in developing this final rule. We agree that patient and clinician perspectives are essential inputs into our policy development. Regarding the commenter who recommended that we explore with the wider patient community and subject matter experts the degree to which application of an MFP on a qualifying single source drug that includes a fixed combination drug constitutes a deterrent for investment and research into novel indications, we appreciate this recommendation. As discussed elsewhere in this final rule, we do not anticipate that proposed § 429.125(b)(4)(i) will meaningfully affect investment in innovation given the narrow scope of products that it covers and that, as previously discussed, researchers have found no association between drug prices and R&D investment levels. We will continue to seek input from patients, clinicians, and other stakeholders as the Negotiation Program is implemented and as we consider future rulemaking.

Final Decision: After consideration of public comments, we are finalizing the general fixed combination drug policy, as well as the proposed policy for specific fixed combination drugs that

are new formulations, with technical modifications to improve organizational clarity. Specifically, we are finalizing the general fixed combination drug policy—which we proposed at § 429.125(b)(4)—at § 429.125(b)(4)(i), and we are finalizing the specific fixed combination drug policy for new formulations—which we proposed at § 429.125(b)(4)(i)—at new § 429.125(b)(4)(ii). We also are adding a paragraph header containing the word ''General'' to finalized § 429.125(b)(4)(i). Finally, in finalized § 429.125(b)(4)(i), we are replacing the reference to ''paragraph (b)(4)(i)'' with a reference to ''paragraph (b)(4)(ii)''. These technical modifications do not substantively change the proposed policy, and the language finalized at § 429.125(b)(4)(ii) is identical to the language proposed at § 429.125(b)(4)(i). CMS will monitor the implementation of the policy for specific fixed combination drugs that are new formulations and will consider potential modifications after gaining experience with the policy.

(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 policy proposed at § 429.125(b)(4)(i) could apply to drugs in the future, we did not propose 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 instead proposed 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 final 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 final 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 a 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 component 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 undermine current program policies, we proposed 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 solicited comments on our proposal and these alternatives.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that CMS' proposal inadvertently creates a loophole for co-packaged products, stating that, in their view, the evidentiary requirements for co-packaging are generally significantly lower than those for reformulating an alternative route of administration, making this pathway both accessible and commercially attractive, and requested that CMS close this potential loophole before it is exploited. These commenters also noted that the proposal creates a distinction between fixed-combination products and co-packaged products that is not grounded in clinical differences and that CMS should clarify whether co-packaged products would be treated the same as fixed combination products under the final rule.

Response: We thank commenters for their feedback. We are not finalizing a change to the treatment of co-packaged drugs in this final rule. Under our existing policy, co-packaged products continue to be treated in the same manner as fixed combination drugs for purposes of identifying qualifying single source drugs under the policy proposed at § 429.125(b)(4). The policy proposed at § 429.125(b)(4)(i) applies only to fixed combination products that differ from the original drug because of an added active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration. It does not extend to co-packaged products as a category. We recognize that commenters raised concerns about the potential for manufacturers to use co-packaging as a means of achieving the same route-of-administration change while avoiding the policy at proposed at § 429.125(b)(4)(i). We take these concerns seriously. Consistent with our

response to similar comments in the Negotiation Program Guidance, we will continue to monitor the use of co-packaged products in the context of the Negotiation Program. Commenters did not identify specific documented instances of manufacturers using co-packaging to circumvent the policy proposed at § 429.125(b)(4)(i) and the underlying statutory provisions. Should our monitoring indicate that co-packaged products present program integrity risks similar to those addressed by proposed § 429.125(b)(4)(i), we will consider whether additional rulemaking is warranted. We will consider these comments in our policy development for this issue in future rulemaking. Regarding commenters' concerns that the policy creates a distinction between fixed combination products and co-packaged products that is not grounded in clinical differences, the policy proposed at § 429.125(b)(4)(i) addresses a discrete and well-defined category of products. We do not agree that extending that policy to all co-packaged products is warranted at this time.

Final Decision: After consideration of public comments, we are not finalizing any of the alternatives considered in section II.B.6.a.2. of the Negotiation Program proposed rule.

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 proposed 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 proposed § 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 proposed § 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.[44] Consistent with prior initial price applicability years, we proposed 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 final rule.

As described in section II.B.6.a. of this final 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 proposed 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 proposed 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 section 351 of the PHS Act (hereinafter

[44] 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 proposed § 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 disease(s), and a biological product with an approved NDA that was deemed to be a BLA.

''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).[45]

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.[46]

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 proposed 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 the 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters acknowledged that proposed § 429.125(c)(1) and (c)(2) appropriately implement the statutory requirement at sections 1192(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act but asserted that this distinction disadvantages certain innovative therapies and can distort research and development incentives based solely on a product's regulatory classification. One of these commenters recommended that CMS work with Congress to establish a uniform 11-year period following FDA approval or licensure before a small molecule drug or biological product becomes eligible for selection under the Negotiation Program.

Response: We agree that § 429.125(c)(1) and (c)(2) would appropriately implement the statutory requirements at sections 1192(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act. As discussed in CMS' response on page 15 of the final guidance for initial price applicability year 2027 and page 17 of the Negotiation Program Guidance, section 1192(e)(1)(A)(ii) of the Act states that for a drug to be considered a qualifying single source drug, at least 7 years must have elapsed since the drug was approved by the FDA. Section 1192(e)(1)(B)(ii) of the Act states that for a biological product to be considered a qualifying single source drug, at least 11 years must have elapsed since the biological product was licensed by the FDA.

Comment: A few commenters raised concerns with our proposal at § 429.125(c)(2)(ii) to consider March 23, 2020 to be the date of licensure of a potential qualifying single source drug that is a biological product 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 is currently a licensed biological product under section 351 of the PHS Act. These commenters stated that the proposal undermines the Negotiation Program because it resets the negotiation eligibility timeline for certain high-cost drugs, works against the BPCI Act's intent to address high drug costs, and represents a departure from the framework used in initial price applicability year 2026. A couple of commenters recommended that CMS measure the time eligibility for such products from the date of the initial NDA approval, with one of these commenters specifying that CMS should continue to consider these products to be biological products subject to the 11-year period for negotiation eligibility. A commenter supported proposed § 429.125(c)(2)(ii), stating that this approach would give effect to section 1192(e)(1)(B)(ii) of the Act. This commenter stated that years during which the product was not licensed under section 351 should not count towards that 11-year period.

Response: We thank these commenters for their feedback and input. CMS clarifies that CMS' proposal at § 429.125(c)(2)(ii) for deemed biologics is an implementation of sections 11001 and 11002 of the IRA. CMS believes that the proposal at § 429.125(c)(2)(ii) to consider March 23, 2020 to be the licensure date for deemed biologics for purposes of identifying the time since licensure under section 1192(e) of the Act is consistent with section 1192(e)(1) of the Act. Sections 1192(e)(1)(A) and 1192(e)(1)(B) of the Act separately describe the qualifying single source drug criteria for drug products and biological products. Section 1192(e)(1)(B)(i) of the Act describes a biological product as a biological product that is licensed under section 351(a) of the PHS Act and is marketed under section 351 of such Act, and section 1192(e)(1)(B)(ii) of the Act requires that at least 11 years will have elapsed since the date of such licensure. FDA's final guidance entitled ''Interpretation of the ''Deemed to be a License'' Provision of the Biologics

[45] 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.

[46] 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.

Price Competition and Innovation Act of 2009'' explains that, as of March 23, 2020, applications for biological products approved under section 505 of the FD&C Act will no longer exist as their NDAs and will be replaced by approved BLAs under section 351 of the PHS Act.[47] Accordingly, it is appropriate to treat deemed biologics as biological products under section 1192(e)(1)(B)(i) of the Act because they are marketed under section 351 of the PHS Act. It is likewise appropriate to consider March 23, 2020 to be the date of licensure under section 1192(e)(1)(B)(ii) of the Act[48] as that is the date on which the approved applications for such products under section 505 of the FD&C Act were deemed to be licenses for such biological products under section 351 of the PHS Act. This interpretation was adopted for initial price applicability year 2027. For initial price applicability year 2026, no interested party suggested interpreting section 1192(e)(1) of the Act to consider the March 23, 2020 deeming date for deemed biologics to be the licensure date for such products, and CMS treated the earliest NDA approval date associated with such products as the approval date for purposes of determining the time since approval under section 1192(e)(1) of the Act. For drug selection for initial price applicability year 2027, in response to interested party feedback received through Negotiation Program Guidance, CMS considered March 23, 2020 to be the licensure date for deemed biologics. To promote transparency under the Negotiation Program and consistent with statute including the statutory directive at sections 11001(c) and 11002(c) of the IRA to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA for 2026, 2027, and 2028 by program instruction or other forms of program guidance, CMS chose to notify interested parties of this interpretation via the selected drug infographic for initial price applicability year 2027[49] and via the Negotiation Program Guidance. Section 429.125(c)(2)(ii) would codify this framework.

Final Decision: After consideration of public comments, we are finalizing § 429.125(c) with technical modifications. Specifically, we are updating cross-references in § 429.125(c)(1) and (c)(2) to reflect that we are finalizing the general fixed combination drug policy at § 429.125(b)(4)(i) (rather than at § 429.125(b)(4), as we proposed), and that we are finalizing the proposed policy for specific fixed combination drugs that are new formulations at § 429.125(b)(4)(ii) (rather than at § 429.125(b)(4)(i), as we proposed).

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 proposed 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)[50] 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.[51]

To determine whether a potential qualifying single source drug qualifies for the orphan drug exclusion, we proposed 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 database[52] and information on FDA-approved indications from other publicly available databases and documents (such as, but not limited to, FDALabel,[53] FDA Online Label Repository,[54] Drugs@FDA,[55] and NLM DailyMed[56]) 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 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.

[47] See: *https://www.fda.gov/media/119590/download?attachment.*

[48] For a biological product with an approved application under section 505(c) of the FD&C Act that was deemed to be a BLA pursuant to section 7002(e)(4)(B) of the BPCI Act, as amended by the Further Consolidated Appropriations Act of 2020, CMS will 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.

[49] See: *https://www.cms.gov/files/document/medicare-drug-price-negotiation-selection-process.pdf.*

[50] 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).

[51] 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.

[52] See: *https://www.accessdata.fda.gov/scripts/opdlisting/oopd.*

[53] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

[54] See: *https://labels.fda.gov.*

[55] See: *https://www.accessdata.fda.gov/scripts/cder/daf.*

[56] See: *https://dailymed.nlm.nih.gov/dailymed.*

(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 proposed 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 proposed 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 final 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 proposed 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,[57] and would refer to databases such as, but not limited to, FDALabel [58] and the FDA Online Label Repository [59] 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 the Negotiation Program Guidance and the text of the statute, for purposes of applying the exclusion, we consider only whether the active ingredient is derived from human whole blood or plasma.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposed approach at § 429.125(e)(1). Many commenters specifically appreciated the criteria to broaden the scope of the orphan drug exclusion to include drugs with multiple orphan drug designations. Many commenters stated that they specifically appreciated, and encouraged CMS to codify, the proposal to evaluate eligibility for the orphan drug exclusion, with respect to a particular initial price applicability year, based on the drug's approval and designation status at the time the drug becomes a selected drug. A few commenters urged CMS to finalize an approach that supports the innovation and development of orphan drugs for rare diseases. A few commenters opposed CMS' proposed approach to broaden the scope of the orphan drug exclusion to include drugs with multiple orphan designations. A couple of commenters urged CMS to apply the exclusion as narrowly as the law permits. A commenter stated that the expansion of the orphan drug exclusion prevents negotiation for high-cost drugs, forcing patients to wait longer for lower prices. A couple of commenters recommended that CMS apply the orphan drug exclusion at the level of the individual drug or biological product approved under a single NDA or BLA, rather than across all products sharing an active moiety/active ingredient with the same NDA or BLA holder. A commenter recommended that CMS retroactively apply the expanded orphan drug exclusion to drugs selected with respect to initial price applicability years 2026 and 2027, rather than just applying the amended exclusion to initial price applicability years beginning with initial price applicability year 2028. This commenter stated the price applicability period for a selected drug should end when a drug no longer meets the definition for a qualifying single source drug because a selected drug's price applicability period is the period during which the MFP applies and during which the Primary Manufacturer is obligated to provide access to the MFP and that section 1191(b)(2) of the Act defines that period as, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug that the price applicability period is defined ''with respect to a qualifying single source drug.'' This commenter recommended that drugs selected for initial price applicability years 2026 or 2027 that would otherwise meet the criteria for the revised orphan drug exclusion should no longer have the agreed-upon MFP apply as of January 1, 2028, because the selected drugs would no longer meet the definition of a qualifying single source drug due to the revised orphan drug exclusion. A couple of commenters recommended CMS explain the event that triggers loss of the orphan drug exclusion and the date used to measure time since approval or licensure. A commenter recommended CMS study and report mechanisms for reinvesting Negotiation Program savings into public rare-disease research, possibly through an expanded orphan drug grants structure.

[57] See: *https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.*

[58] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

[59] See: *https://labels.fda.gov/.*

Response: We appreciate the commenters' feedback. As stated in the Negotiation Program proposed rule (91 FR 36262–36263), 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 proposed 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) [60] 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 at 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.[61]

To determine whether a potential qualifying single source drug qualifies for the orphan drug exclusion, we proposed to consider all dosage forms and strengths of the potential qualifying single source drug, as described previously and as identified in § 429.125(b). We would use the FDA Orphan Drug Product designation database [62] and information on FDA-approved indications from other publicly available databases and documents (such as, but not limited to, FDALabel,[63] FDA Online Label Repository,[64] Drugs@FDA,[65] and NLM DailyMed [66]) 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 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.

In response to the commenters recommending that CMS apply the orphan drug exclusion at the level of the individual drug or biological product approved under a single NDA or BLA, rather than across all products sharing an active moiety/active ingredient, CMS disagrees with this recommendation as it would be in contention with proposed § 429.125(b) and discussed previously.

In response to the commenter's recommendation to retroactively apply the revised orphan drug exclusion to include drugs selected for initial price applicability years 2026 and 2027, CMS disagrees with the commenter's recommendation and interpretation of statute. As stated in the Negotiation Program Guidance, on July 4, 2025, the ''Working Families Tax Cut'' legislation (P. L. 119–21) was signed into law. Section 71203(a) of the ''Working Families Tax Cut'' legislation amended section 1192(e)(3)(A) of the Act and added section 1192(e)(4) to the Act, and section 71203(b) of the ''Working Families Tax Cut'' legislation specifies that these amendments shall apply with respect to initial price applicability years (as defined in section 1191(b) of the Act) beginning on or after January 1, 2028. CMS interprets this new amendment to apply to the identification of qualifying single source drugs, and thus selected drugs, with respect to initial price applicability years beginning on or after January 1, 2028, and does not affect CMS' identification of qualifying single source drugs and selected drugs with respect to initial price applicability years 2026 and 2027. CMS disagrees with the argument that the amendments to the orphan drug exclusion require the termination of the negotiated MFPs for selected drugs with respect to initial price applicability years 2026 and 2027 that would have qualified for the amended orphan drug exclusion applicable to drug selection with respect to initial price application years beginning on or after January 1, 2028. This interpretation conflicts with the effective date in the ''Working Families Tax Cut'' legislation and also the clear statutory language in sections 1191(b)(2) and 1192(c) of the Act which specify the limited circumstances in which a selected drug ceases to be a selected drug and therefore is no longer in its price applicability period. Interpreting the term ''qualifying single source drug,'' as used in section 1191(b)(2) of the Act, to import into these provisions an additional time at which a selected drug's price applicability period (that is, when such drugs no longer meets the requirements for a qualifying single source drug under section 1192(e) of the Act) would conflict with a plain reading of that provision and render its reference to section 1192(c) of the Act superfluous. We believe our interpretation is more consistent with a plain reading of these provisions, under which the reference to ''qualifying single source drug'' in section 1191(b)(2) of the Act denotes that the price applicability period, as defined in section 1191(b)(2) of the Act, is specific to each product that CMS determined was a ''qualifying single source drug'' at the time of selection with respect to a given initial price applicability period and which, for a period of time described in sections 1191(b)(2) and 1192(c) of the Act, is considered a ''selected drug'' within its ''price applicability period.'' We believe that this interpretation gives effect to all relevant provisions and is in accord with the structure of the statute which does not otherwise contemplate a continued requirement that selected drugs remain qualifying single source drugs as defined under section 1192(c) after they are selected.

As stated in the Negotiation Program Guidance, in accordance with section 1192(e)(3)(A) of the Act, as modified by section 71203(a)(2) of the ''Working Families Tax Cut'' legislation, CMS excluded certain orphan drugs when identifying qualifying single source drugs by applying the revised orphan drug exclusion for initial price applicability year 2028. Specifically, CMS excluded 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

[60] 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).

[61] 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 21 CFR 316.24 or a revoked orphan drug designation as described at 21 CFR 316.29.

[62] See: *https://www.accessdata.fda.gov/scripts/opdlisting/oopd.*

[63] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

[64] See: *https://labels.fda.gov.*

[65] See: *https://www.accessdata.fda.gov/scripts/cder/daf.*

[66] See: *https://dailymed.nlm.nih.gov/dailymed.*

for which the only approved indication (or indications) 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).

In response to the commenters recommending that CMS explain the event that triggers loss of the exclusion and the date used to measure time since approval or licensure, CMS directs the commenters to § 429.125(e) of this final rule which states the exclusion criteria a potential qualifying single source drug identified in paragraph (b) of that section must meet to qualify for the orphan drug exclusion. If a potential qualifying single source drug identified in paragraph (b) had met the orphan drug exclusion criteria in an initial price applicability year 2028 or later, but no longer meets the criteria listed at § 429.125(e) of this final rule in a subsequent initial price applicability year, then the orphan drug exclusion would no longer apply to that qualifying single source drug for that respective initial price applicability year. Regarding the date used to measure time since approval and licensure, CMS directs the commenters to § 429.125(c)(3) of this final rule which states the date used to measure time since approval or licensure.

The recommendation for CMS to study and report on mechanisms for reinvesting Negotiation Program savings into public rare-disease research is out of scope for this final rule.

Comment: Many commenters stated that they oppose CMS' proposed approach at § 429.125(c)(3)(i). These commenters disagree with CMS' interpretation of the statute and proposal to measure time since FDA approval of an indication that is not for a rare disease or condition ''irrespective of whether approval of such indication was or is withdrawn after its approval.'' Many commenters recommended that CMS give the orphan drug exclusion a full effect by ''tolling'' (pausing) the negotiation clock whenever a withdrawn indication leaves a product with only rare-disease indications, for the full period the product qualifies and for CMS to only look at the active indications as of the drug selection date. A commenter stated they support CMS' interpretation of statute in the proposed approach and agree that the determination of the date on which the FDA approves an orphan drug or biological product for a non-orphan indication should be made ''irrespective of whether approval of such indication was or is withdrawn after its approval.'' A commenter stated that they appreciate CMS being aware that no current instances of this scenario have occurred yet and recommended CMS to defer the proposal until a case or situation of a drug qualifies for this approach.

Response: We appreciate these comments and feedback. In accordance with section 1192(e)(4) of the Act and as described 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 § 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). As stated in the Negotiation Program proposed rule (91 FR 36262), 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.[67]

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 thus proposed 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 policy could result in a scenario where the 7- and 11-year periods set forth in § 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.

CMS disagrees with the commenter recommending delaying codifying the policy until a case or situation comes up. As stated previously, we believe that this policy is the best interpretation of statute and alignment with section 1192(e)(4) of the Act and we do not see a legitimate reason to delay codifying the proposal.

Comment: A couple of commenters expressed concern that the FDA Orphan Drug Product designation database and the FDA approvals database will not allow CMS to identify whether an indication falls within an orphan drug designation, stating that CMS cannot rely on FDA's databases because those databases principally track orphan exclusivity rather than orphan drug designation. These commenters recommended that CMS should also establish a pathway for manufacturers and other interested parties to demonstrate that an indication falls within an orphan drug designation.

Response: We appreciate the commenters' feedback. Consistent with our response to similar comments in the Negotiation Program Guidance, we believe that consulting the FDA Orphan Drug Product designation database, along with other publicly available databases and documents, in addition to consultation with FDA, as needed, will allow CMS to successfully implement the Orphan Drug Exclusion. The Orphan Drug Product designation database contains drugs with an orphan drug designation. We review designations and approved indications to determine whether the indication falls within a designation. Further, we will consult with FDA if needed. We acknowledge commenters' request to have the opportunity to submit supporting documentation regarding orphan drug

[67] 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.

designations but believes that is unnecessary at this time.

Comment: A few commenters provided feedback on the plasma-derived product exclusion from the definition of a qualifying single source drug. A couple of commenters supported CMS' proposal. A commenter stated that the approach is consistent with the statutory text, longstanding FDA regulatory principles, and Congressional intent underlying the plasma-derived product exclusion. A commenter suggested that CMS codify the proposal in § 429.125(e)(3), but also include in the regulatory text the discussion in the preamble that CMS will only consider the active moiety/active ingredient of a product being derived from human whole blood or plasma because this approach would prevent the inappropriate exclusion of products that include plasma-derived material as an inactive ingredient or in the manufacturing process. A commenter opposed CMS' proposal and stated that CMS should not apply the statutory exclusion for plasma-derived products based on whether the product's ''active ingredient'' alone is derived from human whole blood or plasma as discussed in the preamble. This commenter requested for CMS to state in regulatory text which sources it will use to identify plasma-derived products and how it will reconcile conflicting sources.

Response: We thank these commenters for their feedback and appreciate the support from the commenters. In response to the commenters suggesting additional language be added to the regulatory text, we believe that the regulatory text is consistent with the statutory language.

We disagree with the commenter that stated that CMS should not apply the statutory exclusion for plasma-derived products based on whether the product's active ingredient alone is derived from human whole blood or plasma. When identifying whether biological products satisfy the statutory criteria for qualifying single source drugs, we identify the qualifying single source drug as all dosage forms and strengths of the biological product with the same active ingredient. We believe it is appropriate and consistent with this approach to determine whether such products qualify for the plasma-derived product exclusion based on the biological product's active ingredient alone rather than inactive ingredients or a combination thereof.

In response to the commenter requesting which sources CMS will use and how it will reconcile conflicting sources, consistent with our response to similar comments in the Negotiation Program Guidance and as stated in the Negotiation Program proposed rule (91 FR 36263), we continue to believe that referring to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[68] and databases such as, but not limited to, FDALabel [69] and the FDA Online Label Repository to verify if the product is derived from human whole blood or plasma, are the best ways to identify plasma-derived products for the purpose of implementing the plasma-derived product exclusion in a consistent manner. The sources previously listed in this section are typically consistent in their identification of products that are derived from human whole blood or plasma. Thus, we do not anticipate conflicts among these sources. If differences were identified, we would consult with FDA, as appropriate, to ensure accurate identification of products that are derived from human whole blood or plasma.

Final Decision: After consideration of public comments received, we are finalizing § 429.125(e) as proposed.

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 final 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 qualifying single source drug. We proposed 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

[68] See: *https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.*

[69] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

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 Act[70] 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 any approved generic drug(s) or licensed biosimilar(s) is or are subject to Bona Fide Marketing 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 Drug Inflation Rebate Program (section 1847A(i) of the Act) and the Medicare Part D Drug 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 biological product 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 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 proposed 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 proposed 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 (proposed at § 429.20 and described in section II.A.2. of this final 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

[70] 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.

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 proposed 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 proposed 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 proposed 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 final 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 such generic drug(s) or biosimilar(s) continues to be subject to Bona Fide Marketing 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 proposed 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 proposed 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 specified for CMS' review, 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. To provide further clarity to manufacturers and interested parties in this final rule, we provide the following example. If, in accordance with proposed § 429.130(c)(4), CMS conducts a review in March 2027 to consider whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing for a selected drug selected for negotiation for initial price applicability year 2029, this means CMS may pull the relevant data on any day on or between March 1, 2027 and March 31, 2027. However, as specified in proposed § 429.130(a), the information reviewed is the information ''available to'' CMS when CMS pulls the data. Due to lags in data reporting for various sources, this means the data reviewed may cover a period that ends days, weeks, or months prior to the date of the data pull. For example, if CMS pulled AMP data on March 31, 2027, CMS would review the most recent 12 months of AMP data available as of March 31, 2027. Due to lags in the availability of AMP data, this means CMS would review AMP data covering the period from February 2026 through January 2027.

Further, to continue the previous example, CMS' review of the information pulled on or between March 1, 2027 and March 31, 2027 may extend into the following month to ensure a fulsome consideration of the data available as of the date the information was pulled and may lead CMS to determine as of March 2027 that the drug selected for initial price applicability year 2029 has an approved generic drug or licensed biosimilar, and such generic drug or biosimilar is subject to Bona Fide Marketing. Consequently, CMS may announce after March 2027 that the drug selected for negotiation for initial price applicability year 2029 had an approved generic drug or licensed biosimilar, and such generic drug or biosimilar was subject to Bona Fide Marketing as of March 2027 such that, in accordance with proposed § 429.135(b)(1), the selected drug would cease to be subject to the negotiation process, the selected drug would be deselected as of January 1, 2030, and no MFP would be published for, or apply to, the selected drug.

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 final 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 described in section I.A.2. of this final rule that the provisions of this final 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 proposed 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.[71] 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 as of 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.

We proposed that, if CMS determines as of 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 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, 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 CMS determines as of a date 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 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, 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 as of which CMS determines that the 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 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 II.B1 using a drug

[71] Such date of determination is distinct from, and prior to, the date of Primary Manufacturer notification.

selected for negotiation for initial price applicability year 2029 as an illustrative example.

TABLE II.B1: DESELECTION OF A SELECTED DRUG FOLLOWING GENERIC DRUG OR BIOSIMILAR APPROVAL/LICENSURE AND MARKETING

Date as of 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.
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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters shared their perspectives about the interplay of the definition of a qualifying single source drug and Bona Fide Marketing. Specifically, a commenter suggested that a manufacturer might manipulate the policies by focusing marketing on new formulations and permitting biosimilar competition on the older formulation. The commenter suggested that CMS consider the formulations without a generic drug or biosimilar when considering spending for selection and after selection retain formulations that lack marketing. A couple of commenters expressed concern that generic entry for a minimally utilized dosage form and strength would mean the MFP no longer applies to highly utilized dosage forms and strengths that may not face generic competition and recommended CMS consider the share of utilization when evaluating whether Bona Fide Marketing is occurring. Another commenter suggested measuring utilization across the aggregated dosage forms and strengths may prolong the period the product is subjected to the negotiation process. Another commenter noted their support for CMS' approach to identifying qualifying single source drugs and the interplay with Bona Fide Marketing.

Response: We thank the commenters for their feedback. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, and with respect to a commenter's concern that competition on older formulations or specific dosage forms and strengths could result in a qualifying single source drug avoiding selection or being deselected, we acknowledge this, but for consistency, will continue to mirror the approach to aggregation across dosage forms and strengths of a drug for selection pursuant to section 1192(d)(3)(B) of the Act.

Comment: Many commenters stated that CMS lacks statutory authority to review Bona Fide Marketing to implement the statutory requirement of determining if a generic or biosimilar is ''approved and marketed'' or ''licensed and marketed'' under sections 1192(c) and (e) of the Act. Many commenters stated that ''marketing'' is already a term defined in the pharmaceutical industry, including by FDA and CMS. In addition, these commenters stated that any review of ''marketing'' for purposes of drug selection under section 1192(e) of the Act or deselection under section 1192(c) of the Act must be based on the first ''market date,'' consistent with the plain meaning of ''to market.'' One of these commenters noted this is consistent with the best meaning of the statute. Additionally, a commenter recommended CMS have manufacturers certify that the generic or biosimilar is marketed consistent with such definition. Some commenters recommended CMS withdraw proposed § 429.130. Many commenters recommended CMS utilize an alternative approach when evaluating Bona Fide Marketing, such as distinguishing between market entry

and patient access, and emphasized the importance of transparent and predictable standards. A couple of commenters stated that the FTC would regulate any areas of marketing concern. A few commenters raised concerns about the impact of CMS' review of Bona Fide Marketing on the biosimilar (including a request for a biosimilar delay) and generics markets. Additionally, some commenters suggested that CMS lacks statutory authority to monitor marketing after a drug/biological is determined ineligible for selection or is deselected. A commenter supported the approach, including the ongoing monitoring of selected drugs removed from selection.

Response: Consistent with our response to similar comments in Negotiation Program Guidance, the final guidance for initial price applicability year 2027, and proposed §§ 429.125(d), 429.130 and 429.135, section 1192 of the Act requires CMS to make a determination whether a generic drug or biosimilar ''is marketed'' in order to determine whether a listed drug/reference product should be selected as a qualifying single source drug or whether a selected drug should be deselected. The statute uses different terminology in section 1192 of the Act than in section 1860D–14B of the Act, which established the new Medicare Part D Drug Inflation Rebate Program. In the latter provision, the statute referred to the date that a drug is ''first marketed.'' The absence of similar terminology in section 1192 of the Act demonstrates that, for purposes of the Negotiation Program, a generic drug or biosimilar would have a continuing presence on the market in order to affect the status of a listed drug/reference product. Consistent with the purpose of the statute to lower prices for Medicare through negotiation or price competition, the statute contemplates that, in making this determination, we would consider whether meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar. This determination requires more than solely token or de minimis availability of the products. For example, we are aware of situations in which a manufacturer of a brand name drug or biological product has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar. In the event only a nominal quantity of the generic drug or biosimilar enters the market, the generic drug or biosimilar would not be ''marketed'' within the meaning of that term as it is used in section 1192 of the Act. Given the Negotiation Program is targeted at single source drugs and biological products that have been on the market for some time, for which no generic drug or biosimilar competition currently exists, the statutory directive would not be met if a qualifying single source drug were to avoid selection or be removed from the selected drug list where generic drug or biosimilar availability is limited by the Primary Manufacturer. It is consistent with the purpose of the statute to avoid selection or remove a qualifying single source drug from the selected drug list only when there is evidence that the selected drug is subject to meaningful competition. For example, section 1192(e)(2)(A) of the Act provides that an ''authorized generic'' drug or biosimilar product ''shall be treated as the same qualifying single source drug.'' Although an authorized generic may appear to be competing with the reference drug, authorized generics are marketed by the brand name drug company or another company under the brand company's NDA, meaning that the relationship between the brand drug and its authorized generic is not meaningful competition. Whether such competition exists between a listed drug or reference product and a generic drug or biosimilar will depend on the totality of circumstances in existence at the time that we perform the function of evaluating whether a generic drug or biosimilar is subject to Bona Fide Marketing.

Comment: Some commenters raised concerns with using a ''totality of the circumstances'' approach to review Bona Fide Marketing as a vague standard that may vary by case, while a commenter shared support for the review of Bona Fide Marketing, and another commenter appreciated additional transparency. A commenter stated that CMS' previously stated concern that a manufacturer might ''launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply'' is not a scenario they are aware of ever happening with a biosimilar and a reference product.

Response: We thank commenters for sharing their specific observations of the market and feedback on potential scenarios for review. Consistent with our response to similar comments in Negotiation Program Guidance and the final guidance for initial price applicability year 2027 and as described at § 429.130(b), we reiterate that the determination whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing on an ongoing basis is a totality-of-the circumstances inquiry that will not necessarily turn on any one source of data. Further, it is consistent with the purpose of the statute to avoid selection or remove a qualifying single source drug only when there is evidence that the selected drug is subject to meaningful competition and not just when there are ''any'' sales of the generic drug or biosimilar as suggested by a commenter. We are aware of situations in which a manufacturer of a brand name drug or biological product has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar. In the event only a nominal quantity of the generic drug or biosimilar enters the market, the generic drug or biosimilar would not be ''marketed'' within the meaning of that term as it is used in section 1192 of the Act (for example, specifically within the context of marketed at section 1192(e) of the Act). We note that such a situation has not materialized to date because, in accordance with the statute and CMS' policies established in previous program guidance, such availability would not allow for a manufacturer to claim that the drug should be deselected and no longer subject to an MFP.

Comment: A few commenters shared feedback on the examples provided of when CMS may or may not consider Bona Fide Marketing to be occurring. A commenter stated that the modification to the second example to state CMS ''may'' consider Bona Fide Marketing to be occurring rather than ''will'' introduces additional uncertainty to the example. A couple of commenters raised concerns that the examples do not provide sufficient predictability to manufacturers of the Bona Fide Marketing standard. A commenter disagreed with the third example and recommended it be deleted—according to this comment, this example would result in the wrong outcome where a particular biosimilar has recently launched, for example, at risk or based on a settlement without any patent litigation proceedings as to its biosimilar (notwithstanding the existence of other patent disputes as to biosimilars of the same reference product), but PDE, AMP, and ASP sales do not yet reflect the launch.

Response: We thank commenters for their feedback. The examples provided in section II.B.6. of the proposed rule (91 FR 36266) are for illustrative purposes only to provide interested parties with some instances of how certain factors might weigh in favor of, or against, consideration of Bona Fide Marketing. CMS endeavored to provide

examples both for a drug payable under Part B and a drug covered under Part D, along with including the availability of differing factors in the scenarios. In response to the commenter's feedback on the third example, in its review for Bona Fide Marketing CMS considers whether meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar and, therefore, a biosimilar with no utilization or one that has yet to be launched due to pending patent litigation, may not be considered subject to Bona Fide Marketing because there is no current distribution of the biosimilar and there are potential barriers to its future distribution. However, we reiterate, as stated in section II.B.6. of the proposed rule (91 FR 36263), that CMS' ultimate consideration will be based on the totality of the circumstances and not on the presence, or absence, of any single factor.

Comment: A commenter appreciated the clarifications on timing for review of Bona Fide Marketing offered in the proposed rule. A commenter expressed concerns with CMS' proposal to review up to 12 months of data and stated ordinary data lags may not reflect a recent launch and expressed concerns about the implications for timing of deselection. A commenter recommended CMS consider real-world evidence to consider the practical availability of a generic or biosimilar. A couple of commenters supported CMS' efforts to review additional data sources and recommended CMS consider additional data sources, such as listings in pharmaceutical compendia and Drugs@FDA. The other commenter recommended CMS adopt monthly review for all selected drugs. A couple of commenters recommended CMS conduct reviews more often than monthly, ensure data sources are updated frequently, and allow manufacturers to request review. Another commenter recommended CMS maintain monthly reviews and prompt notification throughout the negotiation period. A commenter recommended CMS conduct the biannual review earlier to allow MA plans and Part D sponsors additional time for plan sponsor bids. A commenter recommended CMS conclude the March review as soon as practicable. Another commenter recommended CMS announce in March and October decisions based on data collected through February and September, respectively, and emphasized the importance of this timing for the March review due to plan sponsor bids.

Response: We thank commenters for their suggestions related to additional data sources with timely utilization data for drugs payable under Part B and/or covered under Part D. We may consider additional data sources to review utilization as available. We clarify in this response to comments that additional data sources may include, for example, MA encounter data (subject to data use and release limitations in 42 CFR 422.310(f)) or OM Part B claims. Consideration of Bona Fide Marketing is based on a review of the totality of the circumstances. Therefore, an uptick in the data alone is not determinative of whether Bona Fide Marketing is occurring. We direct commenters to the additional relevant factors specified in § 429.130, which include, for example, whether the approved generic drug or licensed biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and an approved generic drug or licensed biosimilar manufacturer limit the availability or distribution of the approved generic drug or licensed biosimilar.

We appreciate the commenter's concern about data lags that may not reflect the recent launch of a product. We recognize that the timing for CMS to pull data and compile materials for review may include data covering an earlier time period for lagged data sources. We are finalizing our policy as proposed at § 429.130(a) with modifications at § 429.130(a)(1)(i) through (iii) to clarify the information considered in CMS' review of Bona Fide Marketing, specifically that CMS evaluates the most recent 12 months of PDE data, 12 months of AMP data and 4 quarters of ASP data, as applicable, available to the agency when CMS conducts its review and that the period of such data to be reviewed need not end with the last ''full month'' or ''full quarter'' of data available. Additionally, we clarify in § 429.130(a)(1)(iv) that CMS may evaluate sales and utilization data for the generic drug or biosimilar for the most recent 12 months, 4 quarters, or 52 weeks of a data source, if available and as applicable to such data source, other than those data sources listed in paragraph (a)(1)(i) through (iii) of this section including, but not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available databases, available to CMS at the time CMS reviews such data consistent with paragraph (c) of § 429.130. This modification provides CMS with the flexibility to include data from sources that are updated on a weekly basis so as to not artificially limit the agency's consideration of sales and utilization data that are updated at an interval not included in the proposed rule.

We appreciate commenter feedback on the timing of review. We proposed in § 429.130(c)(6) that we would conduct our review 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 § 429.135(a) to cease being a selected drug. The review in March enables us to determine any selected drugs that must be deselected by the following January. Additionally, 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 proposed to review in 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. We proposed in § 429.130(c)(4) and (5) to conduct monthly reviews during the negotiation and renegotiation period, respectively, because monthly reviews during these periods enable us to promptly determine any selected drugs that are no longer subject to the negotiation or renegotiation process, as applicable. We proposed in § 429.130(c)(1) and (3) to review annually in January to identify potential qualifying single source drugs and any selected drugs ineligible for renegotiation, respectively, prior to the selected drug publication date. After any determination in which CMS finds a generic drug was approved or a biosimilar was licensed and such generic or biosimilar is subject to Bona Fide Marketing, CMS engages in periodic reviews to monitor that meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar as contemplated by the statute. We believe the timing of the review articulated here allows the agency to consider the most recent available information for considering whether an approved generic or licensed biosimilar is subject to Bona

Fide Marketing in accordance with key dates for the Negotiation Program or the submission of Part D plan bids, and thus we decline to alter or conduct more frequent reviews. We believe conducting more frequent reviews would be administratively infeasible at this time and altering the timing of the review to announce decisions earlier would result in less information being available for determining whether a generic drug was approved or a biosimilar was licensed and such generic or biosimilar is subject to Bona Fide Marketing by the key dates previously articulated.

Comment: A commenter requested, based on the commenter's reading of section 1192(c)(1) of the Act, confirmation that, for a selected drug from initial price applicability year 2029, if a generic or biosimilar is approved and marketed by March 31, 2028, the MFP is no longer applicable beginning January 1, 2029.

Response: Consistent with Table II.B1, if CMS determines that as of a date between November 2, 2027 through March 31, 2028, a generic drug or biosimilar is approved or licensed, as applicable, and such generic drug or biosimilar is subject to Bona Fide Marketing for a drug selected for initial price applicability year 2029, the MFP would apply for initial price applicability year 2029 and the selected drug would cease to be a selected drug on January 1, 2030. In other words, the selected drug remains a selected drug and MFP applies for initial price applicability year 2029; the selected drug ceases to be a selected drug on January 1, 2030.

Final Decision: After consideration of public comments, we are finalizing §§ 429.125(d) and 429.135 as proposed, and we are finalizing the policy as proposed at § 429.130 with certain modifications as described later in this section. We also are clarifying as described in section II.B.6 of the proposed rule (91 FR 36264) that CMS has included revisions to more uniformly describe reviews about whether any approved generic drug(s) or licensed biosimilar(s) are subject to Bona Fide Marketing, including the timing of such reviews, as a matter of consistency. As stated previously, we are finalizing our policy as proposed at § 429.130(a) with modifications at § 429.130(a)(1)(i) through (iii) to clarify the information considered in CMS' review of Bona Fide Marketing, specifically that CMS evaluates the most recent 12 months of PDE data, 12 months of AMP data and 4 quarters of ASP data, as applicable, available to the agency when CMS conducts its review and that the period of such data to be reviewed need not end with the last ''full month'' or ''full quarter'' of data available. Additionally, we clarify in § 429.130(a)(1)(iv) that CMS may evaluate sales and utilization data for the generic drug or biosimilar for the most recent 12 months, 4 quarters, or 52 weeks of a data source, if available and as applicable to such data source, other than those data sources listed in paragraph (a)(1)(i) through (iii) of this section including, but not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available databases, available to CMS at the time CMS reviews such data consistent with paragraph (c) of § 429.130. This modification provides CMS with the flexibility to include data from sources that are updated on a weekly basis so as to not artificially limit the agency's consideration of sales and utilization data that are updated at an interval not included in the proposed rule. We are also clarifying in this preamble that other available data sources may include, for example, MA encounter data and OM Part B claims.

Consistent with the modifications made to § 429.130(a)(1)(i) described previously, we are clarifying the example included in the preamble of the proposed rule regarding CMS' review in October to mean that CMS would review PDE data reported from mid-October of the prior calendar year through mid-October of the current calendar year. The clarification of this example is consistent with CMS' process as described in the Negotiation Program Guidance.

We are finalizing as proposed our proposal at § 429.130(a)(2) and (3) with clarification that CMS considers whether an approved generic drug or licensed biosimilar is marketed as described in § 429.130 based on CMS' evaluation of certain information, including information related to additional factors available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section and that CMS may also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar including sales and utilization data for the generic drug or biosimilar not otherwise captured by paragraphs (a)(1)(i) through (iv).

We are finalizing our policy as proposed at § 429.130(b) without modification. We are finalizing our proposal at § 429.130(c) with modifications to change the title from ''Timing for CMS review of Bona Fide Marketing'' to ''Timing'' and to remove ''that is available.'' We also are making modifications at § 429.130(c)(4) and (c)(5) that 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 the earlier of either: (1) 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) or (2) the date as of which CMS determines that a selected drug meets the requirements at § 429.135(b)(1) or § 429.135(b)(2) to cease being subject to the negotiation or renegotiation process, as applicable.

Consistent with the clarifications we provided about the timing of our review in this final rule using the example of a selected drug for initial price applicability year 2029 when we conduct our review in March 2027, we are clarifying in this preamble the timing for our review of Bona Fide Marketing as proposed in § 429.130(c)(4) and (c)(5). Pursuant to these provisions, we will conduct monthly reviews starting in March 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) unless CMS determines as of an earlier date that the selected drug meets the requirements at § 429.135(b)(1) or (b)(2), as applicable, to cease being subject to the negotiation or renegotiation process, as applicable. As described previously, CMS' review refers to the timing for CMS to pull data and compile materials for review which, for lagged data sources, may include data covering an earlier time period. For reviews conducted pursuant to § 429.130(c)(4)(i) or § 429.130(c)(5)(i), CMS clarifies that CMS may pull data from certain sources one or more days prior to November 1 for circumstances in which CMS anticipates the information to be identical to a data pull on November 1. In certain circumstances, CMS may pull data on November 1. However, as previously described, CMS' review and analysis of the data may continue into the next month such that, for reviews conducted in accordance with § 429.130(c)(4)(i) or § 429.130(c)(5)(i), CMS pulls the data and compiles the materials on or before November 1 and continues review of the data into November prior to announcing whether a selected drug ceases to be

subject to the negotiation process or renegotiation process, as applicable, consistent with § 429.135(b)(1) or (b)(2), as applicable, because CMS determined as of November 1, the selected drug has a generic drug that is approved or a biosimilar that is licensed, and such generic drug or biosimilar is subject to Bona Fide Marketing.

We are finalizing § 429.135 as proposed.

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 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 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 proposed 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 proposed 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 final 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 final 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 final 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 final 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 final rule).

Consistent with policies for implementation as described in section 40.1 of the Negotiation Program Guidance, we proposed 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 proposed 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. We also proposed in § 429.20 that the Authorized Representative(s) of the Primary Manufacturer 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 of the Primary Manufacturer 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 proposed 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.[72]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the requirement for Primary Manufacturers to report data of Secondary Manufacturers, such as NDCs, and expressed concerns regarding the distinction between Primary and Secondary Manufacturers as it relates to the Negotiation Program Agreement. One of these commenters stated the use of ''manufactured, marketed, controlled, or sold'' adds ambiguity to the scope of information to be reported. Another commenter recommended CMS allow the Primary Manufacturer or Secondary Manufacturer to determine which should enter into an agreement with CMS. A couple commenters recommended CMS clarify that Primary Manufacturers not be held accountable for noncompliance with the Negotiation Program Agreement based on third party actions outside the manufacturer's control.

Response: As discussed in CMS' response in Negotiation Program Guidance and in the final guidance for initial price applicability year 2027, given that section 1193(a)(1) of the Act instructs CMS to negotiate with ''the manufacturer'' to arrive at the MFP for a given selected drug to which ''the manufacturer'' would provide access in accordance with the statute, and given that the term ''the manufacturer'' appears repeatedly throughout the statutory provisions establishing the Negotiation Program, the best statutory interpretation is to interpret the term ''manufacturer'' as a single entity for the negotiation process, responsible for negotiation of a single MFP for a given selected drug. Thus, in accordance with section 1193(a)(1) of the Act and other statutory references to ''the manufacturer,'' CMS will enter into a Negotiation Program Agreement with ''the manufacturer'' of a selected drug, where ''the manufacturer'' is the NDA/BLA holder. CMS has adopted the designations of ''Primary Manufacturer'' and ''Secondary Manufacturer,'' respectively, to establish a process to negotiate the maximum fair price with ''the manufacturer'' to align with the meaning of the statutory language and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and MFP availability for the selected drug sold by the Secondary Manufacturer(s).

Consistent with sections 1193(a)(3) through 1193(a)(5) of the Act, and as described in 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, and must provide access to the MFP for the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer. The use of the ''manufactured, marketed, controlled, or sold by a Secondary Manufacturer'' language is intended to clarify and standardize the scope of the selected drug for which the Primary Manufacturer is responsible for data collection and submission and MFP availability.

Therefore, as the entity that is party to the Negotiation Program Agreement, in accordance with section 1193(a) of the Act, 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, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

Final Decision: After consideration of public comments, we are finalizing § 429.200 as proposed, but with a clarifying change to § 429.200(c) to add ''as defined in § 429.20'' after Authorized Representative of the Primary Manufacturer.

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 final 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

[72] See ''Instructions for this Agreement'' and the ''Medicare Drug Price Negotiation Program Agreement'' at *https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-negotiated-prices.*

2029 and subsequent years, consistent with the policies for implementation as described in section 40.6 of the Negotiation Program Guidance, we proposed 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 final 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 Drug Rebate Program, the Coverage Gap Discount Program,[73] 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 CMP liability, as described in proposed subpart K and section II.C.10. of this final 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 CMPs 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 proposed the processes by which termination from the Negotiation Program may occur. Specifically, we proposed 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' 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 proposed 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 proposed 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 final 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 final rule.

We proposed 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

[73] 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.

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 of 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 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 NDRAs 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) proposed 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) proposed that a Primary Manufacturer that does not wish to participate in the Negotiation Program and that sought 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 proposed 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) proposed 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 proposed 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 proposed 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 proposed requirements about the effect of termination and the Primary Manufacturer's continuing responsibilities under the Negotiation Program Agreement. That is, we proposed 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 proposed 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.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.205 as proposed.

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 proposed 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 proposed 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 proposed 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 later in this section, must be provided to CMS for review and approval at least 30 calendar days before the intended effective date of the 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 proposed 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 proposed 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple commenters shared appreciation for the proposed novation agreement provision. A few commenters emphasized the importance of clarity regarding which entity is responsible for making the MFP available. A couple of these commenters recommended CMS implement specific safeguards to ensure continuity during a transfer in ownership. Some commenters expressed concern that the novation agreement may interfere with commercial transactions, goes beyond what is required by statute, and lacks specific standards, such as defined timelines and an appeals process. One of these commenters recommended new requirements be prospective only and not impact novation agreements for drugs selected for initial price applicability years 2026 through 2028.

Response: We appreciate commenters' feedback. We agree that promoting continuity during a transfer of ownership and ensuring clarity as to which entity is the Primary Manufacturer of a selected drug responsible for compliance with program requirements are important for successful implementation of the Negotiation Program. Consistent with these goals, the novation agreement provision at § 429.210(c) is intended to ensure that all parties to the Negotiation Program Agreement as well as interested parties know who is the Primary Manufacturer and on which date all of the obligations and liabilities under the Negotiation Program Agreement transfer to an acquiring entity as the successor in interest, including the obligation to provide access to the MFP. Consistent with the Negotiation Program Guidance and as described in § 429.210(c), the Primary Manufacturer of a selected drug remains responsible for all requirements of the Negotiation Program Agreement associated with transferred NDA(s) or BLA(s) of the selected drug, including the requirement to provide access to the MFP, unless and until the Primary Manufacturer transfers all NDA(s) or BLA(s) of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer in accordance with § 429.210(c). If the requirements of § 429.210(c)(1) are met and, as set forth in § 429.210(c)(2), 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.

A novation is a standard instrument by which the parties to an agreement may agree to update a party to such agreement to reflect an original signatory's successor in interest and memorialize the effective date on which the liabilities and obligations under the agreement transfer to the successor in interest. Accordingly, we disagree with commenters that § 429.210(c), which is consistent with the Negotiation Program Guidance and is intended to provide additional details related to the process by which such a novation would be effectuated, interferes with commercial transactions or goes beyond the statute. Section 1193(a) of the Act requires CMS to enter into an agreement with ''the manufacturer'' of a selected drug. If such Primary Manufacturer of a selected drug would like to transfer its NDA(s) or BLA(s) of the selected drug and its Negotiation Program Agreement, including the liabilities and obligations thereunder, to another entity, then § 429.210(c) provides the Primary Manufacturer with a process to do so in a manner that offers clarity and continuity, while ensuring there remains an agreement between CMS and ''the manufacturer'' in accordance with section 1193(a) of the Act.

Additionally, we have specified the requirements for such a novation agreement in § 429.210(c) and do not believe additional details are necessary. As discussed in the proposed rule, CMS encourages Primary Manufacturers to consult with CMS regarding their potential novation before submission to ensure that it meets the requirements of § 429.210(c), including specifying the effective date of such transfer and ensuring that the acquiring entity assumes all obligations and liabilities as the successor in interest. Consistent with the Negotiation Program Guidance, § 429.210(c)(1)(ii) requires at least 30 days' notice to ensure sufficient time for CMS, as the counterparty to the Negotiation Program Agreement, to review and, if approved, for all interested parties to prepare for the transfer of responsibilities, including the transferring and acquiring manufacturers, dispensing entities, Part B providers, and the MTF.

With respect to the commenter's recommendation regarding timing, we reiterate that these regulations are applicable to the Negotiation Program beginning with respect to initial price applicability year 2029 and will apply starting in 2029 with respect to the drugs selected for initial price applicability years of 2026, 2027, or 2028. Requirements for novation of the Negotiation Program Agreement for drugs selected for initial price applicability years 2026, 2027, and 2028 are currently set forth in guidance. As previously discussed, consistent with the Negotiation Program Guidance, § 429.210(c) is intended to provide additional details related to the process for transferring responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity. Prior to 2029, we still encourage Primary Manufacturers to consult with CMS regarding a potential novation before the required submission of the novation to CMS at least 30 calendar days before the intended effective date of any such transfer to ensure that all requirements are met.

Comment: A commenter recommended CMS require notice-and-comment rulemaking for substantive changes to the Negotiation Program Agreement, that such changes operate prospectively, that manufacturers receive at least 90-day notice, and that CMS identify whether future changes are binding, contractual, or non-binding.

Response: We appreciate the commenter's feedback. As described in § 429.210(b), CMS retains the authority to amend the Negotiation Program Agreement to reflect changes in law, regulations, or guidance as applicable. This provision is consistent with the existing Negotiation Program Agreement and is intended to ensure that the Negotiation Program Agreement remains up-to-date in the event of any future changes to law, regulation, or guidance, as applicable. Without such a provision, Negotiation Program Agreements between CMS and Primary Manufacturers would be at risk of including provisions that become out-of-date and inapplicable in the event of, for example, changes to the Negotiation Program statute. As stated in section IV(b) of the Negotiation Program Agreement, when possible, CMS will give the Primary Manufacturer at least 60 days' notice of any change to the Negotiation Program Agreement. We believe this timing is sufficient to provide the Primary Manufacturer with advance notice, but acknowledge that CMS may not be able to provide such notice in cases where changes in law, regulation, or guidance necessitate a more expeditious amendment to the Negotiation Program Agreement to ensure that the Negotiation Program Agreement accurately reflects the law.

We disagree with the commenter's recommendation that any changes to the Negotiation Program Agreement made pursuant to § 429.210(b) require notice-and-comment rulemaking. As previously discussed, CMS reserves the right to amend the Negotiation Program Agreement to ensure that it accurately and timely reflects changes in law, regulation, or guidance, as applicable. Since the Negotiation Program Agreement implements the requirements established for Primary Manufacturers by regulation in this final rule, interested parties have had the opportunity to comment on such requirements through the notice-and-comment process for this final rule.

As described in § 429.205(a), 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. Participation in the Negotiation Program is voluntary. A Primary Manufacturer's options with respect to declining to execute or terminating a Negotiation Program Agreement are discussed earlier.

Final Decision: After consideration of public comments, we are finalizing § 429.210 as proposed.

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 proposed 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 proposed 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 proposed that CMS 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 proposed 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 proposed 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 final 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 proposed 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 final rule), we proposed 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 final rule), as applicable, and the redacted information submitted by interested parties in proposed § 429.505(d)(3) or § 429.615(b)(3), as applicable. We proposed at § 429.300(d) that CMS must redact any information deemed proprietary or covered by the confidentiality policy described in § 429.300(a) and (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 state ''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 final 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.[74] 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.[75]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters requested CMS share additional information regarding the procedures used for protecting confidential information and proprietary information included in the information submitted by Primary Manufacturers. A few commenters suggested CMS develop and publish data privacy and security protection protocols and safeguards for storage and limited access by personnel and, for example, a notification process to Primary Manufacturers of use or disclosure of confidential information outside of the Negotiation Program. A couple of these commenters recommended CMS continue to allow manufacturers to indicate which information submitted they deem to be confidential or proprietary. One of these commenters recommended that CMS indicate that other non-public information related to research and development, such as FDA applications and approvals.

Response: We thank the commenters for their comments on safeguarding data submitted by manufacturers. Consistent with our response to similar comments in Negotiation Program Guidance, we reaffirm our commitment to protect sensitive and confidential data submitted by Primary Manufacturers and continue to acknowledge the importance of data security. Upon establishment of the Negotiation Program, starting with procedures and data related to initial price applicability year 2026, we implemented internal controls to ensure the safeguarding of these data and to provide select CMS staff with access that appropriately aligns with their role and duties. We include later in this section the information previously provided in response to similar comments received for initial price applicability years 2026, 2027, and 2028, and we believe this information is both adequate to detail the protocols and safeguards used in handling manufacturer-submitted data and, as discussed in further detail later in this section, is consistent with other CMS programs suggested by the commenters because of agency-wide CMS requirements. Over the course of the negotiation process, Primary Manufacturers will submit information to CMS via the CMS HPMS or, in some instances, an authorized secure platform such as Box. Box provides a secure way to share content and improve collaboration both within CMS and with outside entities. Box has been authorized as a High Federal Information and Security Modernization Act (FISMA) categorization, which means it can support the storage of all CMS data types, inclusive of PII, PHI, and agency sensitive information. Inviting collaborators through named email addresses of authorized individuals is the preferred method for this collaboration to help ensure the confidentiality and integrity of the content being shared. The CMS HPMS adheres to all applicable policies, procedures, controls, and standards required by HHS and CMS information security and privacy programs to ensure the confidentiality, integrity, and availability of manufacturer information and government information systems. The CMS HPMS system is the primary CMS system for exchange of information between CMS and Medicare Advantage and Medicare Prescription Drug Plans, and as such is designed to receive and keep confidential proprietary and commercially sensitive information. As required by CMS, the CMS HPMS integrates security into every aspect of the system development life cycle. The CMS HPMS is subject to the agency's Security Assessment and Authorization (SA&A) process, a rigorous methodology during which the system must demonstrate a sound and comprehensive information security posture. To achieve and maintain an Authority to Operate (ATO), the CMS HPMS routinely undergoes system penetration testing as well as a Security Control Assessment (SCA), where independent auditors perform a detailed assessment to ensure that the system's security controls meet the CMS Acceptable Risk Safeguards (ARS). An individual must apply for and obtain a CMS-issued user account and password to access the CMS HPMS. In addition to the CMS issued user ID and password, internal CMS staff must use an HHS identification badge (referred to as a ''PIV card'') when accessing the website on the CMS network, while all users accessing the system from outside of the CMS network must use multi-factor authentication. The CMS HPMS further employs role-based access, ensuring that each user is granted access only to those functions required by their position. The CMS HPMS is hosted at a CMS approved cloud service provider. The

[74] See: *https://www.cms.gov/files/document/cms-records-management-policy-2022.pdf.*

[75] See: *https://www.cms.gov/medicare/regulations-guidance/guidance.*

system is protected by a suite of firewall and intrusion detection services, including Akamai Content Delivery Network (CDN), which serves as an additional web application firewall that offers robust distributed denial of services protection and access control. The CMS HPMS utilizes a multizone architecture comprised of a presentation zone, an application zone, and a data zone, designed to provide further defense against security attacks. CMS will employ encryption at rest in the database for sensitive manufacturer data (for example, proprietary information, including trade secrets and confidential commercial or financial information) in addition to encryption in transit. The CMS HPMS adheres to the CMS Information Security Incident Handling Procedures, which are supplemented by the CMS HPMS Security Incident Handling Procedures. These documents outline the procedures for managing known or suspected security or privacy incidents, including, but not limited to, roles and responsibilities, escalation procedures, and guidelines for notifying impacted individuals or organizations. CMS may provide additional information regarding record retention and destruction of section 1194(e) data collected and stored in the CMS HPMS in future rulemaking or in updates to the CMS Record Management Policy, as appropriate. Additionally, as described in section II.D.I of the proposed rule (91 FR 36273), as a part of the Drug Price Negotiation ICR for data submissions in §§ 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 § 429.300(c) as data that must be deemed proprietary information by CMS.

Comment: A couple of commenters supported the confidentiality policy as described in § 429.300(b) but asked CMS to confirm if the Negotiation Program also maintains the confidentiality of information protected against disclosure under all other applicable privacy and confidentiality laws.

Response: Consistent with our response to similar comments in the Negotiation Program Guidance, section 1193(c) of the Act requires that information submitted to CMS by the manufacturer of a selected drug that is proprietary information, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. We are committed to protecting confidential and proprietary information obtained from manufacturers throughout the negotiation process. In addition, CMS is also committed to protecting information that is obtained from Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA–PDs) plans that will inform the negotiation and renegotiation processes. For initial price applicability year 2029, as described in § 429.300, CMS will treat information on non-Federal Average Manufacturer Price (non-FAMP) as proprietary, as well as treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with sections 1194(e)(1) and 1194(e)(2) of the Act as proprietary, if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that meets the requirements set forth under Exemptions 3 and/or 4 of FOIA (5 U.S.C. 552(b)(3), (4)). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 47 U.S.C. 1905 requires executive branch employees to protect trade secrets and certain other information from disclosure unless authorized by law. We understand commenters' concerns pertaining to the confidentiality of proprietary information and will protect confidential and proprietary information as required by applicable law. However, if a Primary Manufacturer chooses to publicly disclose any material that CMS has previously deemed to be proprietary information of that Primary Manufacturer, we will no longer consider that material proprietary as described in section II.D.1. of the proposed rule (91 FR 36273).

Comment: A few of commenters encouraged CMS to publish the maximum amount of information publicly within the confines of the law for the purposes of transparency, stakeholder engagement, and public accountability.

Response: Consistent with our responses to similar comments in the Negotiation Program Guidance, we are committed to negotiation and renegotiation processes that are transparent and respect confidentiality of proprietary information. We appreciate the need to balance transparency in these processes with the need to maintain the confidentiality of certain information, including manufacturers' proprietary data. As described in § 429.705, we will release a narrative explanation of the negotiation process and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. All information that we publish as part of the MFP explanation and any other public documents related to the MFP and negotiation or renegotiation process, as applicable, will be protected under the confidentiality policy described in § 429.300 of this final rule, and we will, as appropriate, redact or de-identify proprietary information, PHI/PII, and information that is protected from disclosure under other applicable law.

Final Decision: After consideration of public comments, we are finalizing § 429.300 as proposed with non-substantive, technical modifications to § 429.300(b), replacing ''CMS would deem'' with ''CMS deems'' *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)).* We also are making technical modifications to § 429.300(c)(6) to capitalize the drug dossier name ''Common'' in the ''Common Technical File'' and to remove erroneous cross-reference ''§ 429.615(b)(1)(i)'' and replace it with ''429.615(b)(3)''.

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 proposed 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 final rule, and for each step in the renegotiation process, as described in proposed § 429.620 and section II.G.5. of this final 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 proposed 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 final 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 final 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 final rule.

Final Decision: We did not receive public comments on this provision; and therefore, we are finalizing § 429.400 as proposed.

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 final 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 proposed 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 proposed 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 final 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter had a few recommendations regarding the collection of non-FAMP. The commenter noted that with this rule, there exists the statutory basis for two Federal ceilings calculated by two agencies under statutes whose Social Security Act cross-references are three decades apart. As such, the VA has an established process for calculating and restating the non-FAMP. The commenter recommended that CMS state how it will verify submitted non-FAMP against the figure reported to the VA for the same product and period. The commenter also recommended stating what occurs when a Primary Manufacturer restates non-FAMP after an MFP has been agreed upon and whether the Calculation of Information and Suggestion of Error stated in § 429.445 would reopen and if it would, on what timeline. Another recommendation from this commenter was to address whether definitional differences arise from the section 8126(g)(1) freeze, if so, whether such definitional differences produce divergent non-FAMP figures for the same product, and if so, to clarify which version governs. Lastly, the commenter recommended CMS align data definitions and audit findings with VA's, to the extent feasible, to reduce duplicative burden on Primary Manufacturers already subject to non-FAMP audit exposure.

Response: We appreciate this commenter's feedback and recommendations. As stated in the Negotiation Program proposed rule (91 FR 36274), section 1193(a)(4)(A) of the Act establishes that a Primary Manufacturer that has entered into a Negotiation Program Agreement with CMS (as described in § 429.200 and section II.C.1. of this final 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. Also as stated in the Negotiation Program proposed rule (91 FR 36275), 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 § 429.405(a)(1), 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 § 429.505 and II.F.2. of this final rule). We intend to collect the non-FAMP through an ICR, which will include additional parameters for this data collection.

Additionally, in accordance with section 1193(a)(5) of the Act, we proposed 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.

The comments regarding how CMS will verify submitted non-FAMP against the figure reported to the VA for the same time period and whether definitional differences arising from the section 8126(g)(1) freeze provision produce divergent non-FAMP figures for the same product are out of scope for this final rule.

In response to the recommendation for CMS to state what occurs when a Primary Manufacturer restates non-FAMP after an MFP has been agreed upon between CMS and the Primary Manufacturer, we note that a Primary Manufacturer of a selected drug has an obligation to provide complete and accurate non-FAMP data in accordance with § 429.405(a) and to update their submitted data as warranted in accordance with § 429.405(b). Failure to report accurately and completely, including failure to comply with information update requirements, may subject a Primary Manufacturer to liability for CMPs. We would evaluate such misreporting on a case-by-case basis. Our evaluation of liability for such misreporting is separate and distinct from any enforcement action that may be taken by any other entity with respect to inaccurate or incomplete non-FAMP reporting.

As for the comment regarding whether the Calculation of Information and Suggestion of Error processes would ''reopen'' in instances in which a Primary Manufacturer restates non-FAMP after an MFP has been agreed to, we direct the commenter to § 429.445 and discussion in section II.E.10. of this final rule.

Final Decision: After consideration of public comments received, we are finalizing § 429.405 as proposed.

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 proposed 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 proposed 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 proposed 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 final rule. The process we proposed 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 proposed 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 final 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 final rule.
- As described in proposed § 429.410(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 final 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 [76], 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 final 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 proposed 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 proposed 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 proposed 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 proposed 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.

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 proposed 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 proposed 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 solicited 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

[76] 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).

Comment: A commenter had a recommendation to use international reference prices as a ceiling and to tie the MFP to what other high-income countries pay.

Response: We thank the commenter for the suggestions. Section 429.410, as proposed, codifies the limitations on CMS' offer amount, including the ceiling amounts specified in section 1194(c) of the Act, and the Temporary Floor for Small Biotech Drugs specified in section 1194(d) of the Act. The commenter's suggestion to impose a ceiling based on amounts other than those described in section 1194(c) of the Act is out of scope.

Final Decision: After consideration of public comments received, we are finalizing § 429.410 as proposed.

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 proposed 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. 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 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 proposed 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 proposed 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 proposed 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 proposed 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.[77] We proposed at § 429.415(a)(2)(ii)(A) if the beneficiary has an instance of 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

[77] 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.

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 proposed 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 proposed 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 proposed at § 429.415(a)(2)(v) steps to determine the total Part B 30-day equivalent supply at the NDC level.

We proposed 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 proposed 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 approach is also 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters suggested for CMS to use a unit of measure approach, rather than a 30-day equivalent supply, for calculation of a single ceiling price and MFP of a selected drug. One of these commenters suggested this approach only for selected drugs payable under Part B. A commenter suggested CMS adopt a lower unit of measure approach for drugs payable under Part B and/or covered under Part D to promote accuracy, transparency, and operational feasibility. A commenter supported CMS' proposed 30-day equivalent supply methodology for calculating the ceiling and MFP because it uses a consistent and uniform approach. A commenter stated they appreciate CMS' proposed methodology and stated that it will be appropriate for many medications and they support the methodology in those cases, but they continue to have concerns if applied to all selected drugs. A commenter stated that a unit-based approach anchored to the price of the product would promote accuracy, transparency, and operational feasibility. Many commenters opposed or expressed concern with CMS' approach of using a 30-day equivalent supply to apply MFP across dosage forms and strengths, particularly with drugs with dosing variation across indications or dosing that involves titration, loading, weight-based, or severity-based variation. A few commenters recommended that CMS calculate the 30-day equivalent supply based on the dosing schedule provided in the prescribing information approved by the FDA (label-based) for selected drugs where dose quantity and schedule do not vary based on patient characteristics. Some commenters suggested CMS work with Primary Manufacturers of a selected drug and to come to an agreement with the Primary Manufacturer on the best approach to use for that selected drug in order to calculate the ceiling and negotiate a single MFP. Some commenters opposed the use of a 30-day equivalent supply, especially applying to drugs payable under Part B and using a ''days between supply'' methodology. A few commenters stated that Part B and Part D claims are fundamentally different and that comparing a 30-day equivalent supply across them produces unequal, untenable, distorted, and invalid comparisons. A commenter stated that nothing in statute requires CMS to calculate the MFP as a price per 30-day equivalent supply, but that statute specifically refers to a ''unit'' with respect to each drug or biologic and that this reference supports the use of a per-unit basis for when determining the MFP.

Response: We appreciate these commenters for their feedback and suggestions. We appreciate the support

from the commenters regarding the 30-day equivalent supply methodology. Section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply agreed-upon MFPs across different 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(a)(1) of the Act directs CMS to develop and use a consistent methodology and process for negotiations that aim to achieve the lowest MFP for each selected drug. Consistent with these statutory directives, in the Negotiation Program proposed rule, and consistent with the Negotiation Program Guidance, we proposed to use a 30-day equivalent supply methodology as it allows CMS to calculate a price for a standardized treatment duration for all dosage forms and strengths of a given drug, and it allows comparison of such standardized prices across drugs. Using the price per 30-day equivalent supply to calculate this amount facilitates aggregation across dosage forms and strengths of a selected drug where units (for example, mg versus mL) and treatment regimens (for example, daily consumption of tablets versus monthly injections of solutions) differ. We believe that the 30-day equivalent supply methodology provides accurate and consistent calculations that can be used for most selected drugs and therapeutic alternative(s) and therefore supports CMS' ability to carry out sections 1194(a)(1) and 1196(a)(2) of the Act. A 30-day equivalent supply methodology is the most transparent and operationally feasible approach.

We disagree with commenters advocating a unit-based methodology. We believe a 30-day equivalent supply creates a more direct comparison for drugs that have different dosage forms, strengths, and treatment regimens than a unit-based approach. We believe that a 30-day equivalent supply methodology also gives a more complete picture of beneficiary utilization. A unit-based approach is less preferable given that unit types may differ across HCPCS codes to which a selected drug payable under Part B is assigned and across therapeutic alternative(s) for a selected drug. We do not believe that a methodology based on the unit of measure assigned to the HCPCS code would work as well as the 30-day equivalent supply methodology because unit types can vary across HCPCS codes to which a selected drug is assigned, and across therapeutic alternatives, especially if the selected drug and/or a therapeutic alternative has both Part B and Part D utilization. Although Part B and Part D claims may differ from one another, a 30-day equivalent supply methodology allows a consistent methodology for comparison of a selected drug and therapeutic alternative(s) that have Part B only, Part D only, or both Part B and Part D utilization. A unit-based approach lacks the benefits of a 30-day equivalent supply methodology that are previously described.

In response to the commenters concerned with CMS' 30-day equivalent supply methodology being used for drugs with dosing variation across indications or dosing that involves titration, loading, weight-based, or severity-based variation and the commenters' recommendation that CMS calculate the 30-day equivalent supply based on dosing schedule provided in the prescribing information approved by the FDA (label-based) for selected drugs where dose quantity and schedule do not vary based on patient characteristics, using an approach to reference the FDA label rather than using actual real-world utilization data, we note that dosing schedules may vary individually for patients (both for patients taking Part B drugs as well as Part D drugs) and statute requires us to have a consistent process and methodology, and the 30-day equivalent supply approach is the most consistent methodology which can be used across selected drugs and which best reflects real-life patterns of use of the drugs among Medicare beneficiaries.

In response to the commenters' suggestion for CMS to work with Primary Manufacturers of a selected drug and to come to an agreement with the Primary Manufacturer on the best approach to use for that selected drug in order to calculate the ceiling and negotiate a single MFP, working with each 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 other selected drugs and its therapeutic alternative(s), if any.

In response to the commenters opposed to the use of a 30-day equivalent supply applying to drugs payable under Part B and CMS using a ''days between supply'' methodology, 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.

In response to the commenter referencing ''unit'' in statute, the meaning is defined at section 1191(c)(6) of the Act, which states that the term ''unit'' means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules or grams) of the drug or biological product that is dispensed or furnished, we disagree that this definition requires the use of a unit based approach to determining offers and counteroffers for selected drugs. For example, there is no reference to ''unit'' in section 1194(c) of the Act, which describes the determination of the ceiling for MFP. The only reference to ''unit'' within section 1194 of the Act, which describes the process for negotiation and renegotiating MFPs for selected drugs, is the requirement in section 1194(e)(1)(B) of the Act that we consider the ''current unit costs of production and distribution'' for a selected drug in determining offers and counteroffers. We do not believe this spare reference is best interpreted as requiring a unit-based approach, particularly when, as previously described, such an approach would be in tension with the statutory directives in sections 1194(a)(1) and 1196(a)(2) of the Act. Therefore, we disagree with the commenter's interpretation of having to use a unit-based methodology versus a 30-day equivalent supply methodology as proposed and finalized in § 429.415. As stated previously in this section, we believe that the 30-day equivalent supply methodology for selected drugs provides accurate and consistent calculations that can be used for most selected drugs and therapeutic alternative(s) and therefore supports our ability to carry out sections 1194(a)(1) and 1196(a)(2) of the Act.

Comment: Many commenters provided feedback on 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), whereby CMS would identify HCPCS codes that generally have a median of one claim per calendar year. Many commenters opposed CMS assigning a value of ''12'' for the 30-day equivalent supply for drugs typically administered

one time. Some commenters recommended for CMS to establish a more tailored and flexible methodology for these selected drugs. A commenter recommended that CMS create an ''outlier policy'' for selected drugs. A commenter encouraged CMS to continue to assess feedback from stakeholders on an adequate approach to use. A couple of commenters stated that they appreciate or understand CMS' goal of standardization but cautioned that this convention does not resolve the underlying problem in that it systematically misvalues therapies whose clinical benefit is decoupled from a monthly dosing and that the proposed methodology is unlikely to produce accurate results for many selected drugs. A commenter stated that regardless of the methodology, it is critically important that CMS use consistent inputs across all phases of the ceiling calculation, MFP determination, and application process.

Response: We thank these commenters for their feedback. Assigning a value of ''12'' as a 30-day equivalent supply for drugs typically administered one time facilitates the necessary ceiling calculations in a manner that is reasonable and accurately reflects the drug's usage because when we look for utilization data, we look within a year's timeframe, so the value of ''12'' represents the maximum value possible in the calculation. Thus, the value of ''12'' for drugs typically administered one time accurately captures and covers a full year and allows comparison to drugs that may be administered multiple times within a year's timeframe. As a commenter suggested, this approach uses consistent inputs that allows for accurate and consistent ceiling calculations, negotiation of a single MFP, and application of the MFP.

As stated in the Negotiation Program proposed rule (91 FR 36277), this approach is also 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). Using this approach could preclude us from comparison with therapeutic alternatives, including those not payable under Part B or those that may be taken daily. 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.

We appreciate the commenters' suggestion to establish a more tailored methodology, the commenter's recommendation to assess feedback from stakeholders on an adequate approach to use, and the commenter's suggestion to create an ''outlier policy.'' We are still considering an outlier policy for future rulemaking and encourages stakeholder input, suggestions, and feedback.

Final Decision: After consideration of public comments received, we are finalizing § 429.415 as proposed, but with a technical modification to the title of § 429.415(a)(2) to change ''selected drug covered under Part B'' to ''selected drug payable under Part B'' for consistency with the use of such term throughout this final rule.

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 proposed at § 429.420(b) to use a 30-day equivalent supply methodology to calculate the sum of the plan-specific enrollment weighted amounts.

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 proposed 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 proposed 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 final 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.[78]

We proposed 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 proposed 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 proposed at § 429.420(b)(5) that December would be the most stable

[78] 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.

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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters had feedback on and recommendations regarding the sum of the plan-specific enrollment weighted amounts. A commenter recommended CMS incorporate all price concessions from manufacturers to Part D plans, including those required under the Manufacturer Discount Program, when calculating the ceiling for the MFP. This commenter believed that including these discounts would meet the definition of a price concession and should be incorporated into the ceiling. A commenter recommended that when rebate and direct and indirect remuneration data are used as inputs to the MFP that CMS should neutralize the percentage-of-price component so that the calculated MFP reflects the actual net acquisition cost and not a figure inflated by compensation that rises with the gross price. A commenter recommended for CMS to explain, with specificity, the data that manufacturers may request to validate the sum of the plan-specific enrollment weighted amounts, what confidentiality protections would apply to any such disclosure, and what recourse exists if a manufacturer identifies a discrepancy that it cannot fully substantiate without access to the plan level data.

Response: We thank these commenters for their feedback and suggestions. Consistent with our response to similar comments in the Negotiation Program Guidance, we disagree with the commenter's suggestion of including the Manufacturer Discount Program discounts as they are not a price concession based on current regulation at § 423.100; we will continue to use the CFR definition of direct and indirect remuneration (DIR) and will not incorporate the Manufacturer Discount Program discounts in the ceiling calculation.

We interpret the commenter's recommendation regarding inputs to the MFP as meaning the MFP is based on the sum of the plan-specific enrollment weighted amounts alone. This interpretation is incorrect as the sum of the plan-specific enrollment weighted amounts is just one component of the ceiling and there are multiple pricing factors that go into the determination of the ceiling as outlined in § 429.410 of this final rule.

In response to the commenter's recommendation regarding the data that a Primary Manufacturer may request to validate the sum of the plan-specific enrollment weighted amounts, confidentiality, and suggestion of error, we note that, as stated in the Negotiation Program proposed rule (91 FR 36278), as directed by statute, and as finalized at § 429.420(a) and (b)(1), we will use plan sponsors' reported Part D PDE data and DIR data to determine the sum of the plan-specific enrollment weighted amounts. Due to the nature of the data described previously as being confidential, we are only able to provide a Primary Manufacturer with limited information and specific numbers in calculations of the sum of the plan-specific enrollment weighted amounts. However, we direct the commenter to § 429.445(c) of this final rule, which states that 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. We also direct the commenter to § 429.300 of this final rule, which is discussed in section II.D.1. of this final rule, regarding confidentiality policy and data use.

Final Decision: After consideration of public comments received, we are finalizing § 429.420 as proposed, with a non-substantive technical modification at § 429.420(b)(8)(i) for an omitted word. We are adding in ''quantity'' for clarity so § 429.420(b)(8)(i) states that for each NDC–11, CMS calculates the quotient of total quantity dispensed and total 30-day equivalent supply to calculate the NDC–11 average number of units per 30-day equivalent supply.

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 proposed 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 proposed 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 final rule).

Additionally, as directed by statute, we proposed 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 proposed 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 proposed 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 proposed 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 annual calendar year ASP or WAC amount for each HCPCS code. We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 Medicare Part B Drug Payment Limit File (or in the OPPS Addendum B file, if it is not available in the Medicare Part B Drug Payment Limit 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 proposed 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 proposed 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 proposed 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, (that is, 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 proposed 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter questioned how CMS calculates the temporary increase in the Part B add-on payment for qualifying biosimilars that Congress provided when the reference product is or has been subject to an MFP. The commenter also questioned whether a biosimilar entering the market after a period of negotiated pricing is disadvantaged in this calculation compared to a biosimilar that entered before negotiated pricing began.

Response: We appreciate this commenter's feedback, but payment for qualifying biosimilars is out of scope for this final rule.

Final Decision: After consideration of public comments received, we are finalizing § 429.425 as proposed, with the following non-substantive technical modifications to the steps described in

§ 429.425(a), (a)(2), (a)(3) and (a)(4) of this final rule:

- At § 429.425(a), we are inserting the words ''for the year'' into the second sentence for clarity and it so it states that CMS calculates the payment amount under section 1847A(b)(4) of the Act, for the year which is 3 years prior.;
- At § 429.425(a)(2)(iii), we are inserting the word ''are'' into the statement in the last parenthetical for clarity and so it states that . . .(including the adjustments made when billing units are zero). . .;
- For improved clarity, we are combining proposed paragraphs § 429.425(a)(3)(i) and § 429.425(a)(3)(ii); all references to these subparagraphs are updated in this section and throughout the rule accordingly;
- For improved clarity, we are deleting the words ''of the total Part B billing units'' from § 429.425(a)(3)(i) so the paragraph now states: ''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 and 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 for the NDC–11 of the selected drug using the following steps:'';
- To be consistent with Negotiation Program Guidance, which the agency had intended to codify, we are adding the following step to allocate HCPCS code-level utilization from Part B data across each NDC–11 of the selected drug assigned to the HCPCS code, in new subparagraph (D), which states thatmultiplies the total Part B billing units from Part B data for that NDC–11, as calculated in paragraph (a)(3)(i)(C) of this section, by the billing unit to NCPDP conversion ratio (calculated by dividing the product of the standard package size and package quantity for an NDC–11 by the number of billing units per NDC–11 reporting unit for the NDC–11) to determine the PDE equivalent of the total Part units for that NDC–11;
- Due to the addition of new paragraph (D), we are renumbering proposed subsequent (D) to (E) and we are revising notwithstanding paragraphs (a)(3)(i)(A) through (C) of this section, to notwithstanding paragraphs (a)(3)(i)(A) through (D) of this section, to capture the entire prior applicable paragraphs;
- For improved clarity, we are striking the words ''set forth in paragraph (a) of this section, for'' at § 429.425(a)(4)(i)(A) and we are modifying regulatory text to clarify the determination of the annual calendar year with cross-reference to paragraph (a)(2) of the section;
- To be consistent with Negotiation Program Guidance, which the agency had intended to codify, we are changing the following cross-reference, at § 429.425(a)(4)(iii), from ''§ 429.425(a)'' to ''§ 429.415(a)(2)'';
- To correct a drafting error involving a citation, at § 429.425(a)(4)(vii), we are changing the cross-reference from ''(a)(4)(v)(B)'' to ''(a)(4)(vi)'' which is now referencing the correct preceding step.

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.[79]

To calculate the amount specified at section 1194(c)(1)(B) of the Act for such selected drugs, we proposed 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 proposed 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 final rule. We proposed 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.

Final Decision: We did not receive public comments on this provision,[80]

[79] 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 proposed 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.

[80] CMS refers readers to the comments and responses under section II.E.5. of this final rule for more information about the sum of the plan specific

Continued

and therefore, we are finalizing § 429.430 as proposed, with the following non-substantive technical modifications:

- For clarity, at § 429.430(a)(1)(iii) we are adding to a cross-reference to more directly correspond to the steps in the cross-referenced section. The cross-reference changes from ''§ 429.425(a)(4)'' to ''§ 429.425(a)(4)(i) through (v)'';
- For clarity, at § 429.430(a)(2)(ii), in the parenthetical, we are adding the word ''and'' between '' . . . PDE records . . .'' and '' . . . associated with HCPCS codes . . .'' and the parenthetical in the paragraph is revised to specify that . . . (including both the Part B version and the Part D version of NDC–11s that are present in both PDE records and associated with HCPCS codes present in Part B data) . . .;
- To address a drafting error at § 429.430(a)(3), we are changing ''NDC–9s'' to ''NDC–11s'' and the paragraph now states: 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–11s of the selected drug.

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 proposed 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 proposed 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 f 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 proposed 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 proposed to base the average non-FAMP calculations on a 30-day equivalent supply. We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 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, the applicable percent for short monopoly drugs and vaccines (that is, 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

enrollment weighted amount component of the combined Part B and Part D amount.

respect to long-monopoly drug will be 40 percent.

We proposed 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters had feedback and recommendations regarding the applicable average non-FAMP amounts. Both commenters noted that the proposal at § 429.435(a)(4)(iv) is inconsistent with the Negotiation Program Guidance and recommended modifying the weighting to rely on the 30-day equivalent supply product mix as opposed to utilizing the product mix based on total units.

Response: We thank these commenters for their feedback and suggestion. We have considered the commenters' feedback and will adjust the steps outlined in § 429.435(a)(4) of this final rule to align with our proposal to adopt a methodology consistent with the Negotiation Program Guidance and the intended steps that we will follow to determine the applicable average non-FAMP amounts and applicable percent of the average non-FAMP.

Final Decision: After consideration of public comments received, we are finalizing § 429.435 as proposed, with the following non-substantive technical modifications to the steps described in § 429.435(a)(4) of this final rule:

- To align with our proposal to adopt a methodology consistent with the Negotiation Program Guidance and the steps the agency intended to codify and will follow to determine the applicable average non-FAMP amounts and applicable percent of the average non-FAMP, we are removing proposed subparagraph (iv);
- Due to subparagraph (iv) removal, we are renumbering subparagraphs (v) through (vii) to (iv) through (vi); all references to these subparagraphs are renumbered in this section and throughout the rule accordingly;
- To align with our proposal to adopt a methodology consistent with the Negotiation Program Guidance and the steps the agency intended to codify and will follow to determine the applicable average non-FAMP amounts and applicable percent of the average non-FAMP, we are adding subparagraph (vii), which states: ''For each NDC–11, CMS then 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 and multiplies this quotient by the amount calculated in paragraph (a)(4)(vi) of this section.''

9. Temporary Floor for Small Biotech Drugs (§ 429.440)

a. Definitions

In proposed § 429.440, we proposed to codify the following definitions applicable to § 429.440 based on policies detailed in this final rule.

(1) ''Part B 2021 Manufacturer''

We proposed 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 proposed 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 proposed 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 proposed 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.

Final Decision: We did not receive public comments on these definitions, and therefore, we are finalizing § 429.440(a) as proposed.

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 proposed at § 429.440(b) to establish the Temporary Floor for Small Biotech Drugs for a selected drug that is 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 final 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 proposed 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 proposed 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 proposed 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 final rule, for a Primary Manufacturer to be considered for the Temporary Floor for Small Biotech Drugs, we proposed 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 the 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) [81] of the Act. 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 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 proposed 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

[81] 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) of the Act 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 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''.

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 final 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, and described at proposed § 429.440(a)(2). In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we proposed 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 proposed 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 proposed 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 final 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)(1) 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, and described at proposed § 429.440(a)(1). In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we proposed 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 proposed that a Primary Manufacturer that seeks the Temporary Floor for Small Biotech Drugs for its selected drug payable 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 proposed 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.[82] 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

[82] *See* 42 CFR 423.2724.

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.[83] 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 proposed 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 proposed 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. The methodology for calculating average non-FAMP in calendar year 2021 is set forth in § 429.435(a)(1) and § 429.435(a)(3), and CMS would apply the temporary floor percentage (66 percent) in place of the applicable percent for the monopoly type. 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 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 noted 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 final rule, for the purpose of calculating the ceiling for renegotiation, we proposed 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 proposed 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 proposed 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 to 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

[83] 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).

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 proposed 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).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters offered feedback on our proposal for a stepwise approach to determining an adjusted ceiling in circumstances in which we determine that the statutory ceiling for a selected drug that qualifies for the Temporary Floor for Small Biotech Drugs is below the Temporary Floor for Small Biotech Drugs. While these commenters acknowledged the Temporary Floor for Small Biotech Drugs provision can conflict with provisions governing the ceiling, these commenters expressed differing views over how we should resolve this conflict. Many commenters proposed eliminating the ceiling in cases where the ceiling determined under proposed § 429.410(b) (negotiation) or § 429.620(b) (renegotiation) is lower than the Temporary Floor for Small Biotech Drugs. Some commenters rationalized that Congress did not intend for any statutory ceiling to apply to long-monopoly and extended-monopoly drugs that qualify for the Temporary Floor for Small Biotech Drugs because, for such drugs, it is mathematically impossible to calculate a ceiling that exceeds the Temporary Floor for Small Biotech Drugs. Other commenters maintained that the proposal for a stepwise approach in these circumstances is arbitrary and capricious because they contended that the ''adjusted'' ceiling has no basis in statute. A couple of commenters stated that the use of ''or'' in section 1194(b)(2)(F) of the Act's prohibition against offering or agreeing to a counteroffer for any MFP that exceeds the ceiling *or* is less than the Temporary Floor for Small Biotech Drugs for the selected drug allows for CMS to apply either the ceiling, or as applicable, the Temporary Floor for Small Biotech Drugs, effectively allowing these provisions to operate as ''separate constraints.'' Further, a few commenters stated that the proposed adjusted ceiling calculation undermines the negotiation process for Small Biotech Drugs. Specifically, these commenters contended that in instances in which the adjusted ceiling would be equal to the Temporary Floor for Small Biotech Drugs, small biotech manufacturers would be obligated to submit data based on factors described under section 1194(e) of the Act and comply with the Negotiation Program Agreement, which would impose substantial and unnecessary burden on both manufacturers and CMS, even though CMS would have ''no need'' to consider data submitted because there would only be one possible MFP available for consideration.

On the other hand, a couple of commenters suggested that for circumstances in which the Temporary Floor for Small Biotech Drugs is above the statutory ceiling for a Small Biotech Drug, CMS should instead raise the ceiling to be equal to the Temporary Floor for Small Biotech Drugs, which the commenters contended gives effect to the provision described under section 1194(b)(1) of the Act (''aim to achieve the lowest maximum fair price''). Finally, another commenter suggested CMS revise its proposal for a stepwise approach under which it would disregard all non-FAMP-based amounts under section 1194(c)(1)(C) of the Act and instead use the specified amount under section 1194(c)(1)(B) of the Act, as applicable, as the ceiling.

Response: We thank the commenters for their feedback, including suggestions for alternative approaches to implementation of the Temporary Floor for Small Biotech Drugs. We proposed the stepwise approach described in proposed § 429.440(b)(4) for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs to address the limited, although possible, scenario in which the ceiling determined under proposed § 429.410(b) (negotiation) or § 429.620(b) (renegotiation) is lower than the Temporary Floor for Small Biotech Drugs. For example, in cases where a long-monopoly drug is selected for negotiation in IPAY 2029 and is determined to be a Small Biotech Drug, the ceiling amount determined under

section 1194(c)(1)(C)(ii)(I) of the Act equals 40 percent of the drug's non-FAMP in 2021, which would be less than the Temporary Floor for Small Biotech Drugs (66 percent of the drug's non-FAMP in 2021). Our proposed stepwise approach would only be triggered in these (and similar) circumstances (that is, where the unadjusted ceiling calculation as described in proposed § 429.410(b) (negotiation) or § 429.620(b) (renegotiation) is less than that of the Temporary Floor calculated under proposed § 429.440(b)(3) for such Small Biotech Drug). Our proposed stepwise approach would not apply for a selected drug that qualifies for the Temporary Floor for Small Biotech Drugs in initial price applicability years 2029 or 2030 for which these conditions are not met, nor for a selected drug that does not qualify for the Temporary Floor for Small Biotech Drugs in initial price applicability years 2029 or 2030.

We disagree that the proposed stepwise approach exceeds the agency's authority or is otherwise inconsistent with statute. Instead, our proposal reflected our intention to give effect to all the relevant statutory provisions governing the determination of offers and counteroffers and negotiation of an MFP for a selected drug. Section 1194(b)(1) of the Act requires the development and use of a consistent methodology and process, in accordance with the requirements set forth in section 1194(b)(2) of the Act, for negotiation that ''aims to achieve the lowest maximum fair price.'' Section 1194(b)(2) of the Act provides for a process that requires an initial offer for the MFP to the manufacturer and allows for an exchange of subsequent offers and counteroffers. Moreover, section 1194(b)(2)(F) of the Act directs that CMS shall not offer (or agree to a counteroffer for) an MFP for a selected drug that exceeds the ceiling determined under section 1194(c) of the Act for the selected drug and year; or, as applicable, is less than the floor determined under section 1194(d) of the Act. In turn, section 1194(c) of the Act requires that an MFP negotiated under section 1194 of the Act 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 amounts under section 1194(c)(1)(B) or section 1194(c)(1)(C) of the Act. Section 1194(d) of the Act expressly directs that for certain qualifying selected drugs, and with respect to initial price applicability years 2029 and 2030, the MFP for such drugs shall not be below the Temporary Floor for Small Biotech Drugs as provided under that subsection.

Our stepwise approach, as finalized in this rule, reflects our interpretation that section 1194(d) of the Act, which provides for the Temporary Floor for Small Biotech Drugs, is not best read as eliminating the rest of the statutory requirements in section 1194 of the Act, as described previously. Instead, our policy reflects our interpretation that the possibility of a direct conflict, with respect to certain drugs as previously described, between the Temporary Floor for Small Biotech Drugs, determined under section 1194(d) of the Act, and the potential ceiling amount is best resolved by removing all non-FAMP (as identified under sections 1194(c)(1)(C)(ii)(I) and 1194(c)(1)(C)(ii)(II)) per our updated stepwise approach, as described in more detail later in this section.

Similarly, we believe that the alternative recommended by commenters that would eliminate the ceiling altogether for Small Biotech Drugs would fail to give effect to all statutory provisions and is inconsistent with the IRA's text, structure, and purpose. We disagree with commenters suggesting that the use of ''or'' in section 1194(b)(2)(F) of the Act's prohibition against offering or agreeing to a counteroffer for any maximum fair price that exceeds the ceiling *or* is less than the floor for the selected drug is best read as requiring CMS to ignore the statutory ceiling provisions for Small Biotech Drugs. We believe that the statutory directive that the MFP cannot be greater than the ceiling *or* less than the floor is more naturally and best read as accounting for the simple proposition that because a ceiling cannot be below a floor, a single offer or counteroffer cannot both ''exceed the ceiling'' *and* be ''less than the floor.'' Accordingly, we believe section 1194(b)(2)(F) of the Act's use of ''or'' is best read as effectuating two distinct prohibitions on offer amounts. Moreover, the commenters' suggestion to read section 1194(b)(2)(F) of the Act as to eliminate the ceiling provisions with respect to Small Biotech Drugs would also fail to give effect to the separate prohibition in section 1194(c) of the Act against an MFP exceeding the amount determined under such subsection; there is nothing in section 1194(d) of the Act to suggest that the Temporary Floor for Small Biotech Drugs should be applied in place of that prohibition. Accordingly, when read in light of the overall structure and purpose of the Negotiation Program statute, including the establishment of a ceiling for MFP negotiations and renegotiations to establish a maximum price above which an MFP cannot be agreed to, we disagree that section 1194(b)(2)(F) of the Act is best read as implicitly nullifying the applicability of the ceiling for Small Biotech Drugs.

For the same reasons, we also disagree that section 1194(b)(2)(F) of the Act can be read as removing the ceiling for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs and whose floor is greater than the applicable ceiling, but not for others that qualify for the Temporary Floor for Small Biotech Drugs. Under such a reading, certain Small Biotech Drugs that have longer periods since the date of approval or licensure would be more likely to qualify for an otherwise unique and unstated exception where their negotiations would have no limitations on the maximum MFP that can be agreed upon. Such a reading conflicts with the ordinary operation of the ceiling provisions, particularly the ceiling amounts determined under section 1194(c)(1)(C) of the Act, which provide for lower ceiling amounts for selected drugs with longer periods since the date of approval or licensure. We do not believe there is any indicia in the statute that in circumstances where the Temporary Floor for Small Biotech Drugs applies, the statute is best read as operating otherwise.

With respect to the comments that the Temporary Floor for Small Biotech Drugs provision is designed to be mathematically impossible to calculate the ceiling for long-monopoly and extended-monopoly drugs at a numerical value that exceeds the Temporary Floor for Small Biotech Drugs, we agree that in limited circumstances with respect to certain selected drugs qualifying for the Temporary Floor for Small Biotech Drugs, the potential ceiling amount determined under section 1194(c)(1)(C)(ii)(I) of the Act would not exceed the Temporary Floor for Small Biotech Drugs determined under section 1194(d) of the Act. However, we disagree that this possibility for a limited set of potential selected drugs is best read as evidence that the statute was drafted to implicitly eliminate the ceiling for such drugs. We believe it would be more likely that such a requirement, which would rewrite much of section 1194 of the Act with respect to a limited and specific set of selected drugs, including eliminating section 1194(c) of the Act for such drugs, would be made explicit. As previously discussed, we believe that the interpretation suggested by the commenters that the statute intends for long-monopoly and extended-monopoly

selected drugs to be negotiated without a ceiling would be contrary to the statute's typical treatment of long-monopoly and extended-monopoly drugs, which are generally subject to lower ceilings.

For the reasons provided previously and in the proposed rule, we disagree with commenters' suggestions not to apply the ceiling otherwise determined under § 429.410(b) or § 429.620(b) when it is below the Temporary Floor for Small Biotech Drugs. However, we agree with the commenter's suggestion regarding the treatment of the other non-FAMP amount described in section 1194(c)(1)(C) of the Act in the adjusted ceiling calculations. We believe that in the event that removing from consideration the potential ceiling amount described in section 1194(c)(1)(C)(ii)(I) of the Act (that is, the non-FAMP for 2021 or first year after market entry) does not result in a ceiling that exceeds the Temporary Floor for Small Biotech Drugs, it is appropriate to include a subsequent step that removes the potential ceiling amount described in section 1194(c)(1)(C)(ii)(II) of the Act (that is, the non-FAMP for the year prior to the selected drug publication date). While our proposal was narrowly tailored to the amount described in section 1194(c)(1)(C)(ii)(I) of the Act, as that amount is determined using the same non-FAMP amount as the Temporary Floor for Small Biotech Drugs, we note that the potential ceiling amount described under section 1194(c)(1)(C)(ii)(II) of the Act may create a similar conflict. Accordingly, we believe we can better resolve such potential conflicts for more Small Biotech Drugs, while preserving a negotiation process subject to a ceiling as described in section 1194(c) of the Act, by incorporating into our stepwise approach an additional step that addresses the potential ceiling amount described in section 1194(c)(1)(C)(ii)(II) of the Act. We believe this revision is consistent with the intent of our proposed stepwise approach, in that it aims to address the direct conflict between the Temporary Floor for Small Biotech Drugs and the ceiling determined under § 429.410(b), while still both providing the Small Biotech Drug the benefit of the floor under section 1194(d) of the Act and preserving a negotiation process subject to a ceiling as described in section 1194(c) of the Act.

In particular, we will consider the treatment of non-FAMP in two distinct stages before determining whether to exclude it from the ceiling calculation. At § 429.440(b)(4)(i), we will exclude the average non-FAMP in 2021 identified under section 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. Under new § 429.440(b)(4)(i), if the resulting amount is equal to or above the Temporary Floor for Small Biotech Drugs, then we will apply that amount as the adjusted ceiling, notwithstanding § 429.410(b) or § 429.620(b). However, under new § 429.440(b)(4)(ii), if the resulting amount determined under § 429.440(b)(4)(i) is lower than the Temporary Floor for Small Biotech Drugs, we will then, notwithstanding § 429.410(b) or § 429.620(b), exclude the average non-FAMP for the year preceding the selected drug publication with respect to the first initial 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), identified under section 1194(c)(1)(C)(ii)(II) of the Act, from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable. Under new § 429.440(b)(4)(ii), if the resulting amount as determined under paragraph § 429.440(b)(4)(ii) is equal to or above the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), we will apply that amount, as applicable, as the adjusted ceiling. Lastly, in § 429.440(b)(4)(iii) (previously § 429.440(b)(4)(ii) in the proposed rule), we stated that the adjusted ceiling will equal the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), notwithstanding § 429.410(b) or § 429.620(b), if the resulting amount determined under § 429.440(b)(4)(ii) is still below the Temporary Floor.

Finally, we also disagree with the proposed alternative to raise the ceiling as otherwise determined under § 429.410(b) or § 429.620(b) to be equal to the Temporary Floor for Small Biotech drugs in lieu of a stepwise approach. We believe our stepwise approach—as revised based on public comments received—is consistent with the text, structure, and purpose of the statute in that it provides a methodology for calculating the Temporary Floor for Small Biotech Drugs for negotiations, allows CMS and the Primary Manufacturer to conduct negotiations subject to a ceiling as described in section 1194(c) of the Act, and provides for the limitations on an offer or counteroffer amount in accordance with sections 1194(b)(2)(F) and 1194(c) of the Act. The approach recommended by the commenters would effectively limit the offers which CMS could consider or make to an amount equal to the Temporary Floor for Small Biotech Drugs in every instance in which the Temporary Floor for Small Biotech Drugs exceeded the amount determined to be the ceiling under section 1194(c) of the Act. Consistent with our response to commenters suggesting that CMS eliminate the ceiling for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs when the ceiling is lower than the Temporary Floor for Small Biotech Drugs, we disagree that the statute is best read as requiring CMS to so limit the negotiation process provided under section 1194 of the Act in every instance because, in limited circumstances, there may be conflict between the ceiling provisions and the Temporary Floor for Small Biotech Drugs. Rather, we believe our stepwise approach, as revised, would give effect to as much of section 1194 of the Act as possible. Under our stepwise approach, the applicable ceiling would be raised to equal the Temporary Floor for Small Biotech Drugs only in instances in which the conflict between the amounts provided under sections 1194(c)(1)(C) and 1194(d) of the Act cannot be resolved; in instances where the conflict can be resolved, the resulting ceiling would be higher than the Temporary Floor for Small Biotech Drugs. Finally, we note our stepwise approach, consistent with section 1194(d) of the Act, would be limited to initial price applicability years 2029 and 2030.

Comment: A commenter expressed concern about CMS' formula for calculating total expenditures for the purposes of determining eligibility for the Temporary Floor for Small Biotech Drugs. This commenter stated that CMS should limit the Total Expenditure calculation of the 80 percent threshold to the manufacturer's qualifying single source drugs and should exclude non-innovator and multi-source drugs. They note that including such drugs in the denominator used for the Total Expenditure calculation may distort the result and potentially disqualify a small biotech manufacturer from being eligible for the Temporary Floor for Small Biotech Drugs. Additionally, this commenter recommended CMS consider a full year of sales to more fully capture a manufacturer's total Medicare expenditures for drugs launched during calendar year 2021.

Response: We thank the commenter for its concern. We note that section 1192(d)(2) of the Act expressly sets forth the denominator and time period to be used for calculating total expenditures

for the purposes of determining whether a drug is a Small Biotech Drug. Sections 1192(d)(2)(A)(i)(II) and 1192(d)(2)(A)(ii)(II) of the Act require that the 80 percent threshold be calculated with respect to all qualifying single source drugs of the manufacturer for which payment may be made under Part B during such year (for calculations involving drugs payable under Part B) or with respect to all drugs covered under Part D for which the manufacturer of the drug has an agreement in effect under section 1860D–14A of the Act during such year (for drugs covered under Part D). With regards to the recommendation to consider a full year of sales for drugs launched in 2021, we similarly note that section 1192(d)(2) of the Act limits us in determining eligibility for the Temporary Floor for Small Biotech Drugs to consider only total expenditures under Part D and Part B ''during 2021.''

Comment: Some commenters supported CMS' proposals related to the implementation of the Temporary Floor for Small Biotech Drugs because it helps protect small biotech manufacturers that may have small business portfolios and less ability to absorb financial risk. One of these commenters also supported CMS' treatment of manufacturers under common control. Another of these commenters suggested CMS explain how corporate relationships, acquisitions, and ownership changes affect a selected drug's eligibility for the Temporary Floor for Small Biotech Drugs or CMS' calculation of the temporary floor amount. Lastly, a commenter recommended CMS should clarify that licensing, co-marketing, and distribution arrangements that in essence function as a transfer of control should render a drug ineligible for the Temporary Floor for Small Biotech Drugs.

Response: We appreciate the support of these commenters. With respect to the commenter's question regarding how corporate relationships, acquisitions, and ownership changes affect eligibility, the policies discussed in section § 429.440 as finalized regarding eligibility for the Temporary Floor for Small Biotech Drugs explain the relevant statutory criteria for eligibility for the Temporary Floor for Small Biotech Drugs. Section 1192(d)(2)(B)(i) of the Act precludes a selected drug from being a Small Biotech Drug if the Primary Manufacturer of the selected 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 the recommendation that CMS extend ineligibility for the Temporary Floor for Small Biotech Drugs based on licensing, co-marketing, and distribution arrangements, our proposal reflects the statutory criteria specified in section 1192(d)(2) of the Act.

Comment: Some commenters suggested various refinements to the proposal to further protect small biotech manufacturers, including revising eligibility standards and extending the Temporary Floor for Small Biotech Drugs provisions beyond initial price applicability years 2029 and 2030. One of these commenters suggested CMS and the Administration work with Congress to preserve and extend the Small Biotech Exception and the Temporary Floor for Small Biotech Drugs. Another commenter suggested that CMS start evaluating whether a temporary floor limited to initial price applicability years 2029 and 2030 is sufficient to protect small biotech manufacturers and to determine if an extension is warranted.

Response: We appreciate commenters' suggestions. The statute provides specific eligibility criteria for the Temporary Floor for Small Biotech Drugs and provides that it applies only for initial price applicability years 2029 and 2030. We do not have the authority to amend the statute to provide additional eligibility standards or extend the Temporary Floor for Small Biotech Drugs.

Comment: A commenter recommended CMS report whether a selected drug was deemed eligible for the Temporary Floor for Small Biotech Drugs in its explanation of the MFP, noting that doing so would not raise confidentiality concerns since CMS has already made the determination and because providing this information could help demonstrate effectiveness of the negotiation process. Additionally, this commenter stated that CMS should publish the drugs excluded under the Small Biotech Exception for previous initial price applicability years to allow stakeholders to understand how the provision affected drug selection. Another commenter suggested that CMS track and publicly report on whether the Temporary Floor for Small Biotech Drugs sufficiently protects small biotech manufacturer innovation.

Response: We thank the commenters for their suggestions to provide public reporting on the Temporary Floor for Small Biotech Drugs, including adding specific information in MFP explanations. Consistent with § 429.705(b), the MFP explanation will include a narrative explanation of the negotiation process that occurred with that Primary Manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. If a selected drug qualifies for the Temporary Floor for Small Biotech Drugs in initial price applicability years 2029 or 2030, we will consider whether to disclose such status in the MFP explanation consistent with our approach to redact confidential information and proprietary information, as well as with our policies finalized at § 429.300. Consistent with our approach to initial price applicability years 2026, 2027, and 2028 to date, we decline to publish the drugs that qualified for the Small Biotech Exception in previous initial price applicability years. The comment to track and report on whether the Temporary Floor for Small Biotech Drugs sufficiently protects small biotech manufacturer innovation is outside the scope of this final rule.

Comment: A commenter stated that CMS should reconsider its proposal to extend the Temporary Floor for Small Biotech Drugs to renegotiation based on section 1194(f)(4)(B) of the Act and instead exercise discretion by adopting a narrower interpretation under section 1194(d) of the Act that the Temporary Floor for Small Biotech Drugs applies only when negotiating the initial MFP for drugs selected for negotiation. This commenter suggested that applying the Temporary Floor for Small Biotech Drugs to drugs selected for renegotiation may limit CMS' ability to fully account for the circumstances that warranted selection for renegotiation or other landscape changes for the pharmaceutical market and constrain the renegotiation process.

Response: We decline to adopt the commenter's suggestion to adopt a narrower interpretation such that drugs selected for renegotiation for initial price applicability years 2029 or 2030 would not be eligible to be considered for the Temporary Floor for Small Biotech Drugs described in section 1194(d) of the Act. Section 1194(f)(4)(B) of the Act describes the statutory requirements that aspects of the renegotiation process be consistent with the negotiation process and states that for purposes of applying section 1194(d) of the Act (that is, the section that establishes the Temporary Floor for Small Biotech Drugs), 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. This reference indicates that the Temporary Floor for Small Biotech Drugs applies with respect to renegotiation under section 1194(f) of the Act. Because of this statutory directive, drugs selected for renegotiation also will be eligible to be considered for the Temporary Floor for Small Biotech Drugs described in section 1194(d) of the Act and § 429.440 as finalized and we do not have the discretion to otherwise limit such eligibility.

Comment: A commenter expressed concern that in therapeutic classes with only two drugs, if CMS applies the Temporary Floor for Small Biotech Drugs to an eligible selected drug and not its competitor in cases where the competitor is also a selected drug, this could distort the market and hurt the manufacturer selling a drug at a lower WAC. To address this concern, this commenter recommended that CMS first request information from the applicant for the Temporary Floor for Small Biotech Drugs regarding the number of competing manufacturers in a class and then grant the Temporary Floor for Small Biotech Drugs to the drug of the other manufacturer, if selected for negotiation.

Response: We appreciate the commenter raising this concern and recommending an approach. We decline to adopt the commenter's suggestion to automatically apply the Temporary Floor for Small Biotech Drugs to both the selected drug and the competing selected drug of another manufacturer in cases when there are only two drugs in a therapeutic class. Section 1194(d) of the Act states that the Temporary Floor for Small Biotech Drugs is only applicable in the case of a selected drug that meets the Small Biotech Exception criteria under section 1192(d)(2) of the Act. As a result, we do not have the authority to extend the Temporary Floor for Small Biotech Drugs to other selected drugs in a therapeutic class when such drugs do not meet the criteria in section 1192(d)(2) of the Act to qualify for the Temporary Floor for Small Biotech Drugs section.

Comment: A commenter recommended CMS apply the Temporary Floor for Small Biotech Drugs to the small biotech company instead of the selected drug to support innovation for certain drugs and help protect small biotech companies that are acquired by another manufacturer. The commenter recognized the statute sets forth limits for drugs being acquired by another manufacturer, but suggested CMS use its rulemaking discretion to apply the Temporary Floor for Small Biotech Drugs to a company and signal this issue for Congress.

Response: We recognize the commenter's interest in having the Temporary Floor for Small Biotech Drugs apply to the small biotech company instead of the selected drug. However, the statute is clear at sections 1192(d) and 1194(d) of the Act that the Small Biotech Exception and the Temporary Floor for Small Biotech Drugs, respectively, apply to the drug specifically that meets the eligibility criteria, not the ''small biotech company'' generally. Furthermore, consistent with section 1192(d)(2)(B)(ii) of the Act, a selected drug is precluded 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. We do not have the authority to change these statutory requirements via rulemaking.

Comment: A commenter identified structural concerns with CMS' implementation of the Temporary Floor for Small Biotech Drugs for drugs and biological products owned by a tribal corporation as the arm of a sovereign government. The commenter requested CMS establish a foundational structure for this provision—and across the Negotiation Program where applicable—whereby CMS consults the tribal corporation before selection and negotiation of a selected drug owned by a tribal corporation and documents a record of selection and agreement on an MFP for such selected drug.

Response: We appreciate the commenter raising these concerns. CMS' Tribal Technical Advisory Group (TTAG), which provides advice and input to CMS on policy and program issues impacting American Indians and Alaska Natives served by CMS programs, as applicable, was informally consulted and they did not provide feedback on either the proposed rule or the final rule. As part of our ongoing implementation of the Negotiation Program, we will engage with CMS' TTAG. CMS, in this final rule, codifies the Medicare Drug Price Negotiation Program under part 429 consistent with the law and with policies established in the Negotiation Program Guidance. We respectfully decline to add a provision to part 429 to establish exceptions to the Negotiation Program or specific requirements governing drug selection, manufacturer agreements, and negotiation and renegotiation processes with respect to federally recognized tribes because the IRA does not contain such provisions.

During our consideration of comments we received on this topic, we identified typographical errors in section II.E.9. of the Negotiation Program proposed rule. First, there are typographical errors in a citation within the third column, line 52 (91 FR 36282) and the second column, line 7 (91 FR 36283). The intended citations should read ''§ 429.100(c)'' instead of ''§ 429.100(d)''. The intended citations (that is, § 429.100(d)) align with data sources used across ceiling calculations (that is, specifically with § 429.420(a)(1), § 429.425(a)(1), and § 429.435(a)(1)(i)). Second, there is a typographical error within the last sentence of the paragraph in the first column that begins with ''In accordance with section 1194(b)(2)(F)(ii) of the Act and as proposed in § 429.405'' (91 FR 36284). The cross-reference to the proposed regulation contains a typographical error. The intended sentence should have read as follows in the proposed rule: ''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)(v)(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).'' Because there is ample discussion of our proposal within the Negotiation Program proposed rule, and the proposed regulatory text reflected our proposal accurately, we believe that the public has had adequate notice and opportunity to comment on our proposal. Additionally, due to the changes made to § 429.435(a)(4) previously discussed, we note that the provision in the final rule that discusses the applicable percent of average non-FAMP for 2021 used in the ceiling calculation for an extended-monopoly drug is now § 429.435(a)(4)(v)(A)(2).

Final Decision: After consideration of public comments received, we are finalizing § 429.440(b) as proposed with modifications to the stepwise approach to calculate an adjusted ceiling 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. Specifically, we will consider the treatment of non-FAMP in two distinct stages of the adjusted ceiling calculation. At § 429.440(b)(4)(i), we will first exclude the average non-FAMP in 2021 identified under section 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. We revised § 429.440(b)(4)(i) to state that if the resulting amount determined under § 429.440(b)(4)(i) is equal to or above the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), then CMS applies that amount as the adjusted ceiling. Under revised § 429.440(b)(4)(ii), we stated that if the resulting amount determined under § 429.440(b)(i) is lower than the Temporary Floor for Small Biotech Drugs, as determined in § 429.440(b)(3), we will then exclude the average non-FAMP for the year preceding the selected drug publication with respect to the first initial price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available in accordance with §§ 429.410(b)(2)(ii) and 429.435(a)(2), identified under section 1194(c)(1)(C)(ii)(II) of the Act from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable. Additionally, under revised § 429.440(b)(4)(ii), we stated that if the resulting amount as determined under paragraph § 429.440(b)(4)(ii) is equal to or above the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), CMS applies that amount, as applicable, as the adjusted ceiling. Lastly, we added § 429.440(b)(4)(iii) to state that the adjusted ceiling will equal the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3) if the resulting amount determined under § 429.440(b)(4)(ii) is still below the Temporary Floor for Small Biotech Drugs.

We also are making non-substantive, technical modifications. In § 429.440(b)(3)(i), we are relocating the words ''calculated using the methodology set forth in § 429.435'' to the end of the provision. In § 429.440(b)(3)(ii), we are adding the words ''calculated using the methodology set forth in § 429.435'' to the end of the provision. In § 429.440(b)(4)(i), we are changing the words ''non-FAMP ceiling amount'' to read ''average non-FAMP in 2021''. To accommodate the revisions described in the previous paragraph to the stepwise approach, we are renumbering § 429.440(b)(4)(ii) as § 429.440(b)(4)(iii), and in § 429.440(b)(4)(iii), we are changing the words ''adjusted ceiling'' to ''resulting ceiling amount'' and are updating the ''§ 429.440(b)(4)(i)'' citation to ''§ 429.440(b)(4)(ii)'' to refer to the new provisions described previously. Lastly, in § 429.440(b)(5)(ii), we are adding a missing '')'' following ''(or adjusted ceiling, if applicable''.

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 proposed 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 proposed 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), (ii), or (iii).

We proposed 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 final rule and proposed in § 429.700(c)(3) has sufficient data, as proposed in § 429.700(c)(4)(i)(B)(2).

Further, we proposed 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 proposed 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 final 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 proposed 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 final 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 solicited comments on our proposed approach for the suggestion of error process. In addition, we solicited comment on whether the regulatory text should expressly identify each of the calculations for which this suggestion of error process would be available.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the reduction of the Suggestion of Error review window from 21 days to 10 days. These commenters stated that the suggestion of error process is the only mechanism by which manufacturers can identify and resolve errors in submitted data before they are used by CMS in the initial offer. They stated the calculations are complex multiple-step computations that can include hundreds of NDC–11s and multiple data sources and stated that the proposal would significantly reduce their review time. A couple of commenters suggested that CMS streamline internal processes instead of shortening the review window for manufacturers. Another commenter

suggested that CMS disclose any analysis or workpapers that support the conclusion that a suggestion of error period of 10 days is adequate for manufacturers.

Response: We thank these commenters for their feedback. As recognized by the commenters, CMS proposed this change in the suggestion of error period for CMS' calculation of the ceiling and for CMS' calculation of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable), as applicable, to ensure that CMS meets the statutory deadlines for the Negotiation Program, where in accordance with section 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug must submit requested information regarding the selected drug not later than March 1 following the selected drug publication date, and, in accordance with section 1194(b)(2)(B) of the Act, CMS must provide the Primary Manufacturer with a written initial offer no later than June 1 following the selected drug publication date. This change in the suggestion of error period provides more time for CMS to engage with Primary Manufacturers regarding their data submissions, provide Primary Manufacturers with the opportunity to supplement or clarify their submissions, and consider their feedback prior to providing the initial offer to the Primary Manufacturer. The proposed review window is based on our experience implementing the Negotiation Program. Given the limited scope of the suggestion of error process as described in § 429.445, CMS expects that the 10-day period will be sufficient for manufacturers to perform their reviews.

Comment: A commenter opposed the identification of the calculations for which a suggestion of error can be made in response to the comment solicitation on whether the regulatory text should expressly identify each of the calculations for which this suggestion of error process would be available. Given the array of potential circumstances that may arise, the commenter encouraged CMS to maintain flexibility to work with manufacturers on suggestions of error. Another commenter supported the clarity provided by the identification of topics in-scope for the suggestion of error process in regulatory text and urged CMS to reconsider the exclusion of objections to policies and methodologies from suggestions of error.

Response: We thank these commenters for their feedback. As described in § 429.445(c), the suggestion of error process is intended to provide Primary Manufacturers with the opportunity to identify potential errors in CMS' calculation of the ceiling, the application of the single MFP across dosage forms and strengths of the selected drug, and CMS' calculation of the Temporary Floor for Small Biotech Drugs, as specified in paragraphs (a)(1), (a)(2), or (a)(3) of § 429.445. Furthermore, the sections referenced in § 429.445(a)(1) through (a)(3) (that is, §§ 429.410 through 429.435, § 429.700(b) and (c), and § 429.440(b)(3) and (4)) specify the provisions describing calculations that may be subject to the suggestion of error process (see § 429.410(c) (specifying the calculation in § 429.410(b) is subject to the suggestion of error process), § 429.415(b) (specifying the calculation in section § 429.415(a) is subject to the suggestion of error process), § 429.420(c) (specifying the calculation in § 429.420(b) is subject to the suggestion of error process), § 429.425(c) (specifying the calculations in § 429.425(a)(2) and (a)(4) are subject to the suggestion of error process), § 429.430(b) (specifying the calculation in § 429.430(a) is subject to the suggestion of error process), § 429.435(b) (specifying the calculations at § 429.435(a) are subject to the suggestion of error process), § 429.440(b)(6) (specifying the calculations in § 429.440(b)(3) and (4) are subject to the suggestion of error process), and § 429.700(d) (specifying the calculations in § 429.700(b) and (c) are subject to the suggestion of error process)). Therefore, we believe it is not necessary to further specify in regulatory text the calculations for which the suggestion of error process will be available. Consistent with our response to similar comments in the Negotiation Program Guidance, submissions related to statutorily required criteria or the policies adopted in Negotiation Program guidance or in this final rule are outside the scope of the suggestion of error process.

Final Decision: After consideration of public comments received, we are finalizing § 429.445 as proposed.

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 proposed to codify these provisions at § 429.500(a). We also proposed 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 final 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 proposed 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.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.500 as proposed.

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 final 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 in the next section, 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 proposed 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 final rule) and in accordance with sections 1193(a)(4) and 1194(b)(2)(A) of the Act, we proposed 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 final rule). We proposed 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 proposed 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 final 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 proposed 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 § 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 final 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 final rule), which cover different reporting periods. As discussed further in section II.G.4.a. of this final 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. 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 proposed 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 (consistent with the process proposed at § 429.510(b) and (c) and described in section II.F.3.c. of this final rule for the purposes of the initial offer). 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 proposed 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 proposed 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 the extent to which the selected drug represents a therapeutic advance compared to 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) including information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, and, information on the extent to which the selected drug and therapeutic alternatives address 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 proposed 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 final 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 proposed 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 proposed 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), well as section 1182(e) of the Act and other applicable law, including section 504 of the Rehabilitation Act. We also proposed 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that CMS establish a minimum threshold for the requirement under § 429.505(c) to update the data submitted under § 429.505(b) (described in section II.F.2.a. of the proposed rule (91 FR 36287)) to avoid added manufacturer burden, without clear benefit to CMS. A commenter requested that CMS allow manufacturers to reopen the HPMS portal to submit required data updates rather than having to request that CMS open the HPMS portal on their behalf. A commenter requested that CMS limit the requirements at § 429.505(c) to only require updated information if such information was inaccurate at the time of submission. A commenter stated that APA requirements for notice-and-comment preclude CMS from including open-ended standards in regulation, such as indicating that information ''will be collected in a form and manner specified by CMS'', for example as in § 429.505(c) and § 429.505(d)(1).

Response: We thank these commenters for their feedback on the data update requirements set forth at § 429.505(c). Consistent with our response to similar comments in the Negotiation Program Guidance and as described in section II.F.2.a. of the proposed rule (91 FR 36287), the requirement proposed at § 429.505(c) is intended to capture instances in which the Primary Manufacturer becomes aware that the information reported for the time period covered by the submission required under § 429.505(b) has changed (for instance because the Primary Manufacturer has received updated data) or is otherwise inaccurate (for instance because the Primary Manufacturer identifies errors in its calculations). We believe that these data update requirements are aligned with statute and important for informing offers, counteroffers, and renegotiation eligibility and selection, as applicable. We therefore decline to establish minimum thresholds for the update requirements for the factors described at section 1194(e) of the Act.

We appreciate the commenter's suggestion regarding the need for CMS to reopen the CMS HPMS portal for a Primary Manufacturer to make updates to submitted data. We will consider this suggestion for future updates. However, to continue to meet statutory timing requirements and due to limitations of the system at this time, it will remain necessary for CMS to reopen the CMS HPMS portal for manufacturer data updates.

Regarding the comment that suggests that APA requirements preclude CMS from stating in regulation that

information ''will be collected in a form and manner specified by CMS'', we disagree with the commenter. This language is commonly used in proposed and final rules, for example in several instances in the CY 2026 Physician Fee Schedule final rule (90 FR 49266), to provide flexibility for submission processes to evolve over time. Further, we issued a proposed rule, including the reporting requirements at § 429.505, for public comment and are now finalizing the rule in a manner fully consistent with the requirements of the APA.

Comment: A few commenters stated that the submission process for information related to section 1194(e)(2) factors, specifically the Patient and Caregiver Focused Input questions, is difficult for patients, caregivers, and other members of the public to navigate and requested that CMS make the submission process clearer and more accessible. A few commenters suggested that interested parties should be provided a later deadline to section 1194(e) data, stating that providing the information in 30 days is not feasible. A commenter suggested that CMS publish a list of organizations and respondent categories that responded to ICRs for the Negotiation Program for each selected drug, similar to how public dockets identify commenters for rulemaking.

Response: We thank the commenters for their input. As noted in our previous response to commenters suggesting options to streamline the submission for information related to section 1194(e)(1) factors, we are also open to streamlining the information collection related to section 1194(e)(2) factors. We appreciate commenters' concern about the 30-day submission timeframe for information related to section 1194(e)(2) factors. We note that the information provided through the Drug Price Negotiation Program ICR is considered when developing the initial offer for a selected drug along with CMS analyses and assessments of evidence as described in § 429.510. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, it is not feasible to extend the timeframe for the submission of information under section 1194(e)(2) of the Act due to the statutory timeline of the negotiation period, including the requirement under section 1194(b)(2)(B) of the Act for CMS to issue an initial offer by June 1 after publication of the selected drug list. As described in § 429.515, interested parties have an opportunity to provide additional section 1194(e)(2) information after the March 1 ICR deadline. With regard to the suggestion to publish a list of organizations and respondent categories that respond to ICRs, we appreciate the suggestion, but we believe the publication of redacted copies of the section 1194(e)(2) factors submitted by interested parties alongside the MFP explanation for each selected drug provides sufficient information and transparency for the public to review. We decline to adopt the commenter's suggestion.

Comment: Some commenters supported CMS' decision not to use Quality-Adjusted Life Years (QALYs) when assessing section 1194(e)(2) factors. Some commenters requested that CMS also exclude the use of other measures of cost effectiveness in addition to QALYs, such as the Equal Value of Life-Years Gained (evLYG). A few commenters opposed CMS' consideration of studies that have content relevant to the negotiation process even if the study uses QALYs and one of these commenters requested additional insight into how CMS considers cost-effectiveness measures other than QALYs. A commenter stated CMS should continue to exclude QALYs from the negotiation process while recognizing that some utilization-and-expenditure analyses would not violate the limitations in section 1194(e)(2) of the Act, section 1182(e) of the Act, and as proposed at § 429.505(e)(1) and (e)(2).

Response: We appreciate these commenters' feedback on cost effectiveness measures. Consistent with our responses in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, we reaffirm that QALYs will not be used in the Negotiation Program. We will consider studies that use QALYs only when they contain other content that is relevant and permitted under applicable law, including section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act and Section 504 of the Rehabilitation Act. We also state in § 429.505(e)(1) that we will review cost-effectiveness measures and studies that use such measures to determine whether the measure may be considered in accordance with section 1194(e)(2) of the Act. However, while such measures are reviewed, they will not be used to adjust the initial offer if the measures do not provide information related to the negotiation factors described in section 1194(e) of the Act or are prohibited under section 1194(e)(2) or under section 1182(e) of the Act. We also note that the explanation of the MFP described at § 429.705(b) will include an explanation of CMS' use of the section 1194(e)(2) factors submitted and redacted copies of the section 1194(e)(2) factors submitted by interested parties.

Comment: A commenter stated that CMS does not need to limit information provided under section 1194(e)(1)(A) through (D) of the Act to data from the United States and could collect international data for these section 1194(e)(1) factors. A commenter stated that CMS should consider evidence on drug prices paid in comparable high-income countries within the bounds of statute.

Response: We appreciate the commenter's suggestion to collect information outside the United States in the submission of information related to factors specified at section 1194(e)(1)(A) through (D) of the Act and to consider certain information about prices paid in comparable high-income countries for therapeutic alternatives within the bounds of statute, which we assume the commenter to be referring to the factor listed at section 1194(e)(2)(A) of the Act. We believe the data submission requirements specified at § 429.505(b), CMS' consideration of the data submitted pursuant to these requirements in the Drug Price Negotiation ICR, and CMS' consideration of evidence about the selected drug and therapeutic alternatives under § 429.505(d)(3) will provide a robust information base for the exchange of offers and counteroffers with the Primary Manufacturer consistent with section 1194(e) of the Act. These requirements reflect the success of negotiating MFPs in prior cycles and lessons learned to date. Based on the information we have to date, we decline to revise the scope of information we proposed to collect and consider under section 1194(e) of the Act in the proposed rule.

Comment: A few commenters recommended that CMS work with external stakeholders to facilitate evidence development to inform the Negotiation Program in the future.

Response: We appreciate this suggestion but note it is out of scope for this final rule.

Final Decision: After consideration of public comments, we are finalizing § 429.505 as proposed with a technical correction to add a missing parenthetical to § 429.505(b)(2)(iv).

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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 and manufacturer effectuation of the MFP in 2026, 2027, and 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. 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 final 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 proposed 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 proposed 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 a medically accepted indication payable under Part B or 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, as defined in proposed § 429.20.

We proposed 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 proposed 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 proposed 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 proposed 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 1194(b)(2)(B) of the Act in accordance with section 1194(e) of the Act, we proposed 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 final 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 final 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 Schedule [84] (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

[84] 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.*

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, CMS would not make any offers or accept any counteroffers that are above the statutory ceiling as required by section 1194(c) of the Act and proposed at § 429.410(b) nor below the Temporary Floor for Small Biotech Drugs, if applicable, as indicated in § 429.440.

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 proposed 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 proposed 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 initial price applicability year (regardless of whether the agreed-upon MFP for such selected drug has become effective). We proposed 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 proposed 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 proposed 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 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) are above the ceiling, we proposed at § 429.510(d)(3) 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 under § 429.505(b); 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 under § 429.505(b); or the ceiling for the selected drug as determined in § 429.410(b).

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 final 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 proposed 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 proposed 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 further described later in this section. We proposed 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 further described later in this section. We proposed 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 later in this section. We also proposed 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 § 429.510(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 2-week period, meaning that one fill would be defined as a 30-day equivalent supply despite lasting only 2 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 approach, 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 proposed 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 final 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. In proposed § 429.510(e)(3)(i)(D), we proposed 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 events described in proposed § 429.515(b).

In all cases, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.[85] However, other drugs may have become available since the selected drug's initial approval and therefore we proposed 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 of consideration based on all available information at such time of consideration. In accordance with section 1194(e)(2)(A) of the Act, we proposed 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 proposed 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 proposed 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

[85] 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.*

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 proposed to consider the selected drug, its therapeutic alternative(s), if 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,'' [86] 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 proposed 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 proposed 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 proposed 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 selected 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 final rule. At proposed § 429.20, we proposed 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 selected 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 proposed 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 selected 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 final rule, we proposed 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 proposed 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 proposed 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 final rule and proposed at § 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 proposed 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 proposed 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

[86] 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.*

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, 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 proposed 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 for Small Biotech Drugs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that while they support clinical practice guidelines as a component of the evidence that CMS considers during the negotiation process, they indicated that guidelines offer the standards of care for a disease based on the information available at the time of publication and may not reflect the current evidence base or advancements in treatments; that is, clinically accepted uses can emerge before guidelines and compendia are updated and CMS should consider guidelines alongside other evidence.

Response: We thank these commenters for their input and agree that clinical practice guidelines, like other forms of evidence, may have limitations and biases. We believe clinical practice guidelines, when available, are an important component of understanding how a drug contributes to the course of care for a condition. As we stated in section II.F.3.d.1. of the proposed rule (91 FR 36292), we will use a qualitative approach to broadly evaluate the body of available evidence, which includes clinical guidelines and other forms of evidence including information received from the public and the Primary Manufacturer, 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 proposed at § 429.510(e)(2) that we may consult with clinicians, patients or patient organizations, researchers, FDA, or some combination thereof. We also note that the Primary Manufacturer can provide additional context or information on clinical guidelines, including whether there may be a change in clinical approach, throughout the negotiation period. We believe the combined approach of discussions with the Primary Manufacturer, reviewing the most recent guidelines, and consulting with clinicians, patients or patient organizations, researchers, FDA, or some combination thereof, as needed, provides CMS with a robust and up-to-date understanding of clinical guidelines and where recommendations may evolve.

Comment: A few commenters stated CMS should provide more transparency in how the section 1194(e)(1) factors are used and weighted during development of the initial offer and counteroffers. A commenter suggested that CMS should adjust the initial offer downward if R&D costs have been recouped for the selected drug. A commenter recommended that CMS place minimal weight on R&D recoupment. A commenter cautioned that CMS should not use prior Federal financial support, the factor listed at section 1194(e)(1)(C) of the Act, to adjust the preliminary price downward because it may discourage future innovation. A few commenters suggested that CMS should provide an upward adjustment for the factor listed at section 1194(e)(1)(D) of the Act (particularly, data on pending and approved patents and exclusivities) to indicate CMS' recognition of the innovation of the selected drug. A few

commenters stated that CMS should review patents and exclusivities for a selected drug to determine if such patents and exclusivities are indicative of innovation or if they indicate efforts to extend monopolies without associated clinical benefit. As a component of the factor listed at section 1194(e)(1)(A) of the Act, a commenter suggested that CMS increase the weighting of post-approval research that results in new indications or addresses an unmet medical need and also increase the weighting for active development of an additional indication. A commenter stated CMS should ''pay for the marginal cost of production and distribution'' for drugs used by Medicare beneficiaries. A commenter requested that CMS state how it considers the gross-to-net relationship of the price of a selected drug when developing the preliminary price. A commenter stated that CMS has not affirmed that section 1194(e)(1) factors may result in an upward adjustment to the preliminary price. A commenter supported the proposal to consider section 1194(e)(1) factors in totality.

Response: We thank these commenters for their input. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, we believe it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and subsequent offers and counteroffers, as applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives. Therefore, we decline to adopt the commenters' suggestions to apply specific positive or negative adjustments to specific section 1194(e)(1) or (e)(2) factors. With regard to suggestions that CMS provide more information on how a factor is weighted when developing the initial offer, we note that, as proposed at § 429.505(e), we consider all factors listed in section 1194(e) of the Act in the development of the initial offer. All applicable negotiation factors will be considered in totality for each selected drug, as proposed at § 429.510(f)(1). We also note that as proposed at § 429.510(f)(2), the preliminary price may be adjusted upward, downward, or not adjusted based on CMS' consideration of the section 1194(e)(1) factors.

Comment: A couple of commenters provided input on how CMS should consider clinical benefit for a selected drug that includes a fixed combination drug subject to the proposed policy described in section II.B.6.a.1. of the proposed rule (91 FR 36260) and at proposed § 429.125(b)(4)(i). One of these commenters recommended that CMS keep separate approaches for identification of potential qualifying single source drugs at proposed § 429.125(b) and valuation of selected drugs during negotiation at proposed § 429.510(e), stating that CMS may properly aggregate two products into the same qualifying single source drug to circumvent program integrity concerns while still recognizing during the negotiation process that each product provides distinct value. A couple of commenters recommended that CMS clarify in the final rule that when a selected drug subject to the negotiation process includes a fixed combination drug in accordance with proposed § 429.125(b)(4)(i), CMS will still consider formulation-specific clinical evidence under § 429.510(e) during the negotiation process.

Response: We appreciate the input from these commenters. As we stated in the Negotiation Program proposed rule at section II.B.6.a.1. (91 FR 36260) and as proposed at § 429.125(b)(4)(i), we clarified how CMS would comply with sections 1192(d)(3)(B) and 1196(a)(2) of the Act for fixed combination drugs that include 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), when identifying qualifying single source drugs for purposes of drug selection. We agree with the commenter that the process for identification of potential qualifying single source drugs is separate from our review of the factors listed at section 1194(e) of the Act, which we will consider as the basis for developing offers and counteroffers. We will follow the process described at § 429.510, including considering clinical and other evidence, for all drugs selected for negotiation for which the Primary Manufacturer has signed a Negotiation Program Agreement.

Comment: Many commenters recommended that CMS provide more detailed information on the framework used to develop the initial offer to promote transparency and consistency. Specifically, many commenters recommended that CMS assign greater weight to section 1194(e)(2) factors because these factors reflect the benefit a selected drug provides to patients, caregivers, society, and the health care system; some commenters also suggested that CMS should place less weight on section 1194(e)(1) factors as placing too much weight on such factors might undervalue innovation and overemphasize manufacturer costs and other manufacturer-submitted data. Some commenters requested that CMS consider factors not mentioned in the proposed rule, including the impact of a selected drug on the health system, costs to the patient, the societal value of a selected drug, cost offsets (such as avoiding ineffective or harmful treatment options and reducing downstream costs to the health care system), adherence, the value of multi-indication drugs, the value of companion diagnostics, and the mental and social wellbeing of patients and caregivers. A few commenters encouraged CMS to consider the full range of patient outcomes including but not limited to patient preferences, caregiver burden, and quality of life. A few commenters recommended applying greater weight to unmet medical need when adjusting for section 1194(e)(2) factors. A commenter suggested that when considering whether a selected drug represents a therapeutic advance, CMS should consider cost and outcomes metrics including patient and caregiver perspectives, reduced treatment burden, reduced hospitalizations, decreased reliance on adjunct therapies, and improved care coordination. A commenter suggested that the safety profile of a drug should be weighted when considering section 1194(e)(2) factors. A commenter recommended that CMS adopt an approach like the one used in Germany by the Institute for Quality and Efficiency in Health Care (IQWiG) to categorize therapeutic benefit. A couple of commenters recommended using the European Society for Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale (ESMO–MCBS)[87] in the assessment of section 1194(e)(2) factors. A commenter requested that CMS consider the full range of patient outcomes when considering evidence related to section 1194(e)(2) factors, including outliers and subpopulations that may benefit from a selected drug more than the mean. A commenter requested that CMS acknowledge the difference between evidence indicating that a drug offers no

[87] Cherney NI, Oosting SF, Dafni U, et al. ESMO-Magnitude of Clinical Benefit Scale version 2.0 (ESMO–MCBS v2.0). Annals of Oncology. 2025: *https://www.annalsofoncology.org/article/S0923-7534(25)00166-8/fulltext.*

additional benefit versus evidence that indicates uncertainty of additional benefit. A commenter suggested that CMS should treat each factor listed at section 1194(e) of the Act independently rather than conducting a holistic inquiry.

Response: We thank commenters for their feedback on the adjustments related to the factors listed at section 1194(e) of the Act. As we stated in the Negotiation Program Guidance, section 1196(a)(4) of the Act provides the Secretary with the authority to establish a negotiation and renegotiation process in accordance with section 1194 of the Act. This section directs the Secretary to establish a consistent methodology and process for negotiation (section 1194(b)(1) of the Act) and to consider the section 1194(e) factors as the basis for determining the offers and counteroffers (section 1194(e) of the Act) but does not dictate the manner in which those factors must be considered. Consistent with our response to similar comments in the Negotiation Program Guidance and the previously provided response related specifically to section 1194(e)(1) factors, we believe that flexibility in determining which section 1194(e) factors to emphasize over others will depend on the unique considerations related to each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives. Considerations for how evidence will be prioritized are proposed at § 429.505(d) and (e) and section II.D.1. of the proposed rule (91 FR 36292); these considerations are also applicable to renegotiation as proposed at § 429.620(d) and section II.G.5.c. of the proposed rule (91 FR 36308). All applicable negotiation factors will be considered in totality for each selected drug.

We appreciate the suggestion to use the ESMO–MCBS to assess section 1194(e)(2) factors and the approach used by IQWiG to categorize therapeutic benefit. As noted in our response to similar suggestions in the Negotiation Program Guidance, we consider whether the general approaches used in these frameworks may be informative for evaluating evidence in the context of the Negotiation Program and whether their use would be consistent with statutory requirements. We also note that the ESMO–MCBS is a tool specifically developed to assess cancer therapies and is not broadly applicable to all selected drugs. In situations where an interested party provides an ESMO–MCBS score for a particular selected drug or therapeutic alternative, we may consider such information in the context of the section 1194(e)(2) factors.

Comment: A few commenters supported CMS' approach described in section II.F.3.d. of the proposed rule (91 FR 36292) to consider source, rigor, and risk of bias, among other factors, when evaluating evidence. A commenter stated that CMS has not articulated an evidence review protocol. A couple of commenters recommended that CMS prioritize high quality, robust real-world evidence (RWE) while a commenter requested additional guidance on how CMS assesses RWE. A commenter suggested prioritizing evidence provided by clinicians and manufacturers given their expertise in the selected drug; a commenter suggested prioritizing evidence submitted by patients and clinicians. A commenter stated the CMS should recognize that while rigorous evidence is important, conventional evidence standards may not be appropriate to apply to rare diseases, small clinical populations, heterogenous conditions, or underrepresented patient populations. A couple of commenters stated that CMS should leverage claims and other datasets to understand utilization and usage patterns for a selected drug and its therapeutic alternative(s), if any.

Response: We appreciate commenters' support and their feedback regarding how we will consider evidence and how we will prioritize such evidence. Consistent with our response to similar comments in the Negotiation Program Guidance and as described in section II.F.3.d. of the proposed rule (91 FR 36292), when reviewing the data submissions from the public and manufacturer (including the previous examples of data) 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 will 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 believe this approach will ensure the integrity of data within the negotiation process.

Comment: Some commenters urged CMS to provide more information on how the information provided by the public, particularly patients, is used in the development of the initial offer. Suggestions included publication of a plain language summary of the major patient and caregiver themes received for each selected drug and an explanation of how those themes informed the negotiation process, publishing decisions throughout the negotiation process, and leveraging the National Health Council Patient-Centered Value Assessment Rubric and Rubric to Capture the Patient Voice to create a public framework for how evidence is considered and included in the negotiation process. A commenter suggested leveraging FDA Voice of the Patient Reports when available for selected drugs. A couple of commenters indicated express support for inclusion of patient and caregiver perspectives in the negotiation process, including related data such as patient-centered outcomes and patient experience data.

Response: We thank commenters for their suggestions. Consistent with the response provided to similar comments in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, we agree that considerations related to the patient and caregiver experience are important and relevant for consideration of the section 1194(e)(2) factors. We direct commenters to the provision proposed at § 429.510 and responses to comments about this section, which concern how we will use the section 1194(e) data, including patient and caregiver perspectives and experiences (such as through FDA Voice of the Patient Reports, as applicable), in developing an initial offer and, if any, counteroffers. We also believe the information provided in the explanation of the MFP as described in II.H.2. of the proposed rule (91 FR 36311), which we will make available to the public per the provision proposed at § 429.705(b), serves to provide sufficient information regarding use of the section 1194(e)(2) factors submitted and redacted copies of the section 1194(e)(2) factors submitted by interested parties that we considered during the negotiation process.

Comment: A commenter stated that CMS should share with the Primary Manufacturer whether CMS used the standard or alternative 30-day equivalent supply methodology described at § 429.510(d)(2)(iv) prior to or within the concise justification for

the initial offer. A commenter suggested that CMS should weight therapeutic alternative utilization such that utilization reflects the populations and uses for which the selected drug is prescribed in cases where aggregate utilization does not reflect the populations and uses for which the selected drug is prescribed. A commenter requested that CMS commit to a process that assesses and weights therapeutic alternatives by utilization across conditions, to avoid devaluing products that have shown benefit across multiple indications. A commenter requested that CMS clarify how it weights net prices across multiple indications and therapeutic alternatives. A commenter recommended that CMS calculate indication-level therapeutic alternative starting points and weight those starting points based on the Medicare utilization of the therapeutic alternatives relative to the selected drug in the same population.

Response: We thank these commenters for their suggestions. Although we do not include a detailed methodology of therapeutic alternative calculations in the concise justification for an initial offer, we welcome specific methodology questions related to how we calculated the starting point using the prices of therapeutic alternatives from the Primary Manufacturer during the optional negotiation meetings. We believe this approach appropriately balances transparency with the Primary Manufacturer while protecting proprietary information related to a therapeutic alternative.

Comment: A few commenters opposed CMS' consideration of off-label use for the purpose of determining indications and therapeutic alternatives to the selected drug stating that this conflicts with section 1194(e)(2)(B) of the Act. A commenter requested clarity on the ''threshold for inclusion'' of an off-label use and a commenter stated CMS should apply the same evidentiary rigor when reviewing off-label use as is applied to review of FDA-approved indications. A commenter suggested that CMS only consider off-label use for negotiation if it is voluntarily submitted by the Primary Manufacturer by adopting the provision for renegotiation eligibility as was proposed at § 429.605(c)(1)(ii). A commenter stated that Primary Manufacturers should not be responsible for submitting information on off-label use. A commenter stated that CMS should ensure that therapeutic alternatives are grounded in clinically appropriate FDA-approved indications and distinguish between approved uses and other off-label uses.

Response: We thank commenters for their feedback on consideration of off-label use of the selected drug when determining conditions for which the selected drug is used (as proposed at § 429.510(a)(2)) and therapeutic alternatives for the selected drug (as proposed at § 429.510(c)(2)(i)). Regarding the comments indicating that section 1194(e)(2)(B) of the Act directs CMS to consider prescribing information approved by FDA for such drug and therapeutic alternatives as the basis for determining offers and counteroffers, we affirm that we consider such information as described at § 429.510(e)(1) in the adjustment to the starting point based on section 1194(e)(2) factors. We also clarified in this final rule that we consider FDA prescribing information when determining therapeutic alternatives, if any, by revising proposed § 429.510(c)(2) to include a new paragraph (ii) indicating that CMS will consider prescribing information as approved by FDA. As other commenters have noted, particularly for rare diseases or small subpopulations or in situations where clinical evidence is not yet published, off-label use is an important component of patient care. Further, the Medicare program recognizes the importance of evidence-based off-label use of certain drugs by making such drugs payable under Part B, covered under Part D, or both for such uses. It is for this reason we define ''off-label use'' as described at § 429.20 as the use of a drug that 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.'' Under this definition, not all off-label uses are considered.

For these reasons, we believe that consideration of off-label use for the purposes of identifying conditions for which the selected drug is used and identifying therapeutic alternatives for those conditions, as applicable, is appropriately grounded in evidence and statute. We also believe that it is not necessary to solely consider off-label use if voluntarily submitted by a Primary Manufacturer for the purposes of identifying conditions for which the selected drug is used and identifying therapeutic alternatives for those conditions. When we are undergoing these processes, a drug has already been selected for negotiation or renegotiation and we are fulfilling our statutory directive to achieve the lowest MFP for the selected drug under section 1194(b)(1) of the Act. These are fundamentally different processes from determining renegotiation eligibility. We also note that neither in negotiation nor renegotiation is a Primary Manufacturer required to submit information on off-label use; in both cases submission of such information is optional.

Comment: A couple of commenters stated that CMS should not use generics, biosimilars and reference products as therapeutic alternatives in the development of the initial offer, as reliance on these products as therapeutic alternatives is not authorized by the statute. A few commenters stated that CMS should select therapeutic alternatives based on clinical appropriateness and solicit input from relevant stakeholders, including clinicians, patients, caregivers, and manufacturers, when evaluating clinical appropriateness. A few commenters suggested that CMS seek input from clinicians with expertise in treating the indications of the selected drug when selecting therapeutic alternatives, as well as seek input from patients, caregivers, manufacturers, and other stakeholders. A commenter stated that therapeutic alternatives should be based on clinical appropriateness and not based on least costly alternatives. A commenter stated that CMS should not rely on off-label use when comparing costs of therapeutic alternatives, absent robust evidence for the relevant condition. A commenter recommended that CMS account for variation in site-of-care practices and explain data and assumptions for determining that use of a drug occurs solely outside of Part B and Part D.

Response: We appreciate commenters' feedback regarding the identification of a therapeutic alternative(s) for the selected drug. Consistent with our response to similar comments in the Negotiation Program Guidance and final guidance for initial price applicability year 2027, we will identify the therapeutic alternative(s) for the indications of a selected drug by using 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 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. We believe the framework

described in the proposed rule allows us to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. We disagree with the commenters that state the statute does not authorize CMS to consider generics, biosimilars, or reference products as therapeutic alternatives in the development of the initial offer. Section 1194(e)(2) of the Act directs CMS to consider various evidence regarding therapeutic alternatives of the selected drug and does not limit the scope of therapeutic alternatives to exclude such products. However, if a Primary Manufacturer disagrees with CMS' identification of appropriate therapeutic alternatives to the selected drug, including any biosimilars or generic drugs, the Primary Manufacturer will have multiple opportunities to share that feedback with CMS, as described in § 429.515 and section II.F.4.a. of this final rule.

We agree with commenters that robust public input can provide important information on the selected drug and its therapeutic alternatives. As described at § 429.510(c), 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, and/or researchers, to ensure that appropriate therapeutic alternatives are identified. As such, we encourage members of the public, including manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties, to provide information about the selected drug and its therapeutic alternative(s), if any, through the Drug Price Negotiation ICR. We will consider information submitted through the Drug Price Negotiation ICR when developing the initial offer and throughout the negotiation process.

Regarding consideration of off-label use for therapeutic alternatives and their associated costs, we note that our policy includes the criteria that must be met for CMS to consider an off-label use of a selected drug as described at § 429.20. That is, we may consider off-label use when identifying indications if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof. In addition to consideration of public input and consultation when considering therapeutic alternatives, we also note that consistent with the policies in the Negotiation Program Guidance, the negotiation process policies described at § 429.515 include an opportunity for the Primary Manufacturer to meet with CMS regarding the data submission for the factors listed at section 1194(e) of the Act prior to CMS sending the initial offer. This initial meeting, as well as the negotiation process, including offer and counteroffer exchanges and negotiation meetings, provide additional opportunities for the Primary Manufacturer to discuss off-label use(s) and therapeutic alternatives with CMS.

Comment: A commenter recommended that CMS not treat within-class drugs as necessarily interchangeable therapeutic alternatives. A commenter suggested CMS limit selection of therapeutic alternatives to products in the same category and class that share a common clinical use. A commenter recommended that CMS limit therapeutic alternatives to pharmaceutical products that share the same mechanism of action as the selected drug, an overlapping indication, and occupy a comparable position in the treatment pathway for the same population. A commenter recommended that CMS identify therapeutic alternatives separately by each indication or line of therapy, or role of the drug in a multi-agent regimen. A commenter recommended that CMS not identify products as therapeutic alternatives that fail a clinical study for use in a condition in which a selected drug is approved. A commenter recommended CMS consider how FDA defines indicated populations and treatment settings, clinical guidelines, how clinician input addresses sequencing, contraindications, and Medicare utilization when considering therapeutic alternatives.

Response: We appreciate commenters' feedback regarding the identification of a therapeutic alternative(s) for the selected drug. Consistent with the response provided to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, as well as the previous comment response, we will identify the therapeutic alternative(s) for the indications of a selected drug by using 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 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. We believe the framework provided at § 429.510(b) allows us to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. As described at § 429.510(c)(1) we may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same condition and may also consult with clinicians, patients or patient organizations, researchers, or some combination thereof to ensure that appropriate therapeutic alternatives are identified.

Comment: A commenter recommended CMS leverage several resources when reviewing evidence related to therapeutic alternatives, including the National Pharmaceutical Council's Guiding Practices for Patient-Centered Value Assessment; The Myth of Average: Why Individual Patient Differences Matter, published by the National Pharmaceutical Council; ISPOR—The Professional Society for Health Economics and Outcomes Research and the International Society for Pharmacoepidemiology (ISPE) practices for real-world data studies of comparative effectiveness; and National Health Council (NHC) resources on patient-centeredness in value assessment. A commenter suggested that CMS adopt best practices from the Agency for Healthcare Research and Quality's (AHRQ) Effective Health Care Program guidance for therapeutic alternative selection.

Response: Consistent with our response in the Negotiation Program Guidance, we appreciate the suggested resources for best practices in observational comparative effectiveness research, real-world data studies of comparative effectiveness, and patient-centeredness in value assessments. We believe the methods and approach to therapeutic alternative selection and review of evidence related to therapeutic alternatives appropriately include similar elements and is aligned with the requirements of section 1194(e)(2) of the Act.

Comment: Some commenters recommended that CMS provide clarity on and adopt a consistent, transparent process for evaluation and selection of therapeutic alternatives. A commenter requested that CMS clarify how appropriate comparators are identified. A few commenters suggested that CMS provide detail on the data sources used to inform identification of therapeutic alternatives. A few commenters suggested that CMS provide

justifications for selections of therapeutic alternatives. A few commenters recommended that CMS disclose to the Primary Manufacturer the list of drugs it considers to be therapeutic alternatives and supporting evidence for those determinations early in the negotiation process. A few commenters recommended that CMS provide more transparency on how CMS distinguishes between clinically meaningful differences in therapeutic alternatives and how the agency selects therapeutic alternatives. A commenter recommended that CMS allow the Primary Manufacturer to object to the determination of a therapeutic alternative and for CMS to consider such objection before making a final determination. A commenter recommended offering Primary Manufacturers the opportunity to submit comparative effectiveness evidence after CMS has identified indications and therapeutic alternatives and seek input from manufacturers and other stakeholders on these alternatives, then using the prioritized alternatives for comparative effectiveness analysis.

Response: We thank these commenters for their input. As discussed in previous responses in this final rule, as well as consistent with our response to similar comments in the Negotiation Program Guidance, we believe the framework provided at § 429.510 allows us to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. We also note that the Primary Manufacturer is provided with information about the therapeutic alternative(s) selected per this process, if any, in the concise justification accompanying the initial offer proposed at § 429.520(b). In addition to consideration of public input and consultation when considering therapeutic alternatives, we also noted in a previous response that, consistent with the policies in the Negotiation Program Guidance, the negotiation process policies at § 429.515 include an opportunity for the Primary Manufacturer to meet with CMS regarding the data submission related to the factors listed at section 1194(e) of the Act prior to provision of the initial offer. This initial meeting, as well as the negotiation process, including offer and counteroffer exchanges and negotiation meetings, provide additional opportunities for the Primary Manufacturer to discuss therapeutic alternatives with CMS, including the opportunity to provide additional information or context, as suggested by a commenter. We believe this provides sufficient opportunity for discussions with the Primary Manufacturer while also adhering to the statutory timeline provided in section 1194(b)(2) of the Act.

Comment: A commenter recommended that CMS publish the list of potential therapeutic alternatives when selected drugs are announced and allow for stakeholder comment, while also allowing the Primary Manufacturer to see the list of therapeutic alternatives before submitting data.

Response: We appreciate commenters' feedback. Currently, the selected drug list is published no later than the selected drug publication date as defined in § 429.20 with respect to such initial price applicability year per § 429.100(b). We do not believe it is feasible to review drugs for selection for negotiation and renegotiation by the selected drug publication date and also determine potential therapeutic alternatives, if any, for such drugs. Further, such a process would preclude CMS' ability to review the information submitted by the Primary Manufacturer and interested parties under § 429.505 to inform selection of therapeutic alternatives, including engagement opportunities described at § 429.515(b). We also reiterate that the negotiation process policies at § 429.515 include an opportunity for the Primary Manufacturer to meet with CMS regarding the data submission related to the factors listed at section 1194(e) of the Act prior to provision of the initial offer and that we provide information about therapeutic alternatives in the concise justification accompanying the initial offer proposed at § 429.520(b).

Comment: A commenter supported CMS' approach for adjusting the starting point of the initial offer but stated that the prices of therapeutic alternatives should not be used as the starting point, as this approach would entrench high prices into the negotiation process. A few commenters opposed CMS' proposals for developing a starting point. A commenter stated that the starting point is extra-statutory. A couple of commenters stated that CMS should anchor its initial offer to the statutory ceiling and evaluate section 1194(e) factors independently from that ceiling. A commenter stated that CMS should not use not-yet-effective MFPs of therapeutic alternatives as the basis for setting a starting point, as the not-yet-effective MFP is not a price that presently exists in the marketplace. A commenter stated that CMS should not build the starting point for a drug in one monopoly status on the price of a drug in a different monopoly status. A commenter stated that CMS should not consider starting points based on reference prices, costs of production or distribution, or other factors that do not provide clinical value to Medicare beneficiaries. A commenter recommended that CMS base an initial offer on risk-adjusted research and development costs; the extent to which those costs have been recouped by the manufacturer; federal investment; and section 1194(e)(2) factors. The commenter also recommended that once an initial offer is determined, CMS should compare the price of the selected drug to therapeutic alternatives and offer an MFP that is no higher than the lowest price of a therapeutic alternative that has a comparable safety and efficacy profile.

Response: We thank commenters for their feedback on determining a starting point for developing the initial offer. We disagree that the approach to determining a starting point for development of the initial offer is not grounded in statute. As described earlier, section 1194(e)(2)(A) of the Act directs CMS to consider both the extent to which a selected drug represents a therapeutic advance compared to its therapeutic alternative(s) and the cost of such existing therapeutic alternative(s). We previously considered several alternative options for what price should be used as the starting point for developing the initial offer, including the unit cost of production and distribution for the selected drug, the ceiling, a domestic reference price (for example, the FSS price), or a ''fair profit'' price based on whether R&D costs have been recouped, and margin on unit cost of production and distribution. We determined using Net Part D Plan Payment and Beneficiary Liability, ASP, WAC, or MFP of therapeutic alternatives is consistent with the Act and provides a point at which 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, if available, and then make adjustments based on the factors listed at section 1194(e) of the Act. 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.

Consistent with our response to similar comments in the Negotiation Program Guidance, we believe the negotiation process described in subpart

F, and the renegotiation process described in subpart G, results in an MFP for a selected drug that reflects each selected drug's circumstances and is based on the factors outlined in section 1194(e) of the Act, which we are required to consider. We believe this includes situations where the starting point is another selected drug's MFP (in cases where there is one therapeutic alternative) or includes an MFP (in cases where there are multiple therapeutic alternatives and only one or some of the therapeutic alternatives are selected drugs). Consistent with the Negotiation Program Guidance, the policy to use the MFP as the starting point in cases where the therapeutic alternative was itself a selected drug and the MFP is lower than the Net Part D Payment and Beneficiary Liability is aligned with the statutory directive in section 1194(e)(2)(A) of the Act to consider the costs of therapeutic alternatives, which may include selected drugs with an agreed-upon MFP, including situations where there is an agreed-upon MFP but such MFP has not taken effect. And, consistent with our response to similar comments in the Negotiation Program Guidance, offering the ceiling without a more thorough review of section 1194(e)(1) factors, including manufacturer-submitted data, may not achieve that objective and is inconsistent with the statutory directive at section 1194(e) of the Act. Regarding the comment that once an initial offer is determined, CMS should compare the price of the selected drug to therapeutic alternatives and offer an MFP that is no higher than the lowest price of a therapeutic alternative that has a comparable safety and efficacy profile if the initial offer is not already below such price, we believe such an approach might overweight the factors listed at section 1194(e)(2)(A) and (C) (and further overweight a single therapeutic alternative, if multiple therapeutic alternatives are identified), as those would be the only factors reflected in an initial offer when such an offer was made, in contrast to the proposed approach in which all factors listed at section 1194(e) of the Act may impact the development of the initial offer. Upon consideration of these comments, we decline to adopt these alternative approaches to establishing a starting point for developing the initial offer to preserve agency flexibility in making adjustments to the price based on section 1194(e) factors.

Comment: A few commenters recommended CMS develop and implement a clear, consistent and transparent methodology for developing a starting point for the initial offer. A commenter offered support for CMS' proposed approach to consider patient-centered outcomes, patient experience data, and patient and caregiver preferences in the framework for evaluation of the initial offer. The commenter also suggested CMS consider whether negotiated prices could correspond with measurable, real-world outcomes, such as medication persistence and reduction in treatment interruptions, while ensuring that these outcomes are examined across patient populations. A commenter stated that CMS does not provide a transparent methodology or information on how factors in CMS' valuation framework are applied and recommended that CMS provide an explanation to manufacturers on how it applies its valuation methodology to each selected drug. A commenter stated that CMS does not articulate how it operationalizes definitions of unmet medical need and therapeutic alternatives, and that Primary Manufacturers are unaware of how such data is weighted, or if a selected drug satisfies either definition. The commenter recommended that CMS specify reference points governing in-scope evidence and describe the process by which such evidence is evaluated. A commenter recommended CMS apply a transparent two-stage qualitative framework that assesses the relevance and credibility of appropriate analyses and then synthesizes the body of work writ large to determine relevance across comparative direction, economic materiality, certainty and Medicare applicability. A couple of commenters recommended that CMS provide transparency on the types of evidence used to evaluate therapeutic advance, unmet need, and effects of the selected drug on specific populations. A commenter requested that CMS disclose the methodology and assumptions used when calculating prices for therapeutic alternatives. A commenter requested that CMS commit to a holistic review of evidence when developing the initial offer, including real world evidence, benefits to subpopulations, patient preferences and treatment of conditions with limited alternatives. A commenter requested CMS specify how it will value unmet medical need when a selected drug is used in combination with a therapeutic alternative. The commenter also requested CMS clarify how the cost of a therapeutic alternative will impact the assessment of a therapeutic advance. A commenter recommended that CMS pursue the lowest MFP permitted by law and give substantial weight to evidence demonstrative what constitutes a reasonable price. A commenter stated that the proposed value assessment framework does not effectively account for viral suppression, adherence outcomes or public health costs of averted HIV transmissions. The commenter recommended that injectable forms of long-acting HIV therapies receive appropriate consideration as therapeutic alternatives, as well as off-label utilization.

Response: We appreciate commenters' feedback and recognize the importance of balancing transparency and confidentiality in the negotiation process. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, we reiterate that we believe it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and subsequent offers and counteroffers, as applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives.

Section II.D.1. of the proposed rule (91 FR 36292) describes how CMS will prioritize evidence related to the section 1194(e) factors; these considerations are also applicable to renegotiation as discussed at section II.G.5.c. of the proposed rule (91 FR 36308). All applicable negotiation factors will be considered in totality for each selected drug.

Consistent with our response to similar comments in the Negotiation Program Guidance, we will evaluate the extent to which a selected drug addresses an unmet medical need or represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

Regarding the commenter's suggestion that we pursue the lowest MFP permitted by law, we refer the commenter to section II.D. of the proposed rule (91 FR 36292) where we introduce our methodology and process as developed in accordance with section 1194(b) of the Act, which requires CMS to aim to achieve the lowest MFP possible. We believe the framework outlined in the proposed rule and adopted by this final rule achieves this statutory directive and decline to adopt commenters' recommendations.

Final Decision: After consideration of public comments, we are finalizing § 429.510(a), (b), and (f) as proposed.

We are finalizing § 429.510(c) as proposed but with a modification to § 429.510(c)(2) to include a new paragraph (ii) indicating that we consider FDA approved prescribing information when determining therapeutic alternatives, if any. We also are adding ''all of the following'' to § 429.510(c)(2) and are deleting ''and'' in the re-numbered § 429.510(c)(2)(iv).

We are finalizing § 429.510(d) as proposed but with the following technical changes: we are adding ''the following'' to § 429.510(d)(1)(i); we are deleting ''or'' in § 429.510(d)(1)(i)(B); we are adding ''the following'' to § 429.510(d)(1)(ii); we are deleting ''or'' in § 429.510(d)(1)(ii)(B); we are adding ''the following'' to § 429.510(d)(3)(i); and we are deleting ''or'' in § 429.510(d)(3)(i)(B).

We are finalizing § 429.510(e) as proposed but with the following technical changes: we are adding ''all of the following'' to § 429.510(e)(3)(i); we are deleting ''and'' at § 429.510(e)(3)(i)(C); we are adding ''both of the following'' to § 429.510(e)(3)(ii); we are deleting ''and'' at § 429.510(e)(3)(ii)(A); we are adding ''both of the following'' to § 429.510(e)(4)(i); we are deleting ''and'' at § 429.510(e)(4)(i)(A); we are adding ''all of the following'' to § 429.510(e)(4)(ii); and we are deleting ''and'' at § 429.510(e)(4)(ii)(B).

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 proposed 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 proposed at § 429.515(a)(2) to continue to limit the number of meeting attendees.

We proposed at § 429.515(a)(3)(i) that Primary Manufacturers may share new information on section 1194(e)(2) factors during meetings. We also proposed that 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 proposed 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, we proposed that 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 proposed 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 final 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 final 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 final 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.

Final Decision: We did not receive public comments on this provision. We are finalizing § 429.515(a) with a technical modification to add ''and'' to § 429.515(a)(3)(i)(A) and (B). We also are making a modification to § 429.515(a)(3)(ii) to clarify that CMS may request that the Primary Manufacturer provide copies of any presented or discussed materials before the meeting in which they are presented or discussed. This modification aligns with current operational practices in

which CMS requests materials prior to a meeting.

b. Engagement With Interested Parties

At proposed § 429.515(b), we proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed appreciation for CMS codifying public engagement events in regulation and supported CMS' continued efforts to engage patients and interested parties in the negotiation process. However, some commenters noted their disappointment that CMS did not establish minimum requirements and standards around public engagement events through rulemaking, such as committing to multiple public meetings for each selected drug. They encouraged CMS to do so. A few of these commenters acknowledged CMS' preference to preserve flexibility but they expressed concern that without clear requirements, CMS falls short of supporting meaningful stakeholder engagement.

Response: We appreciate the commenters' input. By codifying public engagement events in regulation, we are establishing a minimum requirement—that is, we are committing to holding these events for future initial price applicability years. We believe it is important to maintain flexibility when holding these events because of the potential for an increase in the number of selected drugs covered under Part D and/or payable under Part B in future cycles of negotiations. We disagree that maintaining flexibility indicates that these events inadequately support meaningful stakeholder engagement. As stated in the Negotiation Program proposed rule (91 FR 36296), the public engagement events allow us to hear from patients and other stakeholders—directly and in their own words—about patient's personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions.

Comment: Many commenters provided feedback on and recommendations for CMS to improve upon public engagement events held for initial price applicability year 2028. Recommendations included: simplifying the event registration process; publishing CMS' speaker selection criteria; providing a list of discussion questions in advance of the events; providing more time for participants to prepare for the events; broadening the information asked of patients to more holistically address how they value medications and treatment; expanding outreach efforts; expanding the public engagement events to include more participants; providing more accessibility accommodation such as translated materials and interpretation services; expanding conflict of interest disclosure and reporting by CMS; publishing thematic event summaries in addition to event transcripts; providing greater transparency in explaining how information gathered via public engagement events is used in negotiations.

Response: We appreciate commenters providing specific feedback about the public engagement events held for initial price applicability year 2028 and offering recommendations for improvement and refinement. We will consider these recommendations as we plan the events for future negotiation cycles.

Comment: Many commenters recommended that CMS expand the methods for patients and other interested parties to provide information to CMS beyond participating in public engagement events, including offering opportunities for ongoing input. Examples cited include asynchronous input such as written comments, audio submissions, or recorded video statements.

Response: We appreciate these suggestions about increasing the ways interested parties share information with us. We recognize the importance of patients having access to multiple methods for sharing information about their experiences. We hosted such events in a non-livestreamed venue that included only patients, patient advocacy organizations, and caregivers for initial price applicability years 2027 and 2028. Additionally, patients, patient advocacy organizations, caregivers, and others such as clinicians, researchers, and the public at large, may submit written comments via the Drug Price Negotiation ICR. We intend to submit this final ICR for OMB approval upon publication of the final rule. Once approved, patients and others will have the opportunity to submit their information in early 2027 for initial price applicability year 2029. At this time, we are unable to accept recorded comments or audio submissions for the Negotiation Program. However, we broadly welcome input from interested parties and the public by email at: *IRARebateandNegotiation@cms.hhs.gov.* We review and respond to inquiries received via the IRA mailbox.

Final Decision: After consideration of public comments, we are finalizing § 429.515(b) as proposed.

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 proposed 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 proposed 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 described in section II.E.3. of this final rule and in proposed § 429.410(b). Consistent with proposed § 429.440(b), no written initial offer can be less than the Temporary Floor for Small Biotech Drugs, if final, as defined in section 1194(d) of the Act and described in section II.E.9. of this final rule.

With respect to initial price applicability year 2029 and subsequent years, we proposed 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 described in section II.F.3. of this final 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 final rule and in proposed § 429.300, or the starting point.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. Given that commenters combined feedback on these proposals regarding the initial offer and concise justification with feedback on the proposal for counteroffers at § 429.525, we include the comments received on counteroffers and proposed § 429.525 in this section.

Comment: A commenter recommended CMS provide a meaningful justification for the initial offer and provide manufacturers with the opportunity to comment on CMS' response to any counteroffers. Another commenter stated that without a meaningful justification from CMS in the initial offer, manufacturers cannot provide a meaningful justification in a statutory written counteroffer. A few commenters suggested that the concise justification and CMS' response to any counteroffer should detail specific information, such as the sources CMS referenced, evidence considered, section 1194(e) data considered and how they were weighted, therapeutic alternatives considered, interested parties consulted, and benefits and impacts of the drugs considered. Another commenter recommended CMS' concise justification should have a consistent documented structure containing certain elements relevant to the proposal for the MFP.

Response: We thank these commenters for their feedback. Consistent with our response to similar comments in Negotiation Program Guidance and the final guidance for initial price applicability year 2027, section 1194(b)(2)(B) of the Act directs CMS to provide a concise justification to the Primary Manufacturer when the initial offer is made. CMS implements the requirement to provide an initial offer and concise justification to a Primary Manufacturer in a consistent manner across all Primary Manufacturers, as required by section 1194(b)(1) of the Act. We will include information regarding the range of evidence and other information submitted pursuant to section 1194(e) of the Act that CMS found compelling in developing its initial offer, which includes the identification of therapeutic alternatives. Because this information will be shared with the Primary Manufacturer, we believe the concise justification will be meaningful and will provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the initial offer. While any statutory written counteroffer should respond to the justification provided in CMS' written initial offer, a Primary Manufacturer is not limited by the information provided in CMS' written initial offer when developing a statutory written counteroffer. As described in § 429.515(a)(1), the first meeting that we will offer Primary Manufacturers to attend will 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 § 429.505(b)(2) and (d)(3), respectively, as we begin evaluating the data submission and developing an initial offer as described in § 429.510. We will 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. These meetings also provide a Primary Manufacturer with an opportunity to comment on CMS' response to any counteroffer.

Additionally, as described in § 429.530, the additional price exchange opportunities enable CMS and Primary Manufacturers to initiate additional written offers and counteroffers via the CMS HPMS, and this functionality includes an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer.

Final Decision: After consideration of public comments, we are finalizing § 429.520 as proposed but with a technical modification to add ''and'' to § 429.520(b)(1).

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 proposed 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 proposed in § 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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 final 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 described in section II.E.9. of this final rule.

We received public comments on these proposals. The summary of the comments we received and our responses are included in section II.F.5. of this final rule.

Final Decision: After consideration of public comments, we are finalizing § 429.525 with modifications at § 429.525(b)(1) to clarify any statutory written counteroffer must ''do all of the following'' in § 429.525(b)(1)(i) through (iii). We also are making a technical modification to remove ''and'' from § 429.525(b)(1)(ii).

7. Additional Price Exchange Opportunities (§ 429.530)

Consistent with policies for implementation in section 60.4 of Negotiation Program Guidance, we proposed 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 the deadline by which CMS must issue 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 proposed 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 proposed 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 final 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 described in section II.E.9. of this final 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 final rule and in proposed § 429.200(e) that sets forth the agreed-upon MFP.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.530 as proposed.

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 proposed in § 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 proposed 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 final 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 final rule and in proposed § 429.205.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.535 as proposed.

G. Renegotiation of an MFP (§§ 429.600 Through 429.620)

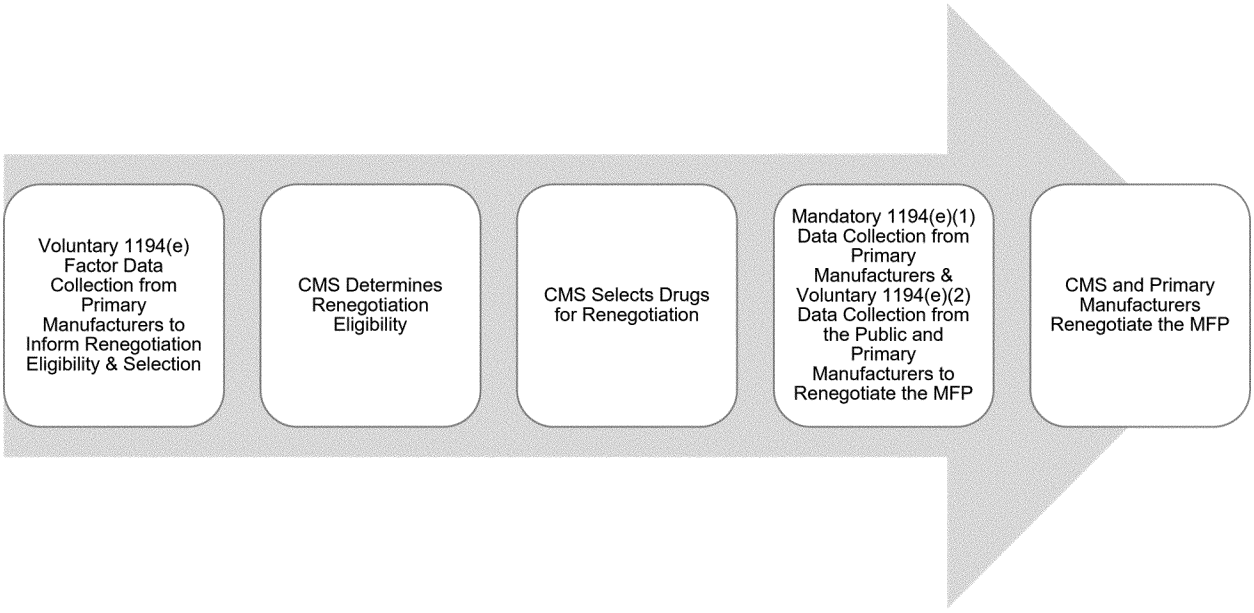
1. General Rule (§ 429.600)

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 proposed to identify renegotiation-eligible drugs in accordance with section 1194(f)(2) of the Act, as described 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 final rule, would be required to adhere to the process and deadlines described throughout this final rule. For example, the policies described in proposed subparts F and H (described in sections II.F. and II.H. of this final 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 proposed 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 proposed 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 proposed 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 proposed 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)).

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.600 as proposed with technical modifications. Specifically, we are deleting ''proposed'' at §§ 429.600(b)(1) and (b)(2) to reflect that this is a final regulation. We also are adding ''of the Act'' to § 429.600(b)(3) to clarify that the reference is to section 1193(a)(3) of the Social Security Act.

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 proposed 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 proposed 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 final 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 proposed 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 proposed 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 § 429.605(a)(1), we proposed 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 proposed § 429.125(b)(4), the distinct combination of active moieties/active ingredients) [88] 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 proposed 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.[89]

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 proposed § 429.125(b)(4), the distinct combination of active moieties/active ingredients) [90] 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 proposed 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

[88] 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.

[89] As we proposed 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.

[90] 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.

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 proposed 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 labeling [91] for a selected drug, we proposed at § 429.605(c) to use a number of sources, for example the Drugs@FDA database.[92] We also proposed at § 429.605(c)(2)(ii) to review voluntary submissions from Primary Manufacturers if any are submitted. We proposed 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 proposed that we would determine a drug to be renegotiation-eligible based on the addition of a new indication if the FDA-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 proposed 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 considered 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 proposed at § 429.605(c)(3) that the 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(a). We are making a technical correction to § 429.605(c)(3). This correction indicates that, in the absence of a voluntary data submission from the Primary Manufacturer, a new indication must be added to the FDA-approved labeling on or before a time specified by CMS, which will be September 30 of the year before the selected drug publication date 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 (CMS–10844, OMB 0938–1443) 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 a new indication, we may incorporate the Primary Manufacturer's submission in determining whether a new indication has been added for a selected drug such that it is renegotiation-eligible. 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 for the Drug Selection ICR.

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 proposed 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 final rule) to determine if there is a material change. We also proposed 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 final 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 considered 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.

[91] Such additions to the FDA approved labeling include new indications approved in both new NDAs/BLAs and supplements to previously approved NDAs/BLAs.

[92] Available at *www.fda.gov/drugsatfda, https://www.fda.gov/vaccines-blood-biologics/cber-regulated-products-supporting-documents.*

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 of information that is available on or before September 30 would not be inclusive of information submitted by the Primary Manufacturer through a voluntary submission through the Drug Selection ICR. 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 II.F1 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 II.F1: 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 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) 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.
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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended that a drug should not be selected for renegotiation until at least one year has passed since its last negotiation or renegotiation period concluded. A commenter recommended that CMS not select drugs for renegotiation that have had an MFP established in the last 2 to 3 years, absent a change in monopoly status or manufacturer request. A commenter requested that CMS not exclude drugs from selection for renegotiation in cases where the MFP might only apply briefly, since even a single year of the MFP could have a substantial impact on beneficiaries and the program.

Response: We appreciate the perspectives offered by these commenters and acknowledge that it is possible under the statute that a selected drug with an agreed-upon MFP could be renegotiated relatively soon after the conclusion of a prior negotiation or renegotiation. However, consistent with our response to similar comments in the Negotiation Program Guidance and as discussed in section II.G.2. of the proposed rule (91 FR 36299), 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. We provided the following 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 described at § 429.605. Sections 1194(f)(2) and (f)(3) of the Act clearly describe the circumstances under which CMS considers renegotiation eligibility and subsequently selects a renegotiation-eligible drug for renegotiation. We believe it is possible that a selected drug could have a change in monopoly status, a material change to a factor

described at section 1194(e) of the Act, or a new indication as described at § 429.605(b) through (d) since its last negotiation or renegotiation period concluded, even if less than one year has passed since that negotiation period or renegotiation period concluded. The statute does not provide for exceptions or delay in selection for renegotiation for any specific category of renegotiation-eligible drugs.

Comment: A commenter requested that CMS clarify that changes in a drug's monopoly status to or from extended monopoly status would not result in such drug becoming eligible for renegotiation under proposed § 429.605(b) before initial price applicability year 2030.

Response: We direct this commenter to footnote 60 in section II.G.2.a. of the proposed rule (91 FR 36300) and to the definition of ''extended-monopoly drug'' proposed at § 429.20 where we indicate that the definition of ''extended-monopoly drug'' 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 per section 1194(c)(4)(B)(ii) of the Act.

Comment: A couple of commenters opposed CMS' consideration of off-label use when determining if there is a new indication for the purpose of renegotiation eligibility under proposed § 429.605(c); a commenter supported this policy. A few commenters supported the inclusion of off-label use when considering new indications for renegotiation eligibility but requested that CMS expand consideration beyond voluntary manufacturer submissions of off- label use information to avoid a situation where a new off-label use emerged but a manufacturer chose not to submit such use for CMS' consideration.

Response: We appreciate the feedback from these commenters. We believe that the consideration of off-label use when determining whether a selected drug is eligible for renegotiation under § 429.605(b) is appropriate as the statutory text at section 1194(f)(2)(A) of the Act does not make specific reference to the FDA, licensures, or approvals as can be seen elsewhere in the Act, therefore CMS is not limited to only consideration of on-label use. Further, the statutory reference to ''new indication'' at section 1194(f)(2)(A) of the Act is best read as including off-label use for consistency with longstanding Medicare program policy to permit coverage and payment of drugs that are supported by evidence-based clinical practice guidelines and the off-label use is a medically accepted indication payable under Part B or covered under Part D and for consistency with the negotiation process.

We note that renegotiation eligibility and selection is a distinct process from selection for negotiation as proposed at § 429.105, which specifically indicates that CMS reviews negotiation-eligible drugs to determine that such drug is approved or licensed under section 505(j) of the FD&C Act or under section 351(k) of the PHS Act. Additionally, the consideration of off-label use for the purpose of renegotiation eligibility is aligned with the negotiation process, specifically, CMS considers off-label use when determining the conditions for which the selected drug is used (as proposed at § 429.510(a)(2)) and when determining therapeutic alternatives for the selected drug (as proposed at § 429.510(c)(2)(i)). Renegotiation eligibility is determined based on changes to the monopoly status of a drug, the addition of a new indication to the drug, or a material change to a factor listed at section 1194(e) of the Act. We believe that off-label use is an appropriate element to consider in the context of renegotiation eligibility, specifically with respect to renegotiation eligibility based on the addition of a new indication to the drug since off-label use is relevant for determining the conditions for which a selected drug is used, and with respect to eligibility based on a material change to a factor listed at section 1194(e) of the Act since off-label use within a previously considered disease or condition could demonstrate a material change to a factor listed at section 1194(e) of the Act.

We considered what sources of information CMS should review for consideration of new off-label uses that might be considered for renegotiation eligibility. When considering off-label use for the purpose of renegotiation eligibility under section 1194(f)(2)(D) of the Act, we believe that the Primary Manufacturer is well-positioned to provide information regarding off-label uses that may be considered to be a new indication as the Primary Manufacturer often has complete information about use of the selected drug, including updates on how the drug might be used off-label, as well as the extent to which CMS and the Primary Manufacturer already engaged on a given potential off-label use during a previous negotiation or renegotiation. We also note that should a new off-label use emerge, in the event it is not submitted to CMS by the manufacturer for CMS' consideration, there would likely be downstream impacts on other factors listed at section 1194(e) of the Act that could lead to consideration for renegotiation eligibility as a material change. In accordance with § 429.605(d)(2), we will review several sources as listed in § 429.510(f) when reviewing whether there has been a material change to a factor listed at section 1194(e) of the Act for a selected drug. For example, a new off-label use could increase utilization of a selected drug and therefore result in changes to the factor listed at section 1194(e)(1)(E) of the Act. Another example is if a new off-label use could meet an unmet medical need per the factor listed at section 1194(e)(2)(D) of the Act and therefore be considered as a potential material change for renegotiation eligibility.

Comment: A few commenters requested that CMS clarify what constitutes a material change within the factors listed at section 1194(e) of the Act. A commenter urged CMS not to finalize the proposed policy at § 429.605(d) and instead requested a narrower and more specific framework for determining what constitutes a material change. A commenter also stated that the proposed rule does not explain how materiality calculations can be made prior to a manufacturer's data submission. A commenter provided a list of changes to each factor listed under section 1194(e) of the Act and recommended that CMS consider such changes material under proposed § 429.605(d). These changes included for the factors listed at section 1194(e)(1)(A) through (D) of the Act: the recoupment of R&D costs if such costs had not been recouped at the time of its initial negotiation; a significant increase or decrease in the manufacturer's unit costs of production and distribution; if primary patents or exclusivities recognized by FDA expire or are invalidated and no generic or biosimilar competition has emerged; if the selected drug no longer represents a therapeutic advance as compared to existing therapeutic alternatives due to new drug or indication approvals or, alternatively, if the costs of existing therapeutic alternatives change or if an existing therapeutic alternative is selected for negotiation and the MFP is lower than its previous price; if prescribing information changes meaningfully; if additional comparative effectiveness evidence becomes available that adds to the existing body of evidence; and if the selected drug is no longer fulfilling an unmet medical need. A commenter stated that the proposed rule did not specify what constitutes the time of

consideration for the purpose of determining whether there has been a material change. A commenter suggested that CMS consider revision in ESMO–MCBS scoring or other clinical benefit frameworks applicable to a selected drug as a circumstance that would represent a potential material change. A commenter also recommended that CMS not allow multiple material changes to cancel one another out, if there would still likely be an impact on the MFP when considered holistically. A commenter recommended that CMS consider whether a Primary Manufacturer has secured longer monopoly protection due to ''patent thicketing'' or other similar strategies.

Response: We thank these commenters for their feedback. Section II.G.2.d. of the proposed rule (91 FR 36301) describes an approach to determine what constitutes a material change to a factor listed at section 1194(e) of the Act, which includes a change(s) that would reasonably be expected to meaningfully alter the consideration of the factor within the context of renegotiation offers and counteroffers compared to offers and counteroffers during the most recent prior negotiation or renegotiation for the selected drug. As stated in the proposed rule, section 1194(f)(2)(D) of the Act provides CMS with the discretion to determine what constitutes a material change. Regarding commenters' concern about material changes effectively ''canceling'' one another out, we note that for the purpose of renegotiation eligibility we consider changes within each factor holistically when considering whether there has been a material change for a given factor for the purpose of renegotiation eligibility. When considering whether a renegotiation-eligible drug that is eligible due to the addition of a new indication or a material change to a factor listed at section 1194(e) of the Act must be selected for renegotiation because CMS expects renegotiation is likely to result in a significant change in the MFP otherwise negotiated, we consider the new indication(s) and material change(s) to factors listed at section 1194(e) of the Act holistically when evaluating the likelihood that the new indication(s) and material change(s) would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and whether such a change in MFP would have a significant impact on the Medicare program. Material changes within different factors would not ''cancel'' each other out for purpose of renegotiation eligibility; however, for selection, CMS would consider the likely impact of the changes to the factors listed at section 1194(e) of the Act holistically. Similar to our approach to considering evidence related to the factors listed at section 1194(e) of the Act (proposed at § 429.510(e) and (f)), we believe a holistic approach is necessary to consider the unique characteristics of each selected drug. Further, due to the unique characteristics of each selected drug and the population and conditions treated by such drug, it is not feasible to provide a list of specific changes that would qualify as a material change for the purpose of renegotiation eligibility. We also note that consideration of data on pending and approved patents may be considered within this holistic framework as part of our consideration of the factor listed at section 1194(e)(1)(D) of the Act. We appreciate commenters' request for additional clarity, and believe the illustrative examples provided in Table II.F1 of the proposed rule (91 FR 36302) help readers understand how we may consider material change in different circumstances and that determining renegotiation eligibility will be drug specific.

Regarding when we will consider material change relative to when information is submitted for the factors listed at section 1194(e) of the Act, we direct commenters to section II.G.2.d. of the proposed rule (91 FR 36301) where we indicated that we will 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 and, should the Primary Manufacturer chose to submit information through the voluntary Drug Selection ICR of that same calendar year, we may update our review of material change(s) with new applicable information. This comment prompted us to make a clarification to when we would consider a new indication for the purpose of renegotiation eligibility as discussed in section II.G.2.c. of the proposed rule (91 FR 36300) where we state that a ''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''. We clarify in this response that we will consider a new indication that is added to the FDA-approved labeling for the selected drug for renegotiation eligibility if such indication is added on or before September 30 of the year prior to the selected drug publication date for the initial price applicability year for which the drug would be selected for renegotiation or, as discussed in section II.G.2.d. of the proposed rule (91 FR 36301), should the Primary Manufacturer choose to submit data through the voluntary submission proposed at § 429.615(a), then we may consider such information in our review of new indication(s).

Regarding the suggestion to consider a revision to the ESMO–MCBS or another clinical framework as a material change for the purpose of determining renegotiation eligibility, we note that should such a change be submitted through the Drug Selection ICR, we may consider such information when determining renegotiation eligibility. A revision in scoring to the ESMO–MCBS or another clinical framework may or may not be indicative of a material change under section 1194(f)(2)(D) of the Act. We believe the criteria under § 429.605(d) provides a clear and appropriate framework for how we will consider information, including changes in scoring for selected drugs within clinical frameworks such as the ESMO–MCBS, for the purpose of renegotiation eligibility.

Comment: A few commenters opposed or requested the removal of the last example in Table II.F1 of the proposed rule (91 FR 36302) regarding how CMS may view an indication for a selected drug that was not covered under Part D or payable under Part B at the time the drug was previously negotiated. A couple of commenters requested that CMS clarify that Part B utilization of a selected drug with an existing MFP would not, alone, constitute a material change. A couple of commenters opposed the notion that a change in coverage status would constitute a material change. A commenter appreciated the example provided in Table II.F1 (91 FR 36302).

Response: We thank these commenters for their feedback on the example included in Table II.F1 of the proposed rule (91 FR 36302) and the interpretation of this example. We assume the commenters requesting that we clarify that Part B utilization alone would not constitute a material change are specifically referring to a situation where a drug was selected for negotiation in initial price applicability year 2026 or 2027 when such selection and negotiation was for coverage under Part D only. In this context, we agree that the existence of Part B utilization of a selected drug would not, alone, constitute a material change. However,

per section 1194(f)(2)(D) of the Act, we would consider changes to the factor listed at section 1194(e)(1)(E) of the Act (''market data and revenue and sales volume data for the drug in the United States''), which could be impacted by the inclusion of, or a change in, Part B utilization for a selected drug. In addition, should a situation arise where a selected drug was either not previously payable under Part B or covered under Part D when it first became a selected drug but later becomes payable under either Part B and covered under Part D, or both, this could be indicative of a change in a factor listed at section 1194(e) of the Act. For example, a coverage change could indicate that there is a new off-label use being added to clinical guidelines or compendia, or could address an unmet medical need, among other possibilities. In such cases, if there were a corresponding change in a factor listed at section 1194(e) of the Act, we would consider such change and determine if the change is material under § 429.605(d)(1). This is explained in the column titled ''Potential Result for Changes in Section 1194(e) Factor'' in Table II.F1 (91 FR 36302). To clarify the last example listed in Table II.F1 (91 FR 36302), the Example Scenario is intended to describe a situation where an indication for a selected drug was either not covered under Part D, not payable under Part B, or both, at the time the drug was previously negotiated but is now payable under Part B, covered under Part D, or both and, as a result, Medicare beneficiaries now have a covered treatment option for an indication for which treatment was previously not addressed adequately by available therapy. A potential result for this illustrative scenario could be that we may determine the selected drug now addresses an unmet medical need for Medicare beneficiaries as an available treatment for the newly covered indication, and this could 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.

Comment: A commenter requested that CMS provide the Primary Manufacturer with the analysis used to determine that the drug was eligible for renegotiation by February 1st of the initial price applicability year.

Response: We thank this commenter for their suggestion. We intend to follow the same process and timeline for publishing the selected drug list for renegotiation as for negotiation. This provides consistency for interested external parties, is operationally feasible for CMS, and aligns the negotiation and renegotiation process timelines. Consistent with our response to similar requests in the Negotiation Program Guidance, we do not believe providing the Primary Manufacturer with additional information prior to the February 1 publication deadline is operationally feasible based on the timelines prescribed in section 1194(b) of the Act, which apply consistently to the renegotiation process to the extent practicable by section 1194(f)(4)(B) of the Act.

Final Decision: After consideration of public comments, we are finalizing § 429.605 as proposed with technical changes. At § 429.605(c)(1), we are revising ''previously indicated condition'' to ''previously considered disease or condition'' to clarify that this refers to a disease or condition as discussed at section III.G.2.c. of this final rule. At § 429.605(c)(2)(ii), (c)(2)(ii)(A), and (c)(3), we are removing ''§ 429.615(b)'' and replace with ''§ 429.615(a)'' such that these cross references appropriately refer to the voluntary submission of information under § 429.615(a) to inform renegotiation eligibility and selection.

In section II.G.c. of this final rule, we make a technical correction to revise the cross reference to § 429.615(b) to refer to § 429.615(a). As discussed in this final rule, a new indication must be added to the FDA-approved labeling for the selected drug information to inform renegotiation eligibility and selection (as proposed at § 429.615(a)) by a time specified by CMS. In section II.G.c. of this final rule, we indicate that such time will be on or before September 30 of the year prior to the selected drug publication date for the initial price applicability year for which the drug would be selected for renegotiation. The technical corrections regarding references to the voluntary submission of information under § 429.615(a) ensures that the submission of information on a new indication from a Primary Manufacturer is aligned with the time during which CMS will be reviewing selected drugs for renegotiation eligibility and selection such that CMS can review the submitted information and consider it accordingly. In alignment with this clarification, we also revised cross references in § 429.605(c)(2)(ii), (c)(2)(ii)(A), and (c)(3) in this final rule to correct the cross reference from § 429.615(b) (which refers to data collection from interested parties to inform renegotiation) to § 429.615(a) (which refers to the voluntary submission of data by the Primary Manufacturer to inform renegotiation eligibility and selection).

We are revising § 429.605(d)(2) to add a cross reference to § 429.505(b)(2), which corrects an inadvertent omission.

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 proposed 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 proposed 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 proposed to consider two criteria to effectuate this statutory standard, as discussed in greater detail in this section. We proposed 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 proposed 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 final 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 final rule) pertaining to section 1194(e)(1) and section 1194(e)(2) factors. We proposed 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 proposed 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 proposed 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, 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 proposed 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 proposed 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 proposed 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 proposed 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 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 final rule.

Table II.F2 provides illustrative examples of how we may consider these criteria to determine whether a renegotiation-eligible drug would be selected for renegotiation.

TABLE II.F2: 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 § 429.620(b) for additional detail on the ceiling that would be used for renegotiation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended that CMS select only drugs that are eligible for renegotiation based on a change in the monopoly status.

Response: We thank these commenters for their input. Section 1194(f)(3) of the Act describes the circumstances under which CMS shall select a renegotiation-eligible drug for renegotiation. The statute does not provide for exceptions or delay in selection for renegotiation for any specific category of renegotiation-eligible drugs and as such we decline to adopt these commenters' recommendation.

Comment: A few commenters recommended that CMS reconsider the criterion that renegotiation should be expected to result in at least a 15 percent or greater change in the MFP. A few commenters supported CMS' codification of the proposed renegotiation process and two-part test for selecting renegotiation-eligible drugs, with a commenter also supporting CMS' consideration of factors beyond spending. A commenter stated that when determining whether a material change could have a significant impact on the Medicare program, that CMS consider whether the underlying material change or new indication reflects greater clinical value for patients, how providers and pharmacies dispensing the product might be impacted, and how the marketplace and development of new therapies might be impacted. A commenter requested that CMS decrease the MFP through renegotiation when evidence indicates that a lower MFP is necessary. A couple of commenters recommended that CMS establish a standard and reproducible methodology for selecting drugs for renegotiation based on a significant change with objective, externally verifiable criteria to determine whether renegotiation is likely to result in a significant change to MFP, and stated that the 15 percent change criterion is discretionary and not reproducible. A couple of commenters requested that CMS provide greater transparency regarding selection criteria, with a commenter suggesting that CMS establish what a ''significant'' change would be and provide illustrative examples of circumstances that would fit this criterion. Among these commenters, one commenter recommended that CMS' analysis of whether a material change is likely to result in at least a 15 percent change to the MFP should include new indications, patient populations evaluated, projected Medicare utilization, the projected range of MFPs, and the calculation of the resulting Medicare expenditures.

Response: We thank these commenters for their input. Consistent with our response to similar comments

in the Negotiation Program Guidance, we reiterate that we developed the criteria related to a significant change to the MFP to serve to support CMS in making a selection determination in alignment with the requirements set forth in section 1194(f)(3)(C) of the Act for drugs eligible for renegotiation because a new indication is added or for which the Secretary determines there has been a material change to a section 1194(e) factor. While statute does not explicitly require any specific criterion to select these drugs for renegotiation in section 1194(f)(3)(C) of the Act, we set forth these criteria to provide transparency for the benefit of interested parties and the public into how the agency would approach determining what constitutes a significant change to the MFP. Our review of the two criteria—(1) the likelihood that the new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and (2) whether such a change in the MFP would have a significant impact on the Medicare program—will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug, including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act as discussed in section II.G.3.b. of the proposed rule (91 FR 36302). The scope of information considered may include a CMS-led review of the information sources discussed in section II.F.2. and II.F.3. of the proposed rule (91 FR 36286 through 36290) pertaining to section 1194(e)(1) and section 1194(e)(2) factors. We note that no criteria to select drugs for renegotiation can predict the actual outcome of a renegotiation. A determination that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation and any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in the MFP, decrease in the MFP, or no change in the MFP. Further, the magnitude of the change in the MFP could be higher or lower than 15 percent.

We also note that adopting a more rigid framework for selecting drugs for renegotiation could result in circumstances that neglect the fact- and drug-specific information that we are able to consider as part of a holistic consideration of information. For example, a methodology that does not offer discretion in drug selection could require selection for renegotiation every time a new indication was added for a selected drug without consideration of information about imminent entry of a biosimilar or generic drug that would result in a renegotiated MFP likely not becoming applicable. Similarly, a more rigid methodology for when CMS determines if a renegotiation-eligible drug is likely to result in a 15 percent change to the MFP is likely to neglect fact- and drug-specific information that is relevant to the consideration of this criterion. For example, the addition of a particular indication for one selected drug could indicate that renegotiation is likely to result in at least a 15 percent change to the MFP, but the addition of the same indication to a different selected drug that serves a different clinical population within Medicare could result in a finding that renegotiation is not likely to result in at least a 15 percent change to the MFP. For these reasons, we decline to adopt a more rigid methodology that would neglect the drug-specific and fact-specific circumstances of each selected drug.

Regarding the comment that CMS should consider clinical value to patients, impact on providers and pharmacies dispensing the product, and impact on the marketplace and development of new therapies when determining the impact on the Medicare program under § 429.610(b)(1)(ii), we may consider certain changes reflecting ''clinical value for patients'', including, for example, the selected drug addressing an unmet medical need that it had not previously addressed, in our holistic inquiry for determining the likelihood that the new indication(s) or material change(s) would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and (2) whether such a change in the MFP would have a significant impact on the Medicare program. The commenter also requested that we consider effects on providers and pharmacies dispensing the product and the impact on the marketplace and development of new therapies. We appreciate the commenters' suggestion, and to the degree that these effects would impact the financial impact to the Medicare program and Medicare beneficiaries, such effects would be considered when we review associated changes in expenditures and beneficiary cost-sharing as described in section G.3.b. of the proposed rule (91 FR 36304). Otherwise, these considerations would be considered out of scope.

Comment: A few commenters recommended that CMS should increase the criterion from 15 percent change to at least 35 percent, and if not adopting a higher threshold, explain why 15 percent is appropriate. A commenter recommended that CMS decrease the criterion to below 15 percent change as potentially significant. A commenter stated that they oppose the criterion that renegotiation should be expected to result in at least a 15 percent or greater change to the MFP as it is arbitrary and capricious and self-validating and that the statutory mechanism CMS uses to justify the 15 percent change criterion is not applicable and that CMS picked the floor of the possible range.

Response: We appreciate commenters' input. As discussed in the Negotiation Program Guidance and section II.G.3.b. of the proposed rule (91 FR 36302 through 36304), we considered a range of percent changes to the MFP that might be appropriate based on percent change to the applicable percentage of non-FAMP used to establish a ceiling during negotiation, including a percent change that is less than 15 percent, and options for a percent change that is higher than 15 percent (including 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) as we believe this range of percent change is informative for interpreting what the term ''significant change'' means in the context of the statute. This is because 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 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. As noted in section II.G.3.b. of the proposed rule (91 FR 36302), the range that we considered is based on the percent change in the applicable percentage for non-FAMP when determining the ceiling was between 15 and 45 percent. We proposed to use a percent change that corresponds with the lower end of this range, that is 15 percent change, so as to not preclude the benefits that could come from a likely change in the MFP that is at least 15 percent (while considering the second criterion that such change in MFP would have a significant impact on the Medicare program). We balanced considerations about the resources invested in renegotiation in determining what constitutes a significant change. Additionally, while statute does not explicitly require any specific criterion to select these drugs for renegotiation in section 1194(f)(3)(C) of the Act, we set

forth these criteria to provide transparency for the benefit of interested parties and the public into how the agency would approach determining what constitutes a significant change to the MFP. Our review of the two criteria—(1) the likelihood that the new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and (2) whether such a change in the MFP would have a significant impact on the Medicare program—will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug, including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act as discussed in section II.G.3.b. of the proposed rule (91 FR 36302 through 36305).

We disagree with the comment that the first criterion (the likelihood that a new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP) is arbitrary and capricious. As discussed earlier in this response, we arrived at this criterion as informed by numerical values in the statute. 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. As previously discussed, we proposed to use a percent change at the lower end of this range so as to not preclude the benefits that could come from a likely change in the MFP that is at least 15 percent while considering the second criterion. In arriving at the first criterion, we balanced considerations about the resources invested in renegotiation in determining what constitutes a significant change. We also disagree with the commenter's assertion that this criterion is ''self-validating''. We refer the commenter to section II.G.3.b. of the proposed rule (91 FR 36304) which states that a determination that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation and any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in the MFP, decrease in the MFP, or no change in the MFP. Further, the magnitude of the change in the MFP could be higher or lower than 15 percent. Consistent with our response to similar comments in the Negotiation Program Guidance, we also 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 proposed the complementary criterion of evaluating whether renegotiation would likely have a significant impact to the Medicare program. We decline to revise the criterion that renegotiation should be expected to result in at least a 15 percent or greater change.

Comment: A few commenters recommended that CMS permit manufacturers of drugs expected to be selected for renegotiation an opportunity to submit information and respond to any factual or methodological errors before selection.

Response: We thank these commenters for their suggestion. We do not believe the commenters' proposal would be operationally feasible to ensure that the selected drug list for both renegotiation and negotiation would be published by February 1. We intend to follow a similar process and timeline that is used for negotiation for renegotiation. We do not believe providing the Primary Manufacturer with additional time to provide more information after the submission of information through the Drug Selection ICR is operationally feasible based on the timelines prescribed in section 1194(b) of the Act. We also note that there is no statutory requirement to provide an opportunity for manufacturers to dispute selection for renegotiation.

Comment: A commenter requested CMS provide examples, such as impact on the ceiling and evidence that CMS would consider, that indicate circumstances where added value would result in an increase in the MFP, such that manufacturers do not view renegotiation as a penalty on indication expansion.

Response: We thank this commenter for their input. Consistent with section II.G.3.b. of the proposed rule (91 FR 36304), 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. We also refer the commenter to Table II.F2 in the proposed rule (91 FR 36302) for example scenarios for renegotiation selection. We also reiterate that the result of a negotiation or renegotiation is not pre-determined and that we will consider evidence related to section 1194(e)(1) and (e)(2) factors in totality, alongside engagement with the Primary Manufacturer, as described in subpart F.

Final Decision: After consideration of public comments, we are finalizing § 429.610 as proposed with one technical correction. At § 429.610(b)(2)(i), we are revising ''section 1194(e) factors'' to ''the factors listed at section 1194(e) of the Act'' for precision.

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 proposed 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 these ICRs alongside this final 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 final 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 final 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 final 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 proposed 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 proposed 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 proposed 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 final 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 solicited 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 proposed 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 proposed 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 final 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).

Similar to the proposal in § 429.505(c) and discussed in section III.F.2. of the proposed rule, we proposed at § 429.615(b)(2) that, 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)), a Primary Manufacturer has an ongoing obligation to report any updates to the information provided in proposed § 429.615(b)(1) 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 § 429.615(b)(1). For example, under proposed § 429.505(c), Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under proposed § 429.615(b)(2) 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 § 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 final rule) and the required submission of data related to section 1194(e)(1) factors to CMS for drugs selected for negotiation (described at proposed § 429.505(b) and section II.F.2. of this final rule), which cover different reporting periods. As discussed further in section II.G.4.a. of this final 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.

We also proposed at § 429.615(b)(3) to provide any interested party with the opportunity to submit information related to section 1194(e)(2) factors, as occurs for negotiation. We proposed 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 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 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 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 proposed that this information collection be a streamlined version of that used for negotiation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested that we streamline the Drug Negotiation Process ICR for drugs selected for renegotiation to reduce manufacturer burden. A few of these commenters suggested that a full submission of information related to the section 1194(e) factors is not necessary for drugs selected for renegotiation and, instead, the Primary Manufacturer should be able to limit its submission to include only information that has changed since the last negotiation or renegotiation and allow the Primary Manufacturer to attest that the information previously submitted is still up to date. A commenter suggested that the Primary Manufacturer only be required to submit information on the section 1194(e) factors for drugs selected for renegotiation if the information was not previously submitted or is not otherwise accessible to CMS. A commenter recommended that CMS only require resubmission of information related to the factors listed at section 1194(e) of the Act if the information provided to CMS was inaccurate at the time of submission.

Response: We appreciate these commenters' suggestions and, as noted previously, we appreciate and continue to consider efforts to minimize manufacturer reporting burden within the Negotiation Program. We note that for both negotiation and renegotiation, information submission related to section 1194(e)(2) factors remains optional for all interested parties, including the Primary Manufacturer. CMS considers the 1194(e)(1) factors for renegotiation pursuant to section 1194(f)(4)(B) of the Act, which directs CMS to adopt a process for renegotiation that is to the extent practicable consistent with the process established for negotiation. We interpret section 1194(e)(1) of the Act as requiring information related to section 1194(e)(1) factors to be submitted by the Primary Manufacturer of a selected drug to CMS for consideration in the negotiation and renegotiation process. We also note that any selected drug with an MFP is considered for renegotiation eligibility under section 1194(f)(2) of the Act and the time between selection for negotiation and renegotiation, if applicable, or renegotiation and a subsequent renegotiation, if applicable, may vary significantly by drug. That is, it may be a relatively short period of time before a drug is selected for renegotiation or it may be multiple years, if ever. We believe that it is important for the same information to be submitted for the section 1194(e)(1) factors for every drug selected for negotiation and renegotiation, if applicable, in a given initial price applicability year. This helps ensure the application of a consistent process and methodology as required by section 1194(b)(1) of the Act. We continue to encourage feedback on ways to streamline reporting requirements for the Negotiation Program, including for renegotiation.

Final Decision: After consideration of public comments, we are finalizing § 429.615 as proposed with modification for clarity. At § 429.615(b), we are adding ''information as specified in (b)(1) and (b)(3) of this section must be submitted to CMS,'' to clarify that this data collection is for the factors listed at section 1194(e) of the Act for use in the renegotiation process. We also are adding text to section II.G.4.b.of this final rule to provide information on the data update requirement listed at § 429.615(b)(2). In addition, we are deleting ''and (B)'' at § 429.615(b)(1)(ii)(B) as it was included in error.

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 proposed 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 proposed 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 final rule. Additionally, consistent with the policies for implementation set forth in section 130.4.1 of the Negotiation Program Guidance, we proposed 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 proposed 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 later in this section, including to account for the statutory directive to update the applicable percent for certain renegotiation-eligible drugs.

We proposed 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 approach would address the fact that the Negotiation Program is no longer limited to drugs covered under Part D. Because renegotiation under this final 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 proposed 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 final 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 proposed 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 2026. 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.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.620(a) through (b) as proposed, but with a technical modification to add the word ''and'' between § 429.620(b)(1)(i) and (ii) to clarify that both steps will be performed.

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 proposed 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 final rule consistent with the policies for implementation at section 130.4.2 of Negotiation Program Guidance.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.620(c) as proposed.

c. Methodology for Developing an Initial Offer

Consistent with policies for implementation as described in section 130.4.2 of Negotiation Program Guidance, we proposed 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 final 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 final 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that CMS should state that the prior agreed-upon MFP is one factor among section 1194(e)(1) factors and would not be weighted more than other such factors. The commenter also requested that CMS not use the prior MFP as the starting point for developing the initial offer as this could result in a situation where renegotiation offer development starts from a starting point based on the preceding negotiation or renegotiation cycle while the ceiling does not reset.

Response: We appreciate this commenter's feedback on the proposals to consider a previously agreed-upon MFP for the selected drug as part of the factor listed at section 1194(e)(1)(E) of the Act and the alternative proposal to consider the agreed-upon MFP as a separate adjustment. As we stated in section II.G.5.c. of the proposed rule (91 FR 36308), we believe that the MFP is an important data point to consider within the context of renegotiation. We also stated that we 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 proposed at § 429.510, and more specifically the adjustment as proposed at § 429.510(f). By considering the previously agreed-upon MFP as part of the adjustment for section 1194(e) factors, the MFP would be one data element considered among many within the various section 1194(e) factors. We also clarify that consideration of the MFP for the selected drug that is being renegotiated is different from the consideration of MFPs for a therapeutic alternative(s), if any, of the selected drug for the purpose of determining a starting point for the initial offer. As described at § 429.620(d), we will adopt the process for developing the initial offer as described at § 429.510. In this process, we consider the cost of therapeutic alternatives, if any, as the starting point, not the MFP of the selected drug itself.

Comment: A commenter supported the use of the same framework for developing the initial offer for renegotiation as is used for negotiation. A couple of commenters recommended CMS create a transparent, predictable, and clear standard for the renegotiation framework.

Response: We thank this commenter for their support of the proposal to adopt the negotiation process for drugs selected for renegotiation. Regarding the framework used for the renegotiation process, we proposed 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 proposed at § 429.510. As stated in similar comment responses in section II.F.3. of this final rule, we believe the process proposed at § 429.510 and adopted for renegotiation as proposed at § 429.620(d) appropriately balances transparency and confidentiality in the negotiation and renegotiation processes and we decline to revise these policies. We refer commenters to similar comments and responses under section II.F.3. of this final rule for more information.

Comment: A commenter suggested that CMS should recognize off-label use, particularly in oncology, consistent with Medicare coverage policy when considering clinical evidence during renegotiation. A commenter proposed that CMS should create a renegotiation pathway wherein if a drug is selected for renegotiation due to a new indication that addresses an unmet medical need or other ''significant'' need, CMS would increase the renegotiated MFP for such drug.

Response: We appreciate the feedback provided by these commenters on the evidence considered and weighting of the factors listed at section 1194(e) of the Act for the purpose of developing the initial offer. We believe that the definition of off-label use proposed at § 429.20 is aligned with Medicare coverage policy as off-label use must be 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.

Regarding the suggestion to increase the MFP for drugs selected for renegotiation due to a new indication that addresses an unmet medical need or other ''significant'' need, we agree that, subject to the ceiling, a drug that meets a previously unmet medical need or other ''significant'' need for patients could be renegotiated and that renegotiation could result in an increase to the previous MFP. However, the outcome of any renegotiation, including offers and consideration of counteroffers, will be subject to consideration of the evidence related to the factors listed at section 1194(e) of the Act, which include but are not limited to unmet medical needs and other clinical factors as part of the adjustment of section 1194(e)(2) factors described at § 429.510(e).

Comment: One commenter stated that CMS should provide a clear explanation as to how data are weighted in the renegotiation process and stated that they believe a lack of transparency limits the ability of a Primary Manufacturer to prepare for renegotiation.

Response: We refer this commenter to our response to similar comments in section II.F.3. of this final rule.

Final Decision: After consideration of public comments, we are finalizing § 429.620(d) as proposed.

d. Engagement With Primary Manufacturers and Interested Parties

We proposed 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 § 429.620(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 final 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 final 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)).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple commenters supported incorporating public engagement events as part of the renegotiation process. One of these commenters recommended the public engagement events for a drug selected for renegotiation focus on the factors that contributed to the drug being selected for renegotiation.

Response: We appreciate commenters' support and recommendations to improve the public engagement events for renegotiation. As stated in the Negotiation Program proposed rule, the public engagement events allow us to hear from patients and other stakeholders—directly and in their own words—about patient's personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions. We do not believe narrowing the scope of the information shared during the public engagement events for drugs selected for renegotiation supports CMS' holistic approach to renegotiation.

Final Decision: After consideration of public comments, we are finalizing § 429.620(e) through (j) and (l) as proposed.

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 proposed 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 final 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 final 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 described in section II.H.2. of this final rule and § 429.705(b) and in accordance with section II.H.2. of this final rule and proposed § 429.705(c) and the confidentiality policy described in section II.D.1. of this final rule and in proposed § 429.300.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended CMS share specific information in the MFP explanation for drugs selected for renegotiation, such as the new changes and evidence considered since the prior negotiation and how these factors influenced the new MFP.

Response: We thank this commenter for their suggestions to include specific information in the MFP explanations. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, the MFP explanation, as described at § 429.705, will include a 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, as described at § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as described at § 429.505(d)(3) or § 429.615(b)(3), as applicable, and in alignment with the confidentiality policy described at § 429.300.

Final Decision: After consideration of public comments, we are finalizing § 429.620(k) as proposed.

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 proposed 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 proposed 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 final 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 proposed 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 later in this section.) 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 final 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 at § 429.120(b)(1)(ii) through (b)(1)(vi) (as discussed in section II.B.5.b. of this final rule). We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 6 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 6 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 proposed 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 proposed at § 429.700(c)(1), the process for how we would apply the MFP to NDCs associated with new NDAs or BLAs and we proposed 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 proposed 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 labeling 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 final rule. We solicited comments on our proposed approaches for the application of the MFP across dosage forms and strengths.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that the application of a single MFP across all dosage forms and formulations may fail to capture meaningful differences in a pharmacy's acquisition costs, storage and handling requirements, dispensing complexity, and associated administrative expenses.

Response: We thank this commenter for their feedback. We interpret section 1194 of the Act to establish a single MFP, updated pursuant to section 1195(b) of the Act, for a selected drug with respect to its price applicability period. While MFP effectuation policies are outside the scope of this final rule, under section 1193(a)(3)(a) of the Act, the Primary Manufacturer must provide access to the MFP to the MFP-eligible individual and to the pharmacy, mail order service, or other dispensing entity with respect to such MFP-eligible individual who is dispensed a selected drug. This means the Primary Manufacturer is responsible for ensuring the dispensing entity's acquisition cost for a selected drug that is dispensed to an MFP-eligible individual does not exceed the MFP, which includes considering differences in acquisition cost across NDCs in order to determine the amount necessary to effectuate the MFP with respect to a particular dispense.

Final Decision: After consideration of public comments, we are finalizing § 429.700 with technical modifications. Specifically, we are updating a cross-reference in § 429.700(c)(1) to reflect that we are finalizing the general fixed combination drug policy at § 429.125(b)(4)(i) (rather than at § 429.125(b)(4), as we proposed). In addition, at § 429.700(c)(4)(i)(B), we are updating the term ''FDA-approved label'' to ''FDA-approved labeling'' for consistency and clarity.

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 proposed 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 proposed 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 file [93] 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

[93] The Maximum Fair Price Layout file would display the NDC–9 MFP per-unit price to 6 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.

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 final 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 final 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 proposed 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 final 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 proposed 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 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 proposed 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 proposed 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 proposed 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 final 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 final 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 final 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS detail specific information in the explanations of MFP. These elements include information such as the starting point for the initial offer, how therapeutic alternatives were selected, specific data and evidence used, benefits and impacts considered, Federal funding, stakeholders consulted and how their input was used, sources for information used in negotiation, specific offers and counteroffers, NDC per unit and per package price, and details on how information influenced the MFP. One of these commenters recommended CMS commit to a schedule for public release of information such as specific offers and counteroffers. A commenter supported CMS' proposal to publish whether an MFP was not agreed upon for a selected drug and the reason a drug ceases to be a selected drug. Some commenters requested CMS discuss in the MFP explanations more information about how stakeholder input was used in negotiations. A commenter supported that CMS publishes the MFPs before the initial price applicability year.

Response: We thank these commenters for their suggestions to include specific information in the MFP explanations. Consistent with our response to similar comments in the Negotiation Program Guidance, as required under section 1195(a)(1) of the Act, we will publish the MFP explanations for all selected drugs where there is an agreed-upon MFP no later than March 1 of the year prior to the initial price applicability year. The MFP explanation, as described at § 429.705, will include a 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, as described at § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as described at § 429.505(d)(3) or § 429.615(b)(3), as applicable, and in alignment with the confidentiality policy described at § 429.300. We will also strive to share the section 1194(e)(2) data submitted by the public with the Primary Manufacturer of a selected drug during the negotiation period. This data will be redacted in accordance with the confidentiality standards described at § 429.300 and will not include proprietary information, PHI/PII, or other information that is protected from disclosure under other applicable law. We also thank commenters for their recommendation to include more detail in the MFP explanations, including regarding how stakeholder input was used in negotiations. We refer interested parties to the MFP explanations published on the CMS website for more information about the negotiation process for initial price applicability years 2026 and 2027 through which CMS and Primary Manufacturers reached agreement on an MFP. Additionally, as discussed in section II.F.4. of the proposed rule (91 FR 36296), we used information shared during the 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 the identification of therapeutic alternatives, key outcomes, and adjustment of the starting point to develop the initial offer.

Comment: A commenter expressed appreciation for CMS' stated goals of protecting proprietary information while avoiding treating non-qualifying information as proprietary and urged CMS to continue refining its approach to transparency and to lean toward disclosure to the maximum extent possible when the statute is silent. Another commenter stated CMS could promote transparency by providing additional detail not included in the MFP explanation directly to the affected manufacturer. A commenter recommended MFP explanations provide information in accordance with the confidentiality policy set forth in § 429.300.

Response: We thank these commenters for their support and suggestions. Consistent with our response in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, and as described at § 429.705, the MFP explanation, subject to the requirements for treatment of confidential and proprietary information as described at § 429.300, will include a 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, as described at § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as described at § 429.505(d)(3) or § 429.615(b)(3), as applicable. We believe that engagement with Primary Manufacturers throughout the negotiation and renegotiation process, as applicable, such as through discussion during the optional meetings and exchange of offer(s) and counteroffer(s), provides Primary Manufacturers with multiple opportunities to receive detailed information from CMS regarding the negotiation and renegotiation process, as applicable, and reaching agreement upon an MFP. CMS therefore declines to provide additional detail not included in the MFP explanation directly to a Primary Manufacturer beyond the information made available during the negotiation and renegotiation process, as applicable.

Final Decision: After consideration of public comments, we are finalizing § 429.705 as proposed.

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 final 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 proposed 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 final 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 final 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.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.710 as proposed.

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 proposed 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 proposed § 429.200, the Primary Manufacturer's obligation to cooperate with CMS' 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) proposed 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 proposed § 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 and in accordance with proposed § 429.900(a), 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 and as proposed in § 429.900(b). 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 proposed 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. As stated in the proposed rule, 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 proposed in § 429.900(b) 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 final 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 outlined in the proposed rule is necessary for 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 CMP as authorized under section 1197(c) of the Act and as described in proposed § 429.1005.

In proposed § 429.900(c), we proposed to 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 CMP 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 proposed to consider such information if timely submitted when determining whether to pursue further enforcement action such as imposition of CMPs.

We received public comments on the proposed provisions to establish the actions CMS may take if the agency concludes that a Primary Manufacturer is noncompliant with one or more 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. The following is a summary of the comments we received and our responses.

Comment: A commenter requested protection from enforcement in instances where 340B covered entities refuse to share data needed for 340B claim deduplication.

Response: We appreciate the feedback provided by this commenter. First, as this comment addresses a process related to MFP effectuation, it is considered outside the scope of this final rule. However, broadly, in the final rule, we decline to designate any specific compliance safe harbors under the Negotiation Program, including related to instances where 340B covered entities refuse to share data related to the 340B eligibility of a claim. CMS reiterates the policy established in Negotiation Program Guidance describing a Primary Manufacturer's obligation to transmit payment of an amount that provides access to the MFP of a selected drug to the dispensing entity within the 14-day prompt MFP payment window and applicability of section 1193(d)(1) of the Act only if: (1) the claim for the selected drug is a 340B-eligible claim; and (2) the 340B ceiling price is lower than the MFP for the selected drug. As described in sections 40.4.3.1 and 40.4.4.2 of the Negotiation Program Guidance, in cases where a Primary Manufacturer receives claim-level data elements for a selected drug that it reasonably believes is subject to the exception under section 1193(d)(1) of the Act, the Primary Manufacturer would indicate so when reporting claim-level payment elements to the MTF and declining to transmit payment in an amount that provides access to the MFP within the 14-day prompt MFP payment window. In this scenario, the Primary Manufacturer would be required to provide documentation demonstrating the claim was 340B-eligible and the 340B ceiling price was lower than the MFP upon request from CMS as described in section 90.2 of the Negotiation Program Guidance.

In the course of its monitoring and oversight functions, CMS may investigate Primary Manufacturer compliance with MFP effectuation requirements, including to assess whether an MFP refund was owed rather than the exception in section 1193(d)(1) of the Act applying. As part of such investigations, CMS will review the extent to which the Primary Manufacturer reasonably believed that the exception in section 1193(d)(1) of the Act applied and the role that any operational barriers played in the Primary Manufacturer being able to take timely action to meet its statutory obligation to make MFP available, as applicable, with respect to these claims. Consistent with enforcement policies described later in this section, in instances where CMS finds noncompliance with Negotiation Program requirements, CMS intends to exercise the authority to impose CMPs for instances of noncompliance that substantively obstruct Negotiation Program processes and/or availability of the MFP.

Comment: A few commenters raised concerns that Primary Manufacturers may be subject to enforcement actions despite acting in good faith to fulfill their compliance obligations under the Negotiation Program. A couple of commenters mentioned that a Primary Manufacturer may reasonably misinterpret an information request for which CMS may deem a response to be incomplete or inaccurate. When addressing noncompliance and imposing CMPs, a commenter felt that CMS was departing from HHS' general practices by penalizing Primary Manufacturers without assessing good faith effort. Another commenter mentioned that there are a number of ways that a Primary Manufacturer could unintentionally omit reporting data when responding to CMS. Another commenter remarked that the proposed changes deviate from principles of good faith and timely resolution of issues related to data integrity. A commenter

suggested that CMS define what constitutes as a good faith compliance effort.

Response: We thank these commenters for their feedback. As discussed in section II.J.1. of this final rule, CMS intends to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct administration of the Negotiation Program. We are establishing a structure for enforcement actions that, among other things, is not punitive in response to immaterial noncompliance or other instances of noncompliance that are not substantive. Consistent with policy established in the Negotiation Program Guidance, we provide in § 429.900(b) that Primary Manufacturers must cooperate with CMS compliance monitoring and evaluation activities, including providing complete and accurate responses to CMS requests for clarifications, corrections, and additional information, and complying fully with all requests for corrective action. These monitoring efforts reflect CMS' intent to continue to engage in Negotiation Program compliance monitoring and oversight activities in accordance with HHS' established practices for managing noncompliance by offering, when warranted and at CMS' discretion, opportunities for correction, including clarification. The determination of whether to exercise enforcement discretion with respect to identified noncompliance is based on the facts, circumstances, and totality of evidence available to CMS for each specific case. Primary Manufacturers are expected to make good faith efforts to resolve compliance issues and maintain open communication with CMS. CMS recommends that Primary Manufacturers maintain documentation evidencing their good faith efforts to comply with Negotiation Program obligations. CMS may request or consider such documentation when considering whether to impose CMPs with respect to identified noncompliance. We intend to offer opportunities for Primary Manufacturers to undertake corrective action when appropriate and at CMS' discretion. Regarding the request for CMS to define what constitutes a ''good faith compliance effort'', we emphasize that every instance of noncompliance is assessed on a case-by-case basis. In all instances, we encourage communication, cooperation, and timely attempts to rectify compliance issues. Where a Primary Manufacturer can demonstrate that it has made reasonable, good faith efforts to fulfill its obligations, or that compliance was impeded by circumstances outside its control, this will be considered in our assessment of whether to impose CMPs.

Comment: A few commenters requested more specificity in proposed § 429.900(c) where CMS outlines the enforcement actions the agency may take in response to Primary Manufacturer noncompliance. To address noncompliance, the proposed language states that CMS may take one or more of the following actions: provide notice of violation, request corrective action, and/or impose a CMP. These commenters expressed that the language is too vague and open-ended. These commenters recommended that CMS provide clarity on the applicable guidance and requirements for the respective enforcement actions. Particularly, commenters are unclear as to which requirements would trigger a CMP response.

Response: We thank these commenters for their feedback regarding enforcement actions CMS may take if we conclude a 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. Our primary goal is to successfully administer all aspects of the Negotiation Program; we intend to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct Negotiation Program processes. In evaluating whether to impose CMPs in instances of identified noncompliance, we will consider the circumstances of each case, taking into account the severity and frequency of noncompliance. As described in section II.J.1. of this final rule, instances of noncompliance that may warrant the imposition of CMPs include, but are not limited to, egregious or knowing violations of Negotiation Program requirements or repeated violations of the Negotiation Program Agreement or other Negotiation Program requirements. Examples of substantive violations for which CMPs may be appropriate can be found in Table 4—Examples of Substantive Violations of this final rule. Note that the examples in Table 4 are not an exhaustive list of violations that may warrant CMPs. As appropriate and upon determination of an instance of noncompliance, we may issue a written notice to the Primary Manufacturer of the violation(s), request the Primary Manufacturer to take specific corrective action to address the noncompliance, and/or impose a CMP. If we make a determination to assess a CMP, we will follow the procedures outlined in section II.J.4. of this final rule.

Comment: A few commenters encouraged CMS to have robust mechanisms in place for compliance oversight to ensure manufacturers fulfill program obligations. A commenter stressed the need for increased enforcement. Another commenter supported CMS' proposed compliance and enforcement efforts, including broad monitoring authority.

Response: We appreciate the feedback provided by commenters regarding the monitoring and enforcement efforts related to Primary Manufacturer compliance with the Negotiation Program Agreement. We recognize the importance of effective oversight mechanisms to ensure that Primary Manufacturers meet their obligations under the Negotiation Program Agreement. Our approach is to maintain a robust monitoring and oversight program intended to foster transparency, accountability, and adherence to established guidelines throughout the operation of the Negotiation Program.

Comment: A commenter encouraged CMS to be cognizant of the administrative burden on downstream entities as the agency continues to develop policies related to compliance monitoring and other procedures. The commenter expressed concern that providing flexibility for manufacturers adopting manufacturer-specific approaches to MFP effectuation could result in inconsistency across different products and markets, resulting in heightened administrative burden in navigating the program for downstream entities.

Response: We appreciate the feedback provided by this commenter. We remain committed to considering stakeholder burden across Negotiation Program operations, including program monitoring, oversight, and enforcement activities; we routinely aim to minimize burden on manufacturers, dispensing entities, and other downstream entities related to compliance activities while balancing the need to operate robust monitoring and oversight as we implement the Negotiation Program. For example, we conduct extensive monitoring and oversight exercises internally at CMS, such as conducting ongoing analysis using program and industry data. With respect to the comment regarding ''manufacturer-specific'' approaches to MFP effectuation, we note that MFP effectuation policies are outside the scope of this final rule. However, we note generally that public input is

considered when designing operational processes, including agency compliance monitoring and oversight processes. CMS works to gather such input both through informal channels (for example, monthly stakeholder technical meetings) and formal channels (for example, public comment periods on program policy and various Information Collection Requests). These collective efforts allow stakeholders to provide insight into real-world perspectives, stakeholder data, and emerging issues to inform agency decision-making to support our goal of streamlining operations and reducing burden. Importantly, we have designed compliance and oversight processes that are applied consistently across manufacturers and intend to continue to operate in a consistent manner.

Final Decision: After consideration of public comments, we are finalizing § 429.900 as proposed.

J. Civil Monetary Penalties (§§ 429.1005 Through 429.1020)

1. Civil Monetary Penalties

Section 1197 of the Act provides for the imposition of CMPs 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 proposed 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 CMP 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 CMP 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 CMPs 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 CMPs 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 CMP 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 CMPs. 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 CMPs in instances of noncompliance that substantively obstruct Negotiation Program processes. Such instances may include, but are not limited to, the examples shown in Table II.F3, 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 CMPs. We reserve the authority to issue CMPs for other violations as required to effectively administer and monitor the Negotiation Program.

TABLE II.F.3: EXAMPLES OF SUBSTANTIVE VIOLATIONS*

Category	Example
Violations of the Negotiation Program Agreement	• Failure to submit data required under §§ 429.100(d), 429.405(a), 429.505(b), and 429.615(b) including failure to engage in requested corrective action to mitigate such failures. • Omission or inaccuracy of manufacturer-submitted information described in §§ 429.100(d), 429.405(a), 429.505(b), and 429.615(b) (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). • 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.
Other Violations	• 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).

*This table does not address violations related to a Primary Manufacturer's failure to make MFP available.

Broadly, we proposed 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 a 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 (b), may be subject to statutorily-specified CMPs 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 CMPs for Primary Manufacturer violations of the Negotiation Program Agreement, we intend to use discretion such that CMPs 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 CMPs 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 the proposed rule, we proposed to consolidate and clarify our approach to monitoring and enforcement in the context of data reporting. Specifically, we did not propose to codify the policies previously stated in section 40.2.3 of the Negotiation Program Guidance but rather we proposed to pursue a consolidated approach to monitoring and enforcement that is consistent with the policies regarding data reporting obligations stated in sections 90 and 100 of the Negotiation Program Guidance. For example, we may impose a CMP 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 final 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 CMP 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 CMP is pursued, we stated that we intended to send a written CMP 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 CMP 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 CMP 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 CMP will continue to accrue until the Negotiation Program Agreement is terminated as described in proposed § 429.205. The imposition of a CMP 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 CMP 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 CMP. In instances of a Primary Manufacturer submitting false information that is required under the Negotiation Program Agreement, in accordance with proposed § 429.1005, a CMP 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 CMP accrual as well as the total amount accrued will be noted on the CMP notification sent by CMS, following the process established in proposed § 429.1020.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters opposed the policy proposed at § 429.1005 because they stated it bypasses the opportunity for corrective action in certain instances of identified noncompliance. These commenters noted that section 40.2.3 of the Negotiation Program guidance governing initial price applicability years 2026, 2027, and 2028 explicitly afforded a 5-business day window to respond to corrective action requests and provided the opportunity to rectify any issues related to submission of information required under section 1193(a)(4) of the Act and that this 5-day window was not included in the proposed rule. A few commenters advocated for CMPs to be imposed only for repeated and severe violations. A commenter stated that the proposed rule is a ''more aggressive approach to enforcement,'' and advocated for warning notices to be issued prior to potential applicability of excise taxes. A few commenters stated that CMS did not provide an explanation as to why the proposed rule no longer includes a 5-day window for rectifying issues regarding noncompliance related to submission of information required under section 1193(a)(4) of the Act and stated that the Supreme Court has held that agencies must provide a reasoned explanation when making new policy changes. A commenter requested that CMS maintain the current oversight and enforcement methods and reserve any process changes for future rulemaking opportunities. A couple of commenters recommended that CMS establish a corrective action process as a mandatory step prior to CMP issuance, rather than limiting corrective action opportunities specifically to circumstances in which CMS determines such opportunities are warranted.

Response: We thank the commenters for their input. In implementing § 429.1005, we reiterate that we intend to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct the processes of the Negotiation Program. We remain committed to providing opportunities for corrective action in situations where we deem it appropriate and intend to maintain our operational approach of providing Primary Manufacturers reasonable time periods to fulfill requests for information and/or corrective action and considering requests for extensions as warranted. For example, if we determine that a submission from a Primary Manufacturer is incomplete or contains inaccurate information, we may issue a written request to the Primary Manufacturer to clarify the submission, correct the inaccuracy, or provide the missing information. This written request will specify a deadline by which the Primary Manufacturer must respond. If the Primary Manufacturer

complies with the request for corrective action by timely providing complete and accurate information, we may exercise enforcement discretion and determine not to impose a CMP for the Primary Manufacturer's initial failure to provide complete and accurate information by the specified deadline. Alternatively, in accordance with§ 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. In evaluating whether to impose CMPs in instances of identified noncompliance, we will consider the circumstances of each case, including but not limited to taking into account the severity and frequency of noncompliance. The enforcement framework outlined in the final rule is designed to ensure that penalties are not imposed in a punitive manner for immaterial or non-substantive instances of noncompliance. In section II.J.2. of the proposed rule (91 FR 36314 through 15), we outlined scenarios demonstrating how outcomes may vary, including situations where corrective action may or may not be pursued.

We intend to be available to engage with Primary Manufacturers about the specifics of a corrective action request and to answer questions and provide clarifications. Additionally, we intend to provide Primary Manufacturers with reasonable deadlines to respond to requests for information requests and/or corrective action. This approach is designed to facilitate timely and effective resolution of compliance issues.

In response to requests for further explanation regarding the absence of the specified 5-day response time to corrective action requests in response to noncompliance related to submission of information required under section 1193(a)(4) of the Act, we note that the policy in the proposed rule, which we are finalizing herein, is not a significant change to the approach previously described in section 40.2.3 of the Negotiation Program Guidance. By consolidating and clarifying the policies described in the Negotiation Program Guidance, we seek to ensure that stakeholders understand the agency's enforcement processes and how they will be applied within the Negotiation Program. The monitoring and enforcement policies adopted in this final rule aim to provide the guidance and support necessary to facilitate consistent, good faith compliance. Operationally, CMS intends to continue to provide Primary Manufacturers with opportunities to correct information submissions or to provide additional information with reasonable timeframes to respond to such actions or both. However, offering these opportunities is not a required precursor to potential enforcement actions for any failure to meet these obligations.

We decline to explicitly establish that a corrective action process will be required as the initial step prior to CMP issuance in every instance under the final rule. We may choose to pursue corrective action, impose a CMP, or both depending on the nature of the violation and its potential effects on program operations. Regarding the comment on potential applicability of excise taxes, we refer this commenter to 26 U.S.C. 5000D for additional information. We note that the Internal Revenue Service (IRS) is responsible for administering and enforcing the excise tax, not CMS.

Comment: Commenters recommended that CMS add to § 429.200(b), which specifies requirements and conditions to which a Primary Manufacturer agrees when executing a Negotiation Program Agreement, a specific reference to a Primary Manufacturer's obligation to timely report updates to the NDC–11 information of the selected drug as described in § 429.100(e), to more explicitly warn manufacturers of a potential CMP for failure to report NDC updates as provided in § 429.100(e) and to further support adherence to program compliance.

Response: We thank these commenters for their feedback. Consistent with the policy described at § 429.1005, failure of a Primary Manufacturer that has entered into a Negotiation Program Agreement to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program, including failure to provide updated NDC–11 information to CMS as described in the proposed rule under § 429.100(e), which we are finalizing herein, may result in CMPs. The specific regulatory sections identified in § 429.200(b) are illustrative and not exhaustive of the Negotiation Program requirements for which a violation may give rise to the imposition of CMPs. As mentioned in previous responses, we intend to use our authority to impose CMPs for substantive noncompliance that obstructs Negotiation Program processes, while remaining committed to offering corrective action opportunities when appropriate. We will provide Primary Manufacturers reasonable timeframes to meet requests for information or corrective action and will consider extension requests as warranted.

Comment: A few commenters raised concerns about the potential for CMS to impose concurrent CMPs for a Primary Manufacturer's failure to provide complete and accurate information. For example, a CMP could be imposed for the initial failure to provide complete and accurate information followed by an additional CMP due to failure to comply with a CMS corrective action request. A few commenters indicated that because of the complexity and extent of the information collection requests for the negotiation process Primary Manufacturers may inadvertently provide inaccurate or incomplete information. A few commenters requested that CMS clarify its intent and recommended the elimination of duplicative CMPs stemming from the same underlying violation.

Response: We appreciate the feedback provided by commenters regarding enforcement actions for program violations. We emphasize that CMS retains the authority to address separate and distinct violations of the Negotiation Program even where such violations may be related or run concurrently. However, CMS is not establishing a policy that more than one CMP would be issued for the same underlying violation. Enforcement actions may be applied separately to each applicable case of noncompliance, ensuring that the response aligns with the specific nature and impact of the violation.

We are establishing an enforcement framework that operates within our statutory authority and provides clear and consistent procedures for addressing noncompliance within the Negotiation Program. Further, we reiterate that the enforcement framework is designed to ensure that penalties are not imposed in a punitive manner for immaterial or non-substantive instances of noncompliance.

Final Decision: After consideration of public comments, we are finalizing § 429.1005 as proposed.

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 proposed at § 429.1010 two circumstances where CMS may impose a CMP due to provision of false information: (1) CMS proposed we may impose a statutorily specified CMP 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

proposed that we may impose a statutorily specified CMP 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 CMP 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 proposed to adopt a standard for ''knowingly'' that conforms with the Office of Inspector General definition at § 1003.110 in the application of CMPs. 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 CMP notification following the process established in proposed § 429.1020.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.1010 as proposed.

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 final rule, CMS proposed at § 429.1015 that the Reference Manufacturer may be subject to a CMP equal to 10 times the amount of the rebate the Reference Manufacturer failed to pay. When CMS makes a determination to assess a CMP under section 1197(b) of the Act, CMS intends to follow the procedures established in proposed § 429.1020.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that, in situations where a Primary Manufacturer does not fulfill its obligation to pay the biosimilar delay rebate, CMS should promptly initiate enforcement actions; these actions would be triggered immediately upon non-payment. Furthermore, the commenter proposed that CMS should refer such cases to the Federal Trade Commission for antitrust evaluation.

Response: We thank this commenter for their feedback. We affirm our commitment to engaging in robust oversight, monitoring, and enforcement activities, in support of successful and effective administration of all aspects of the Negotiation Program. Continuous oversight helps CMS oversee and evaluate adherence, allowing for prompt detection and resolution of compliance issues. We also acknowledge the recommendation to refer cases to the Federal Trade Commission and will take this into consideration.

Final Decision: After consideration of public comments, we are finalizing § 429.1015 as proposed.

5. Notice and Appeal Procedures (§ 429.1020)

Under section 1197(e) of the Act, CMPs 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 CMP, we intend to provide a written CMP 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 CMP. We proposed at § 429.1020(a) that the CMP 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 CMPs with daily accruals as described in proposed § 429.1005, we intend to send the CMP 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 CMP 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 CMPs 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 solicited comment on this alternative option.

Per section 1128A of the Act, CMPs are due 60 calendar days after the receipt of the CMP 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 CMP amount owed, the civil monetary penalty is due within 60 calendar days of the appeal decision.

To operationalize the CMP appeal process in the Negotiation Program, we proposed 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 CMP 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 part 423, subpart T would apply. As set forth in section 1128A(f) of the Act, if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP 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 CMPs imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or CMPs 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.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: Some commenters stated the need for advanced notice prior to any CMP accrual noting that in proposed § 429.1020, CMS proposed to send CMP notification after the accrual has ended to reflect both the start date, end date, and total amount of penalty assessed within the notice. These commenters were concerned that CMPs could accrue daily prior to written notice and requested due process in addressing program violations to mitigate the risk of the CMP appeal process and to avoid unnecessary accrual. Commenters stated that adequate due process should involve a warning notice with the opportunity to cure prior to the issuance and accrual of a CMP. A commenter supported interim notices while a CMP is actively accruing.

Response: We reiterate the established procedures for CMPs, which are consistent with the policies described in the Negotiation Program Guidance. We will issue notice of a CMP to a Primary Manufacturer once the accrual period for the CMP has ended and we have assessed the penalty amount. However, we may also issue earlier notices regarding noncompliant conduct such as a notice of violation or request for corrective action to alert the party that a CMP may be accruing or both. We will take the recommendation to issue interim notices while a CMP is actively accruing into consideration; we anticipate any such interim notice would communicate the amount of the potential CMP accrued to date in the event a violation is ongoing, but these notices would not change the start or end date of CMP accrual. We disagree with commenters' assertion that due process requires advance notice or an opportunity to engage in corrective action prior to CMP accrual.

The CMP determination notification process offers a Primary Manufacturer the opportunity to appeal the penalty. We proposed to adopt § 429.1020(c) providing that the existing procedures codified in part 423 subpart T: Appeal Procedures for Civil Money Penalties (see §§ 423.1000 through 423.1094) will govern any appeal of a CMP imposed pursuant to §§ 429.1005 through 429.1015. These regulations provide an opportunity for Primary Manufacturers to appeal a determination to impose a CMP. The notice of the determination to impose a CMP will include detailed information regarding the appeal process and instructions for filing an appeal.

Comment: A couple of commenters advocated for more transparency and recommended that CMS publicly disclose written violation notices, corrective actions, CMP determinations (including final dispositions), or aggregated information on trending compliance issues. A commenter stated that increased transparency would lead to increased accountability.

Response: We thank commenters for their suggestions related to greater transparency surrounding program oversight and monitoring activities. We will take these recommendations into consideration.

Final Decision: After consideration of public comments, we are finalizing § 429.1020 as proposed.

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 CY 2025 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.

Final Decision: We did not receive public comments on this provision of the proposed rule.

III. 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.[94] 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

[94] *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.*

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 final 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.[95] In section 90 of these program instructions, CMS identified § 423.120(e)(2)(i), and the corresponding notice requirements at § 423.120(f)(2) through (4), as the successor regulation for purposes of implementing section 1860D–4(b)(3)(I)(ii) of the Act, as added by 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 the Negotiation Program proposed rule, we proposed to codify at new § 423.120(b)(2)(vii) and (viii) 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 that we proposed to identify as § 423.120(e)(2)(i), (f)(2), (3), and (4). In alignment with these changes, we also proposed 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.[96] With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we proposed 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 comments[97] 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 stated[98] 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

[95] *https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf.*

[96] 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.*

[97] *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.*

[98] *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.*

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 and similar indications. 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 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 proposed 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to codify the requirement that Part D plan sponsors include each Part D drug that is a selected drug on their formularies if an MFP is in effect with respect to that year.

Response: We thank the commenters for their support.

Comment: Many commenters who supported codifying the selected drug formulary inclusion requirement also argued that formulary inclusion alone does not ensure meaningful, timely, or affordable beneficiary access to selected drugs. Several commenters stated that a selected drug may technically remain on a formulary while being placed on an unfavorable tier, subjected to prior authorization or step therapy, or restricted through a narrow pharmacy network, and that these practices can undermine the practical value of an MFP and can result in delayed treatment, treatment switching, or interruption of established therapy or lead beneficiaries to abandon treatment altogether. A commenter argued that the MFPs under the Negotiation Program alter the underlying economics for selected drugs, for example, by replacing existing rebate arrangements and creating altered incentives that favor cost management strategies over clinically appropriate access decisions. Other commenters raised a related concern that, because Part D plans have historically preferred higher-priced drugs that generate larger rebates, the lower point-of-sale prices resulting from MFPs may lead plan sponsors and their PBMs to favor higher-cost competing therapies in the same class, including non-selected drug alternatives that carry a higher net cost to Medicare and beneficiaries, in order to capture greater rebate revenue, and to steer patients toward those products through less favorable tier placement or utilization management requirements on selected drugs.

Several commenters urged CMS to go beyond formulary inclusion and establish stronger protections, including requiring that selected drugs be placed on a tier no less favorable than coverage for competing therapies and that utilization management for selected drugs be clinically grounded and no more restrictive than what is applied to therapeutic alternatives in the same class. A few commenters urged CMS to prohibit step therapy that is not supported by scientific and clinical evidence, and to implement continuity-of-care protections so that patients already stabilized on a selected drug are not subjected to new utilization management requirements, less favorable cost sharing, or non-medical switching driven by MFP implementation rather than clinical need.

Response: We appreciate the commenters' support of our proposal to codify the formulary inclusion requirement. We are committed to ensuring that beneficiaries can meaningfully access selected drugs.

We appreciate commenters' concerns. However, as we explained in section III.A.2 of the proposed rule (91 FR 36318), section 1860D–4(b)(3)(I)(i) of the Act requires that Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug for which an MFP is in effect. We do not believe additional regulatory requirements beyond the formulary inclusion requirement that we are finalizing in this rule are needed at this time. We do not believe it is necessary to impose tier placement or utilization management requirements specific to selected drugs because Part D regulations already require oversight of tier placement and utilization management. Our existing requirements for Part D plan sponsor Pharmacy and Therapeutics Committees require that these determinations be grounded in clinical evidence. Under § 423.120(b)(1), a Part D plan sponsor's formulary must be developed and reviewed by a Pharmacy and Therapeutics Committee and this committee must, among other requirements, base clinical decisions on the strength of scientific evidence and standards of practice, consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy, review policies that

guide exceptions and other utilization management processes, and review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug. Therefore, the additional requirements the commenters recommend would duplicate requirements that already apply to Part D formulary and utilization management decisions, including those affecting selected drugs.

We are committed to using our existing authorities to monitor and address plan practices that may undermine meaningful beneficiary access to selected drugs and the respective MFPs. As stated in the Negotiation Program proposed rule (91 FR 36318), and consistent with section 110 of the Negotiation Program Guidance, we will 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. We will expect Part D plan sponsors to provide a reasonable clinical justification to support any such formulary design during the annual bid review process, and we will evaluate those justifications for compliance with applicable statutory and regulatory requirements. We will approve a Part D plan bid only if the plan benefit design and formulary design comply with those requirements.

Comment: Several commenters noted that selected drug status is a pricing designation under the Negotiation Program and not a determination of clinical superiority. However, not all these commenters drew the same conclusions from that shared premise. A few commenters recommended that CMS should clearly state that selection of a drug for negotiation or the establishment of an MFP does not, standing alone, provide a clinical rationale for plans to impose more restrictive utilization management requirements on selected drugs. Other commenters argued that selected drug status should not be treated as a presumption of clinical appropriateness that limits a plan's ability to apply otherwise permissible formulary and utilization management requirements on the selected drug.

Response: We thank the commenters for their feedback. As described in section 1192 of the Act and proposed and finalized at §§ 429.105 through 429.125, CMS selects a negotiation-eligible drug based on certain statutory eligibility criteria and total expenditures under Part B and Part D. A selected drug, as defined at § 429.20, is, in part, a qualifying single source drug that ranks among the highest in total expenditures under Part B and Part D and is selected from the ranked list of negotiation-eligible drugs. Selection therefore reflects a drug's total expenditures and eligibility profile under those statutory criteria and is not a determination that the drug is clinically superior or inferior to therapeutic alternatives.

Further, as proposed and finalized at § 423.120(b)(1)(v), a Part D plan sponsor's Pharmacy and Therapeutics Committee must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate. As described in the Negotiation Program proposed rule (91 FR 36318), we also 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 identified in that section of the final rule 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). We evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D plan sponsor only if the plan benefit design and formulary design complies with those requirements.

Comment: Several commenters expressed concerns specifically about access to selected drugs within the six protected classes. A commenter urged CMS to ensure beneficiary access to selected drugs within the six protected classes is not restricted compared to non-selected drugs within the protected classes. This commenter noted that this is particularly crucial, arguing that there have been widespread and significant reductions in beneficiary access since the passage of the IRA. A commenter urged CMS to confirm that nothing in this rule creates a loophole around existing protections for protected class drugs.

Response: We thank the commenters for their input. Consistent with section 1860D–4(b)(3)(G) of the Act and § 423.120(b)(2)(v), Part D plan sponsors are required to include in their formularies all covered Part D drugs in the classes and categories of clinical concern identified by the Secretary, with limited exceptions, as described in § 423.120(b)(2)(vi) and Chapter 6, Section 30.2.5, of the Medicare Prescription Drug Benefit Manual.[99] Part D plan sponsors remain subject to all applicable requirements with respect to protected class drugs, including selected drugs that fall within a protected class, and this final rule does not change that. Our formulary review process will continue to assess compliance with those existing requirements. With respect to the commenter's assertion that there have been reductions in beneficiary access to protected class drugs since the passage of the IRA, based on our review of available data, we have not seen evidence to support this claim.

Comment: Several commenters raised concerns that the Negotiation Program alters the incentive structure for Part D plan sponsors in a way that may affect beneficiary access not only to selected drugs but also to non-selected drugs in the same therapeutic class. A few commenters noted that when prices for selected drugs decrease to reflect the MFP, plans and their PBMs may have financial incentives to favor non-selected drugs in the same class that continue to generate higher rebates and administrative fees. A few commenters also stated that plans may place selected drugs on less favorable tiers or impose more burdensome utilization management requirements than non-selected drugs to encourage patients to prefer higher-cost non-selected alternatives.

Response: We appreciate the commenters sharing their concerns about the potential effects of the Negotiation Program on beneficiary access to selected drugs and non-selected drugs in the same therapeutic class. We recognize that by significantly altering the Part D benefit design and implementing the Medicare Drug Price

[99] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

Negotiation Program, the IRA changed the structure of liabilities for Part D plan sponsors and may create incentives for plans to alter their formulary and utilization management decisions not only with respect to selected drugs but also with respect to non-selected drugs in the same class. As discussed in our response above, our formulary review process assesses whether Part D plan sponsors place selected drugs on higher cost-sharing tiers than non-selected brand drugs in the same class and whether plans impose more restrictive utilization management for a selected drug compared to non-selected brand drugs in the same class. We will continue to monitor formulary and utilization management trends at the class level and will use our existing authorities to address plan practices that are inconsistent with applicable statutory and regulatory requirements.

Comment: Several commenters who supported codification of the selected drug formulary inclusion requirement also noted that they oppose the imposition of additional tier placement, utilization management, or other special formulary requirements for selected drugs. Most of these commenters argued that the statute does not require preferred formulary placement for selected drugs, exemption from utilization management, or treatment that is more favorable than other covered Part D drugs and that the IRA established a formulary inclusion requirement, not a formulary preference requirement for selected drugs. A commenter emphasized that Part D plan sponsors and their P&T Committees must retain the ability to evaluate selected drugs alongside therapeutic alternatives based on clinical evidence, safety, effectiveness, utilization, and net cost, with a couple of other commenters noting that many selected drugs may be older while newer, non-selected drugs may represent the preferred standard of care for new patient initiation. A commenter urged CMS to maintain its existing case-by-case formulary review process for assessing formulary management decisions involving selected drugs. A couple of other commenters urged CMS to review selected drugs under the same formulary standards applied to non-selected drugs, rather than subjecting selected drugs to a higher standard of review.

Several commenters also noted that if CMS were to create additional formulary requirements, they would have concerns about the downstream effects on plan leverage and drug costs, arguing that mandatory preferred placement would significantly diminish the effectiveness of formularies as a key tool to promote competition, inhibit plans' ability to negotiate price concessions on therapeutically similar non-selected products, and could unduly impact formulary, rebate, and other negotiations for non-selected drugs.

A few commenters urged CMS to confirm that its monitoring is intended to assess compliance with the statutory inclusion requirement and existing Part D requirements, rather than establish an implicit expectation regarding tier placement, cost sharing, or utilization-management design, and to avoid using formulary placement trends as a basis for imposing additional requirements not established by statute or regulation. A couple of commenters expressed concern that CMS has begun applying selected drug formulary expectations before the year in which an MFP is in effect and recommended that CMS clarify that such expectations apply only in years an MFP is in effect.

Response: We thank the commenters for their support of our proposal. At this time, we are not imposing tier placement, utilization management, or other special formulary requirements for selected drugs. As discussed in the Negotiation Program proposed rule (91 FR 36318), we believe our current approach provides 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.

Our monitoring of formulary placement for selected drugs is intended to assess compliance with the statutory inclusion requirement and existing Part D requirements, while safeguarding beneficiary access at a time when the Part D benefit has undergone significant change. We will continue to use our existing formulary review process to evaluate plan formulary designs consistent with the standards described in this final rule and applicable statutory and regulatory requirements.

With respect to the commenters' concerns about the application of formulary review standards prior to MFP effectuation for a selected drug, we clarify that our formulary review process, as discussed in the Negotiation Program proposed rule (91 FR 36319), only applies in years for which an MFP is in effect for a selected drug. As discussed in this same section of this final rule, we will separately continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year, and we clarify that our monitoring during this period is intended to identify practices that may undermine beneficiary access.

Comment: Several commenters opposed additional formulary requirements for selected drugs and urged CMS to provide greater clarity and predictability in its formulary review process. A commenter stated that plan sponsors have had limited success obtaining CMS approval for non-preferred placement or utilization management of selected drugs, even when supported by clinical evidence, and urged CMS to establish clear standards identifying the formulary placement and utilization management approaches plans may apply to selected drugs.

A commenter requested that CMS provide clear reasoning and citations when a formulary placement or utilization management choice is rejected and create more windows for plans to update utilization management criteria during the plan year, noting that the current process can lack transparency and result in last-minute formulary changes that increase plan and program costs. Another commenter urged CMS to ensure that its policies encourage preferred formulary placement of lower-cost generics and biosimilars over selected drugs when appropriate and noted that current review practices discourage plans from preferring lower-cost alternatives. A commenter requested that CMS confirm in the final rule that a Part D plan sponsor can provide a reasonable justification for placing a selected drug on a less preferred tier when the plan demonstrates that a more cost-effective, clinically appropriate alternative is available.

Response: We thank the commenters for their feedback. With respect to commenters' requests for clearer standards and more specific reasoning when formulary placements or utilization management choices are rejected, we note that the standards governing our formulary review of selected drugs are described in detail in the Negotiation Program proposed rule (91 FR 36319). In response to the commenter's request to create more windows for plans to update utilization management criteria during the plan year, we note that existing regulations and guidance already provide Part D plan sponsors with meaningful opportunities to make maintenance and non-maintenance formulary changes during the plan year, consistent with § 423.120(e) and Chapter 6, Section 30.3 of the Medicare Prescription Drug

Benefit Manual. We believe our current approach appropriately balances Part D plan sponsors' need for flexibility with the importance of formulary stability for beneficiaries.

Comment: Many commenters stated that CMS' proposed approach to rely on its existing formulary review process and on monitoring formulary trends is inadequate to guarantee that beneficiaries can access their prescribed medications and urged CMS to attach enforcement consequences to its review. Many commenters expressed concern that, without consequences, plans could impose utilization management that limits beneficiary access to selected drugs, undermining the Negotiation Program's intent. A few commenters noted that because plans are facing increased financial liability under the Part D redesign, they have strong incentives to manage utilization of selected drugs through prior authorization, step therapy, and non-preferred tiering. A few commenters stated that CMS is relying too heavily on existing processes and noted that the proposed rule largely defers to the existing formulary review process. A commenter urged CMS to preemptively modernize and strengthen its formulary review standards for a post-IRA era, and another commenter urged CMS to commit additional resources to formulary reviews.

A commenter stated that annual formulary review at the bid submission stage does not constrain plan behavior during the plan year. This commenter also argued that if CMS is only considering restrictive formulary designs individually, there is a risk that broader market-wide trends of restricting access to specific selected drugs may be missed. A couple of commenters urged CMS to attach concrete consequences, such as bid disapproval under § 423.272(b)(2)(i) or a required corrective action plan, to its monitoring so that monitoring results in enforcement, not just observation.

Several commenters recommended year-round monitoring with expedited corrective action, a clearly identified process through which beneficiaries, prescribers, and patient organizations may report emerging access barriers, and routine audits of plan coverage practices for selected drugs. A commenter recommended that CMS treat a plan's use of an identified restrictive practice as presumptive evidence that a plan is impeding meaningful access and also recommended that, in these instances, CMS should require the plan to provide a drug-specific clinical justification supported by scientific evidence and accepted standards of care, noting that a generalized assertion of cost management would be insufficient to meet that standard.

Response: We appreciate the commenters sharing their concerns about CMS' formulary review process and enforcement recommendations. We are committed to ensuring that beneficiaries can meaningfully access selected drugs.

As described in the Negotiation Program proposed rule (91 FR 36318), we conduct a robust review of each Part D plan's formularies and expect Part D plan sponsors to provide a reasonable clinical justification for any formulary design that: (1) places a selected drug on a non-preferred tier; (2) places a selected drug on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) requires utilization of an alternative non-selected brand drug prior to a selected drug (that is, step therapy); or (4) imposes 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. We will approve a Part D plan bid only if the plan benefit design and formulary comply with applicable requirements, and we may disapprove a bid under § 423.272(b) when a plan's formulary design does not meet those requirements. For this review, we consider, class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action and similar indications.

As stated in Chapter 6, Section 30.3.3 of the Medicare Prescription Drug Benefit Manual, both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the contract year. We believe that formulary stability is extremely important so that beneficiaries maintain access to the benefit they chose during enrollment as represented to them by the Part D plan sponsor. We note that Part D plan sponsors are subject to limitations on mid-year formulary changes under § 423.120(e). Except in limited circumstances, such as immediate substitutions under § 423.120(e)(2)(i) and market withdrawals under § 423.120(e)(2)(ii), Part D plan sponsors must submit a negative formulary change request to CMS prior to implementing any negative formulary change, and non-maintenance changes, as defined at § 423.100, may not be implemented until CMS provides approval of the change. These limitations provide an important safeguard against mid-year access disruptions for beneficiaries.

We will continue to monitor formulary and utilization management trends for selected drugs and will use the information gathered through that monitoring to inform our formulary review standards and guidance in future years and to identify any systemic trends that may warrant further action.

Finally, we note that beneficiaries may report any issues or concerns regarding access to their prescribed medications, including selected drugs, to their plan first, and also to CMS by utilizing the public-facing online portal [100] for the Negotiation Program, supported by the MTF platform, or by contacting 1–800–MEDICARE.

Comment: Many commenters urged CMS to expand the scope of its monitoring of selected drugs beyond formulary inclusion and recommended that monitoring assess not only whether a selected drug appears on the formulary but also how it is treated relative to comparable alternatives, including its formulary placement and utilization management. A commenter specifically recommended that monitoring assess whether a selected drug's placement or utilization management materially disadvantages it relative to clinically comparable non-negotiated alternatives without a sufficient clinical justification. Several commenters recommended that CMS monitor formulary tier placement and cost sharing, prior authorization, step therapy, and quantity limit requirements, approval, denial, appeal, reversal, and decision-time measures, and treatment switching and prescription abandonment. A few commenters urged CMS to evaluate the actual out-of-pocket financial impact of plan cost-sharing designs, including shifts from copayment to coinsurance, rather than relying solely on tier placement. A commenter also urged CMS to monitor the average number of medicines covered per class and ensure the number does not decrease.

Several commenters also urged CMS to evaluate access longitudinally by comparing formulary placement and utilization management before selection, after selection, and after the MFP takes effect to identify changes associated with the Negotiation Program, with a commenter noting that plans may alter formulary placement or utilization management in anticipation of future MFP implementation. A commenter urged CMS to monitor changes in comparator medications and clinical alternatives to selected drugs, noting

[100] *https://mtf.cms.gov/.*

that comparators should be defined broadly, not just by pharmacologic class, as clinical substitution can occur across classes. Another commenter recommended that CMS monitor and publish pharmacy-level access measures for selected drugs, including dispensing and reversal rates, dispensing delays, inventory-related complaints, and geographic availability, to identify access problems arising specifically from MFP effectuation at the pharmacy counter.

A commenter expressed concern about the impact on beneficiaries in long-term care and nursing facility settings and recommended that monitoring specifically account for continuity of care disruptions in those populations. A couple of commenters also noted that patients with rare diseases and cancer typically have a limited set of effective therapeutic options and that monitoring should account for rare-disease subtypes, patient-specific characteristics, and the lack of clinically interchangeable alternatives in these populations. Another commenter recommended that CMS collect plan-level data on treatment continuity within specific disease areas, such as antiretroviral therapy stability for people living with HIV.

Response: We appreciate the commenters' detailed recommendations regarding the scope of our monitoring of selected drugs and the importance of a comprehensive monitoring framework that captures a range of plan practices that may affect beneficiary access to selected drugs. As described in the Negotiation Program proposed rule (91 FR 36319), our formulary review process already assesses a range of formulary and utilization management practices for selected drugs. We will continue to use that framework as a foundation for our ongoing monitoring of selected drug access. We appreciate the commenters' recommendations and will take these recommendations into account as we continue to refine our monitoring framework in future years. We also note that public use files are available on *CMS.gov* for external researchers.[101] These files include formulary inclusion, tier placement, utilization management edits such as prior authorization, step therapy and quantity limits, as well as plan-level cost sharing and pricing data available for each contract year.

Comment: Many commenters urged CMS to publicly report the data it collects through monitoring activities, arguing that the current process remains largely opaque to beneficiaries and the patient organizations that advocate on their behalf. Several commenters urged CMS to publish the information it already collects and reviews as part of its bid review, formulary review, and Negotiation Program oversight activities so that researchers, beneficiary advocates, and policymakers can identify potential access concerns before they become widespread. A commenter noted that existing Part D reporting is aggregated and does not provide the drug- and plan-level transparency needed.

Several commenters recommended that CMS publish drug and plan-level data at the product, therapeutic area, and disease level, including formulary tier placement and cost sharing, prior authorization, step therapy, and quantity limit requirements, and approval, denial, appeal, reversal, and decision-time measures. A couple of commenters also requested CMS to publish a plain-language account of its formulary review criteria and oversight process and to provide sufficient information regarding the basis and disposition of individual formulary reviews to provide meaningful public accountability. A commenter further requested that CMS make public any specific formulary or utilization management approaches CMS will not approve, so that stakeholders have clear visibility into the standards CMS applies. Another commenter noted that formulary submissions and written criteria do not show how those policies operate in practice and urged CMS to publish operational measures rather than relying solely on plan-submitted formulary information.

Response: We appreciate the commenters' recommendations regarding public reporting on formulary placement, utilization management, and access outcomes for selected drugs. We will take these recommendations into consideration. We note that public use files are available on *CMS.gov* for external researchers.[102] These files include formulary inclusion, tier placement, utilization management edits such as prior authorization, step therapy and quantity limits, as well as plan-level cost sharing and pricing data available for each contract year. We further note that CMS does not publish the results of its formulary reviews or the clinical justifications submitted by Part D plan sponsors or publicly share such clinical justifications with any external stakeholders, including manufacturers.

Comment: Many commenters urged CMS to strengthen and streamline the appeals, exceptions, and coverage determination processes for selected drugs, arguing that the existing processes are insufficient to provide timely beneficiary relief when formulary changes or utilization management requirements interfere with access. A few commenters stated that exceptions and appeals must be clear, accessible, and timely, with expedited review available when a preferred alternative is unsuitable and urged CMS to ensure that beneficiaries and prescribers have clear, timely information concerning coverage requirements and the ability to seek an exception when a preferred alternative is not appropriate.

A few commenters recommended that CMS create a more robust step therapy exceptions process for selected drugs, requiring plans to respond within 24 to 72 hours, and a commenter recommended allowing exceptions in specified clinical circumstances, including where the patient has already tried and failed the required drug, where delayed treatment will cause irreversible consequences, where the required drug will cause harm to the patient, or where the patient is stable on their current medication. A commenter urged CMS to require rapid, clinically meaningful exceptions and appeals, with timelines appropriate to progressive, life-threatening, or irreversibly disabling conditions.

A few commenters recommended that CMS establish an expedited process through which beneficiaries, prescribers, and patient organizations can report access barriers associated with selected drugs directly to CMS. A commenter requested that CMS' monitoring include the availability of expedited review and whether beneficiaries experience interruptions while an exception or appeal is pending. Another commenter also recommended that CMS actively monitor appeals, grievances, and exception requests that beneficiaries file with their plans in order to maintain a near real-time view of emerging access issues for selected drugs and improve the underlying appeals and grievance processes.

Response: We appreciate the commenters' recommendations regarding the coverage determination, exceptions, and appeals processes for selected drugs. We note that existing Part D requirements under subpart M of part 423 (§§ 423.558 through 423.638) already provide robust due process for enrollees seeking access to selected

[101] *https://resdac.org/cms-public-use-files-for-researcher-use.*

[102] *https://resdac.org/cms-public-use-files-for-researcher-use.*

drugs, and this process applies to selected drugs in the same manner as other covered Part D drugs. With regard to the commenters' recommendations on timing, we note that § 423.568(b) already requires that when a party makes a standard request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. Consistent with §§ 423.570 and 423.572, an enrollee or an enrollee's prescribing physician or other prescriber may also request that a Part D plan sponsor expedite a coverage determination or exceptions request, which requires that a Part D plan sponsor make a determination no later than 24 hours after receiving the request or the physician's or other prescriber's supporting statement.

We appreciate the commenters' recommendations that CMS establish a process through which beneficiaries, prescribers, and patient organizations can report access barriers associated with selected drugs directly to CMS. Beneficiaries may report any issues or concerns regarding access to their prescribed medications, including selected drugs, to their plan first, and also to CMS by utilizing the public-facing online portal [103] for the Negotiation Program, supported by the Medicare Transaction Facilitator (MTF) platform, or by contacting 1–800–MEDICARE. Beneficiaries may also submit inquiries, complaints, grievances, appeals, and requests for information to the Medicare Beneficiary Ombudsman. Additionally, we developed the Complaint Tracking Module (CTM) in the Health Plan Management System (HPMS) to track complaints received by CMS from beneficiaries, providers, and their representatives regarding specific plans. Complaints are recorded in the CTM and assigned to the appropriate plan and, as required under the contract provisions established at §§ 422.504(a)(15) and 423.505(b)(22), plans are required to address and resolve the complaints received by CMS against them in the CTM. Plans must also adhere to the timelines to resolve complaints in compliance with §§ 422.125 and 423.129.

We also appreciate the commenters' recommendations that CMS monitor appeals, grievances, and exception requests. One way that CMS is able to monitor appeals requests is through the review of the Appeals Decision Search Tool on *CMS.gov* which provides summaries of the Qualified Independent Contractor's (QIC) decisions on Part C and Part D appeals.[104] Further, consistent with § 423.514(a), each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report information to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires. As stated in the CY 2026 Medicare Part D Reporting Requirements document, this required information includes data on grievances (section III) and coverage determinations and redeterminations, including utilization management, formulary, and tiering exceptions (section v).[105]

Additional guidance on coverage determinations, exceptions, and appeals processes is available in subpart M of part 423 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.[106]

Comment: A few commenters requested that CMS amend the proposed regulatory text at § 423.120 to reflect the language CMS states in preamble, that: ''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.'' Therefore, the commenters requested that the language ''include each Part D drug'' in proposed § 423.120(b)(2)(vii) be replaced with ''include all dosage forms and strengths of each Part D drug''. A commenter stated that this will clarify Part D plan sponsors' legal obligations and ensure that the regulation aligns with CMS' stated policy in the preamble.

Response: Under our proposed regulation, because a selected drug includes all dosage forms and strengths to which the MFP applies, the formulary inclusion requirement applies to all dosage forms and strengths of a selected drug for which an MFP is in effect. Our regulation at § 429.700(a), which we are finalizing in this rule, states that the MFP is computed and applied across different dosage forms and strengths of the selected drug, as defined at § 429.20. Additionally, the Part D regulations already define ''selected drug'' at § 423.100 as having the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance, which will include our regulations at part 429. As such, we do not believe it is necessary to revise our proposed regulation at § 423.120(b)(2)(vii) and are finalizing § 423.120(b)(2)(vii) as proposed.

Comment: A commenter urged CMS to adopt new actuarial equivalence tests to more accurately and quantitatively track whether plan sponsors are offering what the commenter described as sufficient coverage of drugs selected for negotiation. The commenter argued that existing formulary review processes do not provide a sufficiently rigorous or quantitative basis for assessing whether a plan's overall treatment of selected drugs—across tier placement, cost sharing, and utilization management—is equivalent to its treatment of comparable non-selected drugs, and recommended that CMS develop and apply actuarial equivalence standards as part of its formulary oversight framework for selected drugs.

Response: We thank the commenter for their feedback. As discussed in the Negotiation Program proposed rule (91 FR 36319), section 1860D–4(b)(3)(I)(i) of the Act requires that Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug for which an MFP is in effect. Sections 1860D–2(b)(2)(B) and 1860D–4(c)(1)(A) of the Act continue to permit Part D plan sponsors to use formularies, tiered cost sharing, and cost-effective drug utilization management programs, subject to applicable statutory and regulatory requirements. We do not believe it is necessary at this time to implement requirements that Part D plan sponsors treat selected drugs in a manner that is equivalent to their treatment of non-selected drugs through an actuarial equivalence standard.

Comment: A commenter requested that CMS to clearly distinguish authorized generics on the Formulary Reference File (FRF) so Part D sponsors can ensure inclusion of authorized generics that are selected drugs on their formularies when their MFP takes effect and can separately administer formulary status for authorized generics and

[103] *https://mtf.cms.gov/.*

[104] *https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d.*

[105] *https://www.cms.gov/files/document/cy2026-part-d-reporting-requirements-12-01-2025.pdf.*

[106] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

ANDA generics. The commenter states that the FRF does not always distinguish authorized generics from ANDA generics through separate RXCUIs, such as when the products share the same drug name. The commenter states that as a result, Part D plans may either inadvertently fail to include an authorized generic on formulary when required or be unable to assign different formulary treatment to authorized generics and ANDA generics, including different tier placement or utilization management requirements, or to submit an immediate substitution change.

Response: We appreciate the commenter's concern regarding the ability of Part D plan sponsors to distinguish between ANDA generic products and NDA authorized generic products when NDCs for those products are associated with the same RxCUI. RxNorm generally associates NDCs for ANDA generic products and authorized generic products with the same RxCUI when the products share the same RxNorm concept. CMS relies on the RxCUI assignments established in RxNorm and therefore cannot independently assign separate RxCUIs to distinguish these products on the FRF.

We recognize that a shared RxCUI may affect Part D plan sponsors' ability to separately administer formulary status for an authorized generic and an ANDA generic associated with that RxCUI. Accordingly, we will continue to provide submission guidance to Part D plan sponsors when an ANDA generic product (of a selected drug) becomes available on the market and is assigned the same RxCUI as the authorized generic product. We provided such technical guidance to all Part D plan sponsors when ANDA dapagliflozin NDCs became available and were associated with the same RxCUI as authorized generic dapagliflozin NDCs marketed under an NDA. This guidance is intended to assist Part D plan sponsors in complying with applicable formulary requirements for selected drugs and, where applicable, appropriately reflect separate formulary treatment for ANDA generic products and authorized generic products that share the same RxCUI.

Final Decision: After consideration of public comments, we are finalizing § 423.120(b)(2) as proposed.

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 sponsors 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) through (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 proposed 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 proposed, 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 also proposed 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 proposed 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 make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval . . . 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 [§ 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.

We proposed to codify the current identification of § 423.120(e)(2)(i) as part of the successor regulation, we also proposed 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.[107]

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,[108] 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 proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to codify our identification of § 423.120(e)(2)(i), (f)(2) through as the successor regulation for the purposes of § 423.120(b)(2)(viii).

Response: We thank the commenters for their support of our proposal.

Comment: Several commenters requested that CMS expand the scope of the successor regulation. A few commenters recommended that CMS expand the successor regulation exception to include maintenance changes. Other commenter requested that CMS expand the successor regulation exception to include substitutions of biosimilar biological products other than interchangeable biological products. A commenter stated that allowing formulary substitutions for all biosimilars, not only those designated as interchangeable, will strengthen competition, reduce beneficiary cost-sharing, and better align formulary management with the affordability goals of the Negotiation Program. Another commenter requested

[107] 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 final 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.

[108] *https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf.*

that CMS clarify that the successor regulation framework can evolve as the generic and biosimilar markets mature.

Response: We appreciate the commenters' recommendation to expand the scope of the successor regulation to include maintenance changes and biosimilar biological products other than interchangeable biological products. We understand that the commenters are interested in the successor regulation expanding to accommodate a broader range of formulary substitutions and to evolve as the generic and biosimilar markets mature. However, the successor regulation we are codifying at § 423.120(b)(2)(viii) is limited to § 423.120(e)(2)(i) and (f)(2) through (4), which govern immediate substitutions of corresponding drugs, consistent with our previously issued guidance in the Final CY 2026 Part D Redesign Program Instructions and the Negotiation Program Guidance. After consideration of the comments received, we decline to expand the scope of the successor regulation exception beyond what was proposed in the proposed rule. However, in the future, we 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).

Comment: A commenter requested that CMS explain the scope of the successor regulation exception at § 423.120(e)(2)(i) and (f)(2) through (4), including any broader alternatives considered and the reasons for rejecting them. The commenter stated that because these provisions define the only circumstances permitting removal of a selected drug, they are the sole residual source of plan leverage.

Response: We thank the commenter for their comment. As discussed in detail in section III.A.3.a of this final rule, we are finalizing the identification of § 423.120(e)(2)(i), and the associated notice requirements at § 423.120(f)(2) through (4), as the successor regulation to § 423.120(b)(5)(iv) for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act and new § 423.120(b)(2)(viii), which we are finalizing in this rule. This identification is consistent with the Negotiation Program Guidance and the Final CY 2026 Part D Redesign Program Instructions.

To ensure we fully considered alternative approaches to identifying the successor regulation, we solicited input in the Draft CY 2026 Part D Redesign Program Instructions on the advantages and disadvantages of identifying as the successor regulation the regulatory provisions that encompass only immediate substitutions of generic drugs and interchangeable biological products; immediate substitutions and maintenance changes of generic drugs and interchangeable biological products; and immediate substitutions and maintenance changes of generic drugs and interchangeable biological products, as well as maintenance changes of biosimilar biological products other than interchangeable biological products. More than half of the comments received supported identifying § 423.120(e)(2)(i), and the associated notice requirements at § 423.120(f)(2), (3), and (4), as the successor regulation to § 423.120(b)(5)(iv). After consideration of the comments received, we declined to adopt an alternative approach to identifying the successor regulation.

Comment: A commenter urged CMS not to permit, under the successor regulation, immediate substitution of interchangeable biological products and to identify a successor regulation that conforms with the plain language of the statute. The commenter stated that the plain language of the IRA limits immediate substitution to generic drugs, and the authority to identify a ''successor regulation'' does not permit CMS to materially expand immediate substitution to an entirely different class of drugs (that is, interchangeable biological products). The commenter stated that if Congress intended for immediate substitution to apply to newly marketed biosimilars, it would have said so in the statute. The commenter further argued that CMS' expansion exacerbates inequities in the underlying statute, in particular, the requirement that a manufacturer continue to offer the MFP throughout the drug's price applicability period, because a selected drug could be removed from formulary yet remain subject to the MFP for nearly two years after generic or biosimilar entry. The commenter stated that this would dissuade generic and biosimilar manufacturers from entering the market and result in manufacturers bearing the economic obligations associated with the MFP even though beneficiaries could lose access to the selected drug.

Response: We disagree with the commenter's assertion that our proposed codification of the successor regulation exception is extra-statutory. The statute does not explicitly limit the exception to § 423.120(b)(5)(iv) at the time of enactment. We believe it is significant that the statute did not establish a static exception (for example, by indicating that the exception was limited to § 423.120(b)(5)(iv) at the time of enactment), but rather expressly indicated that the exception would include ''any successor regulation.'' The statute could have limited the meaning or scope of ''any successor regulation'' to apply only to the scope of § 423.120(b)(5)(iv) at the time of enactment (that is, brand name drugs and their therapeutically equivalent generic drugs), but it did not do so. Other provisions of the Part D statute make clear that when the statute limits a provision that cross-references an existing regulation to the terms of such regulation at a particular point of time, the statute expressly states that this is the case. For example, section 1860D–14A(g)(6) of the Act defines ''negotiated price'' to have ''the meaning given such term in [42 CFR 423.100] (*as in effect on March 23, 2010*)'' (emphasis added). However, section 1860D–4(b)(3)(I)(ii) of the Act does not state that the exception is limited to 42 CFR 423.120(b)(5)(iv) as codified at a specific time, but instead expressly includes the words ''or any successor regulation,'' leaving it to CMS to identify any such successor regulation as necessary.

Furthermore, the statute does not explicitly limit the exception to brand name drugs and their therapeutically equivalent generic drugs. When CMS codified § 423.120(b)(5)(iv), there were no Part D drugs that were interchangeable biological products. At the time the IRA was enacted, there were no codified requirements for immediate substitutions with interchangeable biological products, nor were there codified requirements for maintenance changes with interchangeable biological products or biosimilar biological products other than interchangeable biological products. As a result, at the time of enactment, it would not have been possible for the statute to point to specific regulations permitting formulary changes other than those related to therapeutically equivalent generic drugs. Therefore, the inclusion of interchangeable biological products reflects the evolution of the Part D regulations since the IRA was enacted and is consistent with our statutory authority to identify a successor regulation.

With respect to the commenter's concerns about patient access, we note that the immediate substitution framework includes notice and timing requirements designed to protect beneficiaries during formulary transitions, and that existing coverage determination and exception processes remain available to beneficiaries with a documented medical need to remain on a particular product.

After consideration of public comments, we are finalizing § 423.120(e)(2)(i), (f)(2) through (4) as the successor regulation for the purposes of § 423.120(b)(2)(viii) as proposed.

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) through (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.

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 final 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—:

- 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
- 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 final 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 final rule states that, for drug products, CMS proposed 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 final rule states that, for biological products, CMS proposed 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) through (4) are met.

To ensure consistency with the IRA's formulary inclusion requirement, which we proposed 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 proposed 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.

We did not receive public comments on this provision, and therefore, we are finalizing the definition of corresponding drug at § 423.100 as proposed.

c. Timing of Immediate Substitutions

Section 423.120(e)(2)(i), (f)(2), (3), and (4), which we proposed 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 proposed to codify as § 423.120(e)(2)(i), (f)(2) through (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 proposed 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 proposed that removals under the statutory formulary inclusion exception, which we proposed 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested that CMS allow immediate substitutions for selected drugs in one year to carry over to subsequent years in order to prevent situations where a selected drug may need to be re-added to a formulary after it has been removed under an immediate substitution. The commenters recommended that CMS allow for the removal of selected drugs from a formulary as soon as a competitor generic or interchangeable biological products becomes available on the market, regardless of whether this is before or after the initial formulary submission. A commenter argued that Congress likely intended for the exception to the formulary inclusion requirement to consistently apply once generic or biosimilar competition exists for a selected drug to promote greater competition and affordability. Another commenter expressed concern that the requirement to re-add drugs to a formulary could artificially limit effective member migration from the selected drug to its generic or biosimilar equivalent. An additional commenter stated that requiring a selected drug that has lower cost alternatives to be re-added to a formulary can reduce incentives for competition, impede the adoption of generic and biosimilar alternatives, and prevent plans from realizing the full benefits of generic and biosimilar entry.

Response: We appreciate the commenters' recommendations to allow immediate substitutions to carry over to subsequent plan years. However, we decline to adopt this recommendation as our approach is consistent with CMS' longstanding policy to consider each plan year's formulary to be separate and distinct from the prior year. In this final rule, we are maintaining that 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.

Comment: A commenter requested that CMS require Part D plan sponsors to retain on formulary any selected drug for which an MFP remains in effect, regardless of whether a generic or biosimilar has entered the market. The commenter stated that this protection should apply equally to small molecule drugs and biological reference products and would help ensure that the IRA's pricing provisions continue to function in a manner that meaningfully benefits patients. The commenter shared an example of a plan using immediate substitution to remove an innovator drug as soon as an interchangeable biological product is approved, but before that interchangeable biological product is stocked and available at local pharmacies, which would leave patients without access to their prescribed therapy. The commenter also requested that CMS implement ''grandfathering'' requirements to protect patients currently stabilized on a selected drug from abrupt access disruptions when plans utilize immediate substitution, particularly when a newly approved substituting product is not yet widely available at pharmacies.

Response: We disagree with the commenter's recommendation that Part D plan sponsors be required to retain on formulary any selected drug for which an MFP remains in effect regardless of whether a corresponding generic or biosimilar has entered the market. As described in section III.A.3.a. of this final rule, section 1860D–4(b)(3)(I)(ii) of the Act expressly provides that nothing in the formulary inclusion requirement 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 the successor regulation. The immediate substitution framework at § 423.120(e)(2)(i) and (f)(2) through (4) includes notice and timing requirements designed to protect beneficiaries during formulary transitions, and existing coverage determination and exception processes remain available to beneficiaries.

Comment: A commenter raised concerns about the operational impact of mid-year immediate substitutions in long-term care (LTC) settings and recommended that CMS establish LTC-specific safeguards for immediate substitutions, including advance notice to the dispensing LTC pharmacy, a reasonable transition period that aligns with LTC dispensing and unit-dose packaging cycles, and protections to ensure continuity of care for stabilized residents during any mid-year product transition.

Response: We appreciate the commenter's recommendations regarding LTC-specific safeguards for immediate substitutions and recognize the operational complexities that mid-year formulary changes can present in LTC settings. However, we decline to establish LTC-specific requirements for immediate substitutions. The immediate substitution framework at § 423.120(e)(2)(i) and the notice requirements at § 423.120(f)(2) through (4) apply uniformly to Part D plan sponsors and already include beneficiary protections relevant to the commenter's concerns, including the requirement that a corresponding drug be added on the same or a lower cost-sharing tier and with the same or less restrictive formulary prior authorization, step therapy, or quantity limit requirements, and advance general and retrospective notice requirements. In addition, for beneficiaries who have

a medically necessary reason to remain on a selected drug that has been removed from the formulary, they may seek continued coverage through the coverage determination and exception processes under subpart M of part 423.

Comment: A commenter supported CMS' proposal to apply the immediate substitution regulation consistently to generic and interchangeable biological products. They urged CMS to provide clear operational guidance—including when a sponsor may implement a substitution, what notice is required, and how the change should be reflected in the applicable formulary and beneficiary materials—for circumstances in which such products become available during or after the formulary development and bid submission cycles. The commenter requested that CMS ensure that the timing of these requirements does not unnecessarily delay adoption of clinically appropriate lower-cost alternatives.

Response: We appreciate the commenter's support for our proposal and agree on the importance of clear operational guidance to support Part D plan sponsors in implementing the immediate substitution framework. As discussed in section III.A.3.a. of this final rule, we are codifying § 423.120(e)(2)(i) and (f)(2) through (4) as the successor regulation for purposes of new § 423.120(b)(2)(viii). Part D plan sponsors should refer to those regulations and the preamble discussion in this final rule for guidance on when an immediate substitution may be implemented, what notice is required, and how the change should be reflected in applicable formulary and beneficiary materials.

Comment: A commenter requested that CMS clarify that plans may begin a contract year with a qualifying corresponding biosimilar on formulary in place of a selected drug when the biosimilar is already available on the market at the time of bid submission. The commenter stated that plans have reported operational challenges when attempting to do so and the practical result is that beneficiaries may face a full plan year of higher cost-sharing on a reference product before substitution can occur, even when a lower-cost biosimilar was available on the market before the plan year began.

Response: We thank the commenter for this recommendation. We interpret this comment as a request that CMS permit a Part D plan sponsor to begin a contract year with a biosimilar on its formulary in place of a selected drug that is a reference product, where the biosimilar was available on the market at the time the sponsor submitted its bid and initial formulary. As explained below, the successor regulation does not permit removal of the selected drug in that circumstance, and we decline to adopt the recommendation.

Under the successor regulation we are finalizing, § 423.120(e)(2)(i) and the notice requirements at § 423.120(f)(2) through (4), a Part D plan sponsor may remove a selected drug that is a reference product from its formulary via an immediate substitution and replace it with an interchangeable biological product only if the Part D plan sponsor previously could not have included the drug on its formulary when it submitted its initial formulary for CMS approval because such drug was not yet available on the market. In the circumstance the commenter describes where the biosimilar is already available at the time of bid and initial formulary submission, the Part D plan sponsor could have included that product on its initial formulary, and therefore the immediate substitution exception is not permitted.

In addition, we note that only an interchangeable biological product qualifies as a corresponding drug for the purpose of the successor regulation exception. Accordingly, a Part D plan sponsor must include the selected drug that is a reference product on its formulary for the year in which the MFP is in effect, consistent with section 1860D–4(b)(3)(I)(i) of the Act and new § 423.120(b)(2)(vii).

We also note that including the selected drug on its formulary does not prevent a Part D plan sponsor from also covering an available biosimilar. A Part D plan sponsor may add a biosimilar biological product to its formulary at any time during the plan year, while retaining the reference product that is a selected drug on the formulary.

Final Decision: After consideration of public comments, we are finalizing § 423.120(b)(2)(vii) and (viii) as proposed.

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.

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 applied the statutory negotiated price requirements for selected drugs through the applicable Negotiation Program guidance for 2026, 2027, and 2028. Specifically, we stated that under section 1860D–2(d)(1)(D) of the Act, the negotiated price for selected drugs ''must not exceed the applicable [maximum fair price (MFP)] plus any dispensing fees for such drug.'' We 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 proposed to codify the statutory amendments to the definition of negotiated price for selected drugs in the definition of ''negotiated price'' at § 423.100 for 2029 and subsequent years. We proposed 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 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, to better align the definition of ''negotiated price'' at § 423.100 with our historical interpretation of this definition, we proposed to revise the required elements of the negotiated price in subparagraph (2) to add sales tax and vaccine administration fees to the definition of ''negotiated price'' without altering any existing elements of that definition. Specifically, we proposed deleting the word ''and;'' from the end of paragraph (2)(ii), redesignating paragraph (2)(iii) as 2(v), and adding new paragraph (2)(iii) to require the inclusion of sales tax and new paragraph (2)(iv) to require the inclusion of vaccine administration fees.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to codify section 1860D–2(d)(1)(D) of the Act to require that the negotiated price paid to dispensing entities for a selected drug not exceed the MFP plus applicable dispensing fees. A commenter requested that CMS confirm Part D sponsors or pharmacy benefit managers (PBMs) have the ability to negotiate rates for selected drugs that are lower than the MFP, and that the ceiling does not alter the ability of Part D sponsors or PBMs to negotiate permissible pharmacy reimbursement arrangements or other contractual terms, provided that the resulting negotiated price used for payment complies with the statutory ceiling.

Response: We thank commenters for their support and note that under section 1860D–2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the MFP plus any dispensing fees for such drug. This does not prohibit plans from negotiating rates for selected drugs that are lower than the MFP. We encourage plan sponsors to work with pharmacies to ensure adequate and fair compensation for dispensing selected drugs.

Comment: A commenter supported CMS' inclusion of sales tax and applicable vaccine administration fees in the definition of negotiated price.

Response: We thank the commenter for their support.

Comment: Several commenters expressed concerns regarding pharmacy reimbursement for selected drugs. A commenter recommended that CMS revise the program such that Part D plans and PBMs must pay pharmacies no less than the MFP plus a commensurate dispensing fee when providing selected drugs with an agreed-upon MFP, and that Part D plans and PBMs must not assess Direct and Indirect Renumeration (DIR) fees on selected drugs with an agreed-upon MFP. A couple of commenters urged CMS to ensure that dispensing fees adequately compensate pharmacies and provided recommendations, such as requiring dispensing fees and any service fees be stated as flat, service-based amounts rather than as a percentage of the MFP, requiring the provision of a minimum dispensing fee, and affirming that dispensing fees for selected drugs must reflect the actual cost of dispensing selected drugs for long-term care (LTC) pharmacies.

Response: We thank the commenters for their input. We expect plans and PBMs to engage in sustainable and fair reimbursement practices with all pharmacies to ensure access to selected drugs, consistent with their statutory obligations, for individuals with Part D. As noted in our response to a similar comment in the Negotiation Program Guidance, under section 1860D–2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for a selected drug with an agreed-upon MFP. We are not establishing requirements for dispensing fees for selected drugs but will continue to closely monitor plan reimbursement for selected drugs, including pharmacy price concessions and dispensing fees.

Final Decision: After consideration of the public comments we received, we are finalizing § 423.100 as proposed.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 through 3520), 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, 44 U.S.C. 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 solicited public comment (see section II. of this final rule) on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that the burden estimate should include tasks other than submission of data that are involved with the production of the requested data, including internal review, legal analysis, data extraction, documentation, certification, and correction processes.

Response: CMS thanks this commenter for their feedback. As noted in the description of the roles involved with responses to information collections, the burden estimates already include the tasks related to the preparation of submissions. For example, the burden estimate for each Primary Manufacturer to submit negotiation data elements for drugs selected for negotiation includes 200 hours for business operation specialists to gather cost data and compile required information, 600 hours for economists to perform economic analyses, 50 hours for a financial manager to review the analysis results and cost estimates, 4 hours for a lawyer to review the data submission, 142 hours for a cost estimator to compile and report the data to CMS and 4 hours for a chief executive to review the data submission and certify the submission.

Comment: A commenter stated that CMS' interpretation that CMS can only consider section 1194(e)(1) factors submitted by manufacturers is incorrect. The commenter stated that the phrase could instead be providing clarification that CMS is able to require manufacturers to submit data on the 1194(e)(1) factors but not necessarily requiring CMS to exclude publicly available information. Similarly, a couple of commenters stated that CMS should not require manufacturer submission of data that is otherwise accessible to the Agency. A commenter

requested CMS extend the timeframe for manufacturers to submit required data. A few commenters asked that CMS decrease the burden imposed by the data collection requirement at § 429.505(b)(1), and among these commenters, a few suggested options to streamline the collection of information on section 1194(e)(1) factors. A commenter stated that aligning manufacturer requirements more closely with section 1194(e)(1) of the Act would minimize manufacturer burden and, as such, stated that CMS should not expand on the factors as provided in section 1194(e)(1) of the Act—for example by requesting information on anticipated loss of exclusivity, litigation updates, payer mix by indication, or other commercial data. A commenter suggested that CMS allow manufacturers to submit information that they believe is most relevant to the section 1194(e)(1) factors and provide a justification for the submission. A few commenters suggested that CMS should allow a single response from manufacturers to attest as to whether they have recouped research and development costs as required by section 1194(e)(1)(A) of the Act. A commenter suggested that CMS invest in the CMS HPMS submission portal to support standardized formatting and streamlined document upload, which could improve the accuracy and completeness of the information CMS relies upon during negotiation, and in any dispute or during the suggestion-of-error process.

Response: We appreciate these comments and acknowledge the burden on manufacturers as described in the Drug Price Negotiation ICR and the Drug Selection ICR. We endeavor to continue to refine these ICRs to minimize burden on Primary Manufacturers and the public. Consistent with our response to similar comments in the Negotiation Program Guidance, we respectfully disagree that we can obtain the information related to the factors listed at section 1194(e)(1) of the Act from sources other than the manufacturer of a selected drug. Section 1194(e)(1) of the Act specifically refers to the list of section 1194(e)(1) factors as, ''. . . the following data, with respect to such selected drug, as submitted by the manufacturer.'' We believe this indicates that the information for section 1194(e)(1) factors must come from the manufacturer of the selected drug. Additionally, consistent with our response to similar comments received in relation to the collection of section 1194(e)(1) data for initial price applicability years 2026 and 2027, we maintain that although some of the information may be available through other sources, we may not be able to ensure that such data are complete or up to date, and, ultimately, we believe that the Primary Manufacturer is best positioned to provide the requested data.

With regards to the comments on data collected on section 1194(e)(1) factors, including more closely aligning with section 1194(e)(1) of the Act and allowing manufacturers to determine what information is most relevant to submit, based on experience thus far, we determined that the information to be collected informs our consideration of the factors listed in section 1194(e)(1) of the Act and is needed to ensure a holistic evaluation of the selected drug. For example, payer mix is core to understanding a selected drug's market data in the United States consistent with section 1194(e)(1)(E) of the Act, which requires CMS to consider ''market data and revenue and sales volume data for the drug in the United States''. We believe this additional information is a low burden for manufacturers as this information is estimated in the ordinary course of business.

With regards to the comment on allowing an attestation for recoupment of research and development costs, at this time we believe that the full information sent and received is consistent with the statutory intent to collect ''research and development costs of the manufacturer for the drug'' as specified in section 1194(e)(1)(A) of the Act and supports a holistic evaluation of the selected drug. Based on experience to date, we do not believe that allowing solely an attestation in lieu of collecting this information would be sufficient.

With regards to the comment regarding the CMS HPMS submission portal, we continue to identify opportunities to apply lessons learned and to improve this process, including by considering respondent feedback and suggestions. We appreciate the suggestions brought forward by this commenter on potential submission options. However, in order to continue to meet statutory timing requirements, we will not adopt these suggestions at this time. We remind interested parties that we provide technical assistance throughout the ICR submission process if a Primary Manufacturer has questions about the CMS HPMS.

Comment: A few commenters expressed concern with CMS' data collection and notification processes for the Temporary Floor for Small Biotech Drugs. A commenter requested greater transparency around the deadlines for the application, notice of determination, and calculation as it relates to the Temporary Floor for Small Biotech Drugs. Some commenters suggested CMS determine eligibility for the Temporary Floor for Small Biotech Drugs using information CMS possesses.

Response: We thank commenters for raising these concerns. The Temporary Floor for Small Biotech Drugs ICR Form may be submitted to CMS no later than March 1, 2027 for initial price applicability year 2029. Primary Manufacturers that submit an application will receive a notice in writing, including eligibility and the calculation of the floor if applicable, alongside the calculation information provided as set forth in § 429.445(a). This ICR is required to accurately identify whether a given drug qualifies as a ''small biotech'' drug, consistent with section 1192(d)(2) of the Act, for purposes of determining if the drug is eligible for the Temporary Floor for Small Biotech Drugs, in accordance with section 1194(d) of the Act. CMS does not have information to determine whether manufacturers of drugs and biological products payable under Part B and/or covered under Part D were treated as a single employer with other entities under subsection (a) or (b) of section 52 of the IRC as of December 31, 2021. CMS also needs information to assess whether the Primary Manufacturer was the subject of an acquisition which would render the selected drug ineligible for the Temporary Floor for Small Biotech Drugs, per the limitation at section 1192(d)(2)(B)(ii) of the Act.

Comment: A commenter shared that the burden in completing the Drug Price Negotiation ICR is higher on individual patients and patient advocacy organizations than the burden estimates suggest. They note that the ICR instructions do not differ for manufacturers and non-manufacturers. However, the burden estimates are much higher for manufacturers. They recommend providing more time for patients and patient advocacy groups to respond, create a dedicated section of the ICR for patient advocacy organizations with questions that are more relevant and focused for that population, simplify the submission process for patients, clinicians, and organizations by accepting letters or create a direct-entry form, and publish a list of those who submitted comments.

Response: We thank this commenter for their feedback. The burden estimate is lower for non-manufacturers since they are not expected to provide responses to many of the burden-intensive questions, such as those requesting pricing and sales information

about selected drugs. Non-manufacturers are able to respond to such questions as not applicable.

Final Decision: After consideration of public comments, we are finalizing the collection of information requirements as proposed.

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.[109] 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 IV.A1 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 IV.A1: 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[110]	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[111]	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[112]	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

B. Information Collection Requirements (ICRs)—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)

1. 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).[110] [111] [112]

a. Biosimilar Delay

This ICR addresses information for CMS to determine the applicability of section 1192(f)(1)(B) of the Act (which is finalized at § 429.110 of this final 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 IV.A1 of this final rule, we expect, for a Biosimilar Manufacturer, a lawyer will take 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.

[109] 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.*

[110] 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.*

[111] 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.*

[112] 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.*

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 IV.B1).

TABLE IV.B1: 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

b. 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 finalized at § 429.605 of this final rule, and may be selected for renegotiation in accordance with section 1194(f)(3) of the Act, and as finalized at § 429.610 of this final 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 finalized at § 429.610(b) of this final 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 IV.A1 of this final rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists will take 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 IV.B2: 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 IV.B3: 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

2. 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).

a. 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 finalized at § 429.200(b)(5) of this final 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) of the Act, 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 IV.A.1of this final 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 IV.B4: 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

b. Negotiation Data Elements for Selected Drugs for Renegotiation From Primary Manufacturers

In accordance with section 1194(f)(4)(B) of the Act and as finalized at § 429.615(b) of this final 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 IV.A1 of this final 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 IV.B5: 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

c. 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 IV.A.1 of this final 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 IV.B6: 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

d. 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 finalized at § 429.445 (the ''Temporary Floor for Small Biotech Drugs'') of this final 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 IV.A1 of this final 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 IV.B7: 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

e. 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 IV.A1 of this final 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 x $355.30/hr)].

TABLE IV.B8: 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 IV.B9: 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 IV.C1 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 IV.C1: 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 rule finalizes and codifies, 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, reduce prescription drug costs for beneficiaries, or achieve cost savings provided under statute.

This rulemaking finalizes and codifies 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 finalized new policies for the Negotiation Program as follows: a policy for specific fixed combination drugs that are new formulations; clarification 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; 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. 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; 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.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant under section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule meets the criteria set forth in 5 U.S.C. 804(2).

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 final 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 MFP. 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 V.C1.

TABLE V.C1: CUMULATIVE NEGOTIATION DISCOUNT FROM ALLOWED COSTS

	2026	2027	2028	2029	2030	2031
Part B	0%	−1%	−5%	−6%	−9%	−12%
Part D	−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 V.C2.

TABLE V.C2: IRA PART D BENEFIT AND PREMIUM CHANGES

	2023	2024	2025–2029	2030
Benefits	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
Premium	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 MFPs; 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 MFPs 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 V.C3 using the 2024 President's Budget as a basis.

TABLE V.C3: 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

[1] 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.

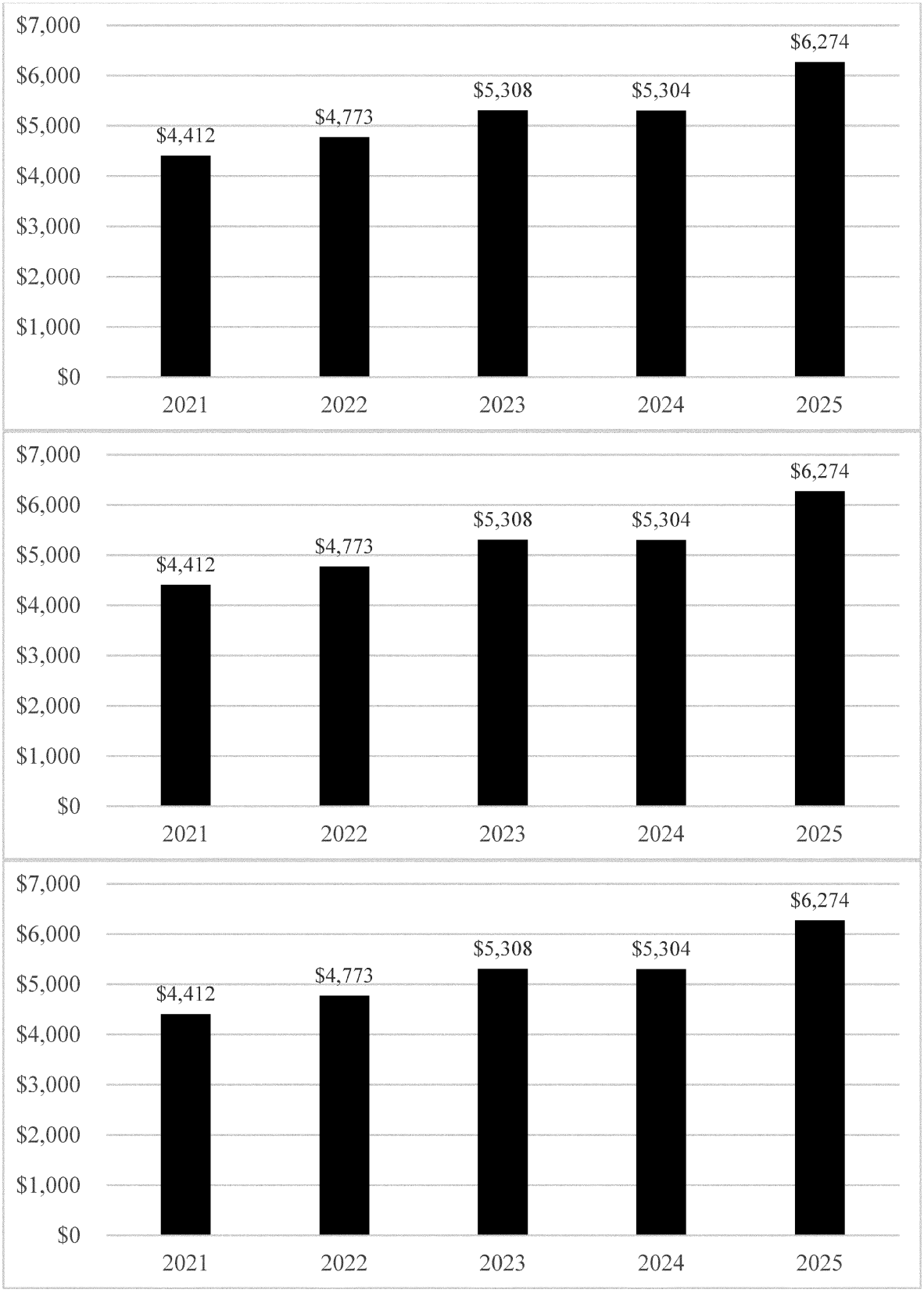
Note: Totals do not necessarily equal the sums of rounded components.

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 biological products 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 V.C1. 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.

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FIGURE V.C1: 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 V.C1, 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 V.C3. 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 Cut'' legislation (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 ''Working Families Tax Cut'' legislation 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 ''Working Families Tax Cut'' legislation 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 V.C4 shows the impacts to Medicare Part B and Part D benefits and premiums. These impacts are reflected in accounting Table V.E.

TABLE V.C4: PART B AND PART D WORKING FAMILIES TAX CUT LEGISLATION 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 finalized new policies for the Negotiation Program as follows: a policy for specific fixed combination drugs that are new formulations; clarification related to 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 finalized provisions, only the policy for specific fixed combination drugs that are new formulations 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 provision involves costs and savings that extend outside the budget window for this regulatory impact analysis. For purposes of this discussion, consider Product A, which contains the active ingredient X; and consider a later-developed Product B, which contains active ingredient X plus another active ingredient Y, and which meets the criteria finalized at § 429.125(b)(4)(ii). The final policy would aggregate Product A and Product B into the same potential qualifying single source drug and, if such potential qualifying single source drug were ultimately selected, result in Product A and Product B being part of the same selected drug. This would result in any agreed-upon MFP being applied earlier, with respect to the later-developed Product B, than under the current general fixed combination drug policy in which Product A and Product B would be treated as separate potential qualifying single source drugs. This may result in savings in the short term. This 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 an agreed-upon MFP applied earlier, but 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, thus resulting in potential lost savings in the long term. 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 Medicare Prescription Drug Inflation Rebate Program for drugs payable under Part B.[113] In addition, a policy for specific fixed combination drugs that are new formulations 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 qualifying single source 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, consider a biological product that has a new formulation that is a fixed combination drug containing hyaluronidase. Under the finalized policy, for drug selection with respect to initial price applicability year 2029, the formulations of that biological product both with and without hyaluronidase would be considered the same potential qualifying single source drug, and potentially selected drug, if the criteria in finalized § 429.125(b)(4)(ii) were met. In this case and with respect to this biological product if it were selected, the MFP, if one is agreed to by CMS and the Primary Manufacturer, would apply to all dosage forms and strengths of the selected drug, including the new formulation containing hyaluronidase, in initial price applicability year 2029 and each subsequent year 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, most likely, the earlier-formulated non-hyaluronidase product has been licensed and is subject to Bona Fide Marketing. Alternatively, if we had not finalized the proposal, the new formulation containing hyaluronidase would not be considered the same potential qualifying single source drug as the original biological product, and so 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-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 policy for specific fixed combination drugs that are new formulations 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 welcomed comments on methodologies to estimate these effects.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the Negotiation Program being described as saving money and protecting the drug development pipeline. They suggested potential uses for the savings generated by the Negotiation Program.

Response: CMS appreciates the support from the commenter. However, the comment regarding how savings from the Negotiation Program should be used are out of scope for this final rule.

Comment: A commenter stated that the analysis does not account for impacts from other changes to Part D spending, such as benefit redesign, the Manufacturer Drug Program, and general drug utilization trends. This commenter stated that this lack of separation of impacts from different changes to Part D spending causes the true fiscal impact of the Negotiation Program to be unclear and may lead to misinterpreted conclusions about the impact of the Negotiation Program.

Response: We thank this commenter for their input. CMS clarifies that these estimates are inclusive of the Inflation Reduction Act provisions for the Negotiation Program, Part D benefit redesign, the Medicare Prescription Drug Inflation Rebate Program, and related sections. They do not address the Negotiation Program in isolation,

[113] 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.)

because we do not have estimates using a pre-statute baseline that isolates the impacts of that program. Furthermore, we clarify that the impact on benefits and premiums and the impact in total are shown in Table V.C3 using the 2024 President's Budget as a basis and reflect net impacts to the programs.

Comment: A commenter noted that the regulatory impact analysis is based on gross expenditures so it does not account for rebates that are not realized due to the Negotiation Program. They stated that use of gross expenditures overstates the Negotiation Program's fiscal impact and suggest CMS either restate the analysis using net expenditures or clarify that realized savings would be smaller by the amount of rebates displaced.

Response: We thank this commenter for their feedback. As clarified in the preceding response, the impacts shown in Table V.C3 are net impacts to the program. We recognize that the required formulary inclusion for selected drugs is likely to significantly reduce rebates on selected drugs. The paragraph preceding Table V.C3 also mentions that manufacturer rebate losses are accounted for in the estimates.

Comment: A commenter noted that the regulatory impact analysis does not account for dynamics that shift drug development costs to other products in a manufacturer's portfolio through adjustment of list prices, adjustment of launch prices, and deprioritization of formulations of drugs that are likely to be selected for the Negotiation Program. The commenter concludes that these actions cause the Negotiation Program to not create as much savings to the overall health care system as the RIA suggests. Another commenter stated that funding for small-molecule innovation has fallen since the passage of the IRA and that nothing in the proposed rule's impact analysis suggested CMS has weighed the cost of this dynamic.

Response: We thank this commenter for their feedback. We do not anticipate significant changes to market list price measures such as the Average Wholesale Price as a result of the IRA, so the direct shifting to commercially insured patients is unlikely. It is possible that manufacturers could reduce their rebates in the commercially insured business, but we anticipate that insurers will maintain their formulary leverage in negotiations. Regarding the comment on funding for small-molecule innovation, CMS is not aware of evidence indicating that the change stated by the commenter is widespread throughout the market. Therefore, we do not think it is appropriate to include in this analysis.

Comment: A few commenters raised concerns that the proposed policy for specific fixed combination drugs that are new formulations could reduce savings under the Negotiation Program because, once a generic or biosimilar emerges for the original product, both the original formulation and the new formulation will be deselected from the Negotiation Program, even though the reformulated products themselves may not yet face generic or biosimilar competition. One of these commenters stated that manufacturers could exploit this dynamic by shifting utilization to the reformulated version, leaving consumers and Medicare to pay monopoly prices on a product to which the MFP no longer applies. To address this concern, the commenter recommended that CMS monitor prescribing and pricing patterns for reformulated products after deselection, use the material-change and renegotiation authorities in § 429.605(d) to bring reformulated products back into the program when warranted, and work with Congress so that a reformulation without genuine generic or biosimilar competition cannot evade the MFP. A commenter noted CMS' statement in the Regulatory Impact Analysis that the relevant costs and savings of the proposed policy for specific fixed combination drugs that are new formulations extend outside the budget window for the analysis. The commenter stated that CMS' inability to quantify the proposal does not establish that its effects are negligible but rather demonstrates that CMS lacks an adequate basis to conclude that the proposal will improve the Negotiation Program without producing material unintended consequences. A few commenters requested that CMS analyze changes in research programs, clinical development, and regulatory applications to attempt to quantify the foregone innovation and regulatory cost if the proposal is finalized.

Response: We appreciate the input and reiterate our statement in the proposed rule (91 FR 36333) that the proposed policy for specific fixed combination drugs that are new formulations involves costs and savings that extend outside the budget window for the rule's regulatory impact analysis. There, we acknowledged that 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. However, we also noted that 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.[114] While we are unable to produce a quantitative estimate of the financial impacts on the Negotiation Program, we do not treat this uncertainty as evidence that such costs are negligible. We disagree that our inability to quantify these effects means CMS lacks an adequate basis for this policy and have carefully considered the costs qualitatively. We weighed the statutory requirement to aggregate new formulations under sections 1192(d)(3)(B) and 1196(a)(2) of the Act, the program integrity risks of not doing so, and the narrow scope of drugs affected, against the acknowledged but unquantifiable potential foregone savings in the long term were a new formulation to have an agreed-upon MFP applied earlier but for a shorter period of time due to an approved generic drug or licensed biosimilar for a product included in the qualifying single source drug engaging in Bona Fide Marketing, as compared to potential foregone savings in the short term if it had been identified as a separate qualifying single source drug. We weighed the potential responses to this policy against the risk that, absent this policy, manufacturers could use the development of new formulations that enable an alternative route of administration to avoid or delay MFP applicability, an outcome that would undermine the statutory purpose of sections 1192(d)(3)(B) and 1196(a)(2) and create the program integrity risk the policy proposed at § 429.125(b)(4)(i) is designed to address. On balance, we believe the qualitative benefit of closing this gap and the potential short-term savings generated outweigh the uncertain and likely limited foregone long-term savings under the Negotiation Program given that the policy applies only to a narrow set of new formulations meeting specific criteria proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii).

Regarding the recommendation that CMS monitor prescribing and pricing patterns for reformulated products following deselection, we intend to monitor utilization and pricing trends for such products as part of our ongoing

[114] 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.)

program oversight. Regarding the recommendation that CMS work with Congress to address reformulations that lack genuine generic or biosimilar competition, we appreciate the suggestion. However, statutory changes are outside the scope of this final rule. Regarding the request that CMS use the material-change and renegotiation authorities in § 429.605(d) to bring reformulated products back into the Negotiation Program when warranted, we understand this comment as a request that CMS use our renegotiation authorities under section 1194(f) of the Act to select for renegotiation a drug that has been deselected due to the approval or licensure and engagement in Bona Fide Marketing of a generic drug or biosimilar for a product included in the selected drug. We decline this request because section 1194(f)(2) of the Act limits renegotiation-eligible drugs to selected drugs.

Final Decision: After consideration of public comments, we are finalizing our regulatory impact analysis as proposed.

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 have further narrowed the scope of the policy for specific fixed combination drugs that are new formulations proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii) to biological products only. As compared to the policy proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii), this alternative may not meaningfully impact which products would be aggregated under a qualifying single source drug.

The second alternative we considered was an articulation of the policy as aggregating drugs for which one of the active moieties, active ingredients, or antigen components 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 believe the policy proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii), provides a clearer and more administrable standard for CMS and manufacturers to apply consistently, which is why we did not pursue this alternative.

The third alternative we considered would have maintained 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, or antigen components, we would treat the distinct combination of active moieties, active ingredients, or antigen components as one active moiety, active ingredient, or antigen component. We did not adopt this alternative because we believe our proposed policy better applies, in a predictable and administrable way, our interpretation of the directives in sections 1192(d)(3)(B) and 1196(a)(2) of the Act, which require the aggregation of data across dosage forms and strengths of the drug, including new formulations of the drug, and not based on the specific formulation or package size or package type of such drug. As compared to the policy proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii), 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, which would otherwise be aggregated with and subject to the MFP under the finalized policy at § 429.125(b)(4)(ii), could instead 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 the policy finalized at § 429.125(b)(4)(ii) is included in section II.B.6.a. of this final 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 V.E1 showing the classification of the impact associated with the provisions of this rule.

TABLE V.E1: ACCOUNTING STATEMENT ($millions)

Category	3% Discount Rate	7% Discount Rate	Period Covered	Notes:
COSTS				
Annualized monetized costs			CY 2029	$8.38
TRANSFERS				
From Federal Government and Medicare Enrollees to pharmaceutical manufacturers	$9,976	$8,695	CYs 2028-2034	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 final 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.[115] 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 final 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 this final rule may directly impact one category of small entities, Primary Manufacturers. Given the uncertainty on negotiation outcomes and available data, CMS concludes that this final rule may have an economic impact on small entities. This analysis as well as other sections in this final rule, serves as the Final Regulatory Flexibility Analysis, as required by the RFA. 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. We have determined that this threshold will not be reached by the requirements in this final rule. The resources needed to produce and distribute a drug with expenditures that exceed the low-spend Medicare drug exclusion described in section II.B.6.c.2. of this final rule is expected to require a workforce larger than the small entity threshold; thus, we expect that no Primary Manufacturer would qualify as a small entity. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

1. Description and Number of Affected Small Entities

We use the NAICS to identify the industry potentially affected by this final rule. We also use the Small Business Administration (SBA) size standards in ''number of employees'' and ''millions of dollars'' to identify small entities.[116] The SBA considers any ''Pharmaceutical Preparation Manufacturing'' firm (NAICS code 325412) with fewer than 1,300 employees as a small business. 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 final 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 V.F1 demonstrates, none of the drugs that were selected for negotiation, as set forth in § 429.105 of this final rule, were manufactured by small entities during the first 3 years of the Negotiation Program.

TABLE V.F1: PERCENT OF SMALL ENTITY PRIMARY MANUFACTURERS WITH SELECTED DRUGS DURING INITIAL PRICE APPLICABILITY YEARS 2026 – 2028[117]

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.[117]

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 final rule. Despite this uncertainty, CMS certifies that the final rule will 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

[115] 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.*

[116] Small Business Administration. Table of Size Standards, Available at: *https://www.sba.gov/document/support-table-size-standards.*

[117] 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.

Negotiation Program are shown in Table V.F2. CMS requested comments on our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE V.F2: 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 excepted small biotech drugs now eligible for Negotiation Program	Small Biotech Exception no longer applies; previously excepted small biotech drugs now eligible for Negotiation Program

3. Alternatives To Minimize the Impact on Small Entities

The vast majority of the policies discussed in this final 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 final rule, CMS was 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with the expectation that no Primary Manufacturer would be considered to be a small entity because the resources needed to produce and distribute a drug with Medicare expenditures that meet the low-spend Medicare drug exclusion threshold would require a workforce larger than the small entity threshold of 1,300 employees. The commenter contended that there are small biotech drug manufacturers who could have fewer than 1,300 employees and over $200 million in Medicare expenditures.

Response: We thank the commenter for their feedback. The estimate in this analysis is based on the information currently available, which does not indicate a manufacturer of a drug selected for the Negotiation Program would meet the characteristics described by the commenter.

Final Decision: After consideration of public comments, we are finalizing our RFA analysis as proposed.

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 final rule will not have a significant impact on small rural hospitals because our analysis shows that this final rule may directly impact one category of entities, Primary Manufacturers, and small rural hospitals are not entities involved in the Negotiation Program. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 final rule is not anticipated to have an unfunded effect on State, local, or tribal governments, in the aggregate, or on the private sector of $193 million or more. The analysis of impacts on this final 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 final rule will 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 final rule. We requested comments, including on the potential magnitude of this impact. We did not receive public comments on this URMA conclusion, and therefore, we are finalizing as proposed.

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 final rule does not impose any substantial costs on State or local governments, preempt State law or have Federalism implications, the requirements of Executive Order 13132 are not applicable.

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.'' This rule may generate substantial Federal savings. A regulatory action that generates substantial Federal budget savings may be exempt from Executive Order 14192's requirements.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided a final Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 14, 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 amends 42 CFR chapter IV as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 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 read as follows:

§ 423.120 Requirements related to qualified prescription drug coverage.

* * * * *

(b) * * *

(2) * * *

(vii) Except as specified in paragraph (b)(2)(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

Sec.

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—[Reserved]

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 Social Security Act (''the Act''):

(i) 1191. Establishment of the Program.

(ii) 1192. Selection of Negotiation-Eligible Drugs as Selected Drugs.

(iii) 1193. Manufacturer Agreements.

(iv) 1194. Negotiation and Renegotiation Process.

(v) 1195. Publication of Maximum Fair Prices.

(vi) 1196. Administrative Duties and Compliance Monitoring.

(vii) 1197. Civil Monetary Penalties.

(viii) 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:

(i) 11001. Providing for Lower Prices for Certain High-Priced Single Source Drugs.

(ii) 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 of the Primary Manufacturer means an individual that has the authority or capacity to legally bind the Primary Manufacturer 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.

Authorized representative of a Biosimilar manufacturer means an individual that has the authority or capacity to legally bind the Biosimilar Manufacturer and meets one of the following criteria:

(1) Chief Executive Officer of the Biosimilar Manufacturer.

(2) Chief Financial Officer of the Biosimilar Manufacturer.

(3) An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Biosimilar 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 § 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 § 429.430.

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 other 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 described 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) 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 product 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 §§ 423.2716, 423.2720, and 423.2724 of this chapter.

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 purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS will 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.

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 § 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 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.

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.

There is no administrative or judicial review of any of the following:

(a) The determination of a unit, with respect to a drug or biological product, under section 1191(c)(6) of the Act.

(b) 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.

(c) The determination of a maximum fair price under subsection (b) or (f) of section 1194 of the Act.

(d) 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) *Publication of the selected drug list.* 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.* 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) *Applicable terms.* 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 and is not contingent on the outcome of pending litigation.

(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) and (B) 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 (f)(1) through (3) of this section, 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 this paragraph (f) 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.

(ii) [Reserved]

(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.

(ii) [Reserved]

(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)(i)), 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 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) *Tie-breaker methodology.* 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 (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) *Drug products.* 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) *Biological products.* Subject to paragraphs (b)(3) and (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) *Vaccines for infectious disease(s).* 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*—(i) *General.* Subject to paragraph (b)(4)(ii) of this section, for purposes of the identification of potential qualifying single source drugs under paragraphs (b)(1) and (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.

(ii) *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 paragraph (b)(4)(i) of this section, 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 paragraph (b)(4)(i) of this section, the distinct combination of active moieties). For potential qualifying single source drugs identified under paragraph (b)(4)(ii) of this section, CMS uses the date of approval of the FDA application belonging to the NDA holder and containing the shared active moiety(ies) identified at paragraph (b)(4)(ii) of this section 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 (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 paragraph (b)(4)(i) of this section, 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 paragraph (b)(4)(i) of this section, the distinct combination of active ingredients). Subject to the exceptions set forth in paragraphs (c)(2)(i) and (ii) of this section, for a potential qualifying single source drug identified under paragraph (b)(4)(ii) of this section, CMS uses the date of licensure of the FDA application belonging to the BLA holder and containing the shared active ingredient(s) identified at paragraph (b)(4)(ii) of this section, 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 this paragraph (c)(2).

(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 this paragraph (c)(2). 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 this paragraph (c)(2).

(3) *Certain former orphan drugs.* Notwithstanding paragraphs (c)(1) and (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 (2) of this section, CMS measures the 7- and 11-year periods described in paragraphs (c)(1) and (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 paragraph (b) of this section, 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 most recent 12 months of PDE data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section;

(ii) The most recent 12 months of AMP data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section;

(iii) The most recent 4 quarters of ASP data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section; and

(iv) For data sources other than those sources listed in paragraphs (a)(1)(i) through (iii) of this section, including, but not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available data sources, CMS may evaluate the most recent 12 months, 4 quarters, or 52 weeks of any such data source, if available and as applicable to such data source, at the time CMS reviews such data consistent with paragraph (c) of this section.

(2) Information related to additional factors, available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section, 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, including sales and utilization data for the generic drug or biosimilar not otherwise captured by paragraphs (a)(1)(i) through (iv) of this section.

(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.* CMS reviews the information set forth in paragraph (a) of this section 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 or until the negotiation process ceases to apply.* 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 the earlier of either:

(i) 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

(ii) the date as of which CMS determines that a selected drug meets the requirements at § 429.135(b)(1) to cease being subject to the negotiation process.

(5) *Drugs selected for renegotiation until renegotiation ends or until the renegotiation process ceases to apply.* 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 the earlier of either:

(i) November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for renegotiation; or

(ii) The date as of which CMS determines that a selected drug meets the requirements at § 429.135(b)(2) to cease being subject to the renegotiation process.

(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 renegotiation 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 paragraph (a) of this section 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 paragraph (a) of this section 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) *Timing of determination for renegotiation eligibility.* A drug previously selected for negotiation is not eligible for renegotiation if CMS has made a determination described in paragraph (a) of this section, 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, as defined in § 429.20, 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—

(i) A request for termination of the Primary Manufacturer's applicable program agreements; and

(ii) An attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer must not seek—

(A) To enter any subsequent applicable program agreement; or

(B) 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) of this section, CMS—

(i) Confirms receipt of the Primary Manufacturer's notice; and

(ii) Executes the actions with respect to termination of the Primary Manufacturer's applicable program agreements as described in paragraphs (b)(3) through (5) of this section, if applicable.

(3) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1) of this section, 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 (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 paragraph (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 (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 paragraph (b)(1)(ii) of this section, 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 of this part, 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 this paragraph (c).

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 deems 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).

(2) [Reserved]

(c) *Primary Manufacturer data.* The following data when submitted by the Primary Manufacturer as set forth at §§ 429.405, 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)(3) (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.

(2) [Reserved]

(b) [Reserved]

§ 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 (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 (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*) of this chapter.

(2) *30-day equivalent supply for a selected drug payable 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 this paragraph (a)(2)(ii), 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 § 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)(i) 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)(*1*) 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.

(*2*) 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 § 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 (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 paragraph (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 paragraph (b)(1) of this section.

(v) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (5).

(2) [Reserved]

(b) *Determination of the sum of the plan-specific enrollment weighted amounts.* Using the 30-day equivalent supply methodology set forth at § 423.104(d)(2)(iv)(A)(*2*) of this chapter, 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 § 423.100 of this chapter), 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—

(i) 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

(ii) Divides by the total units dispensed as 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)(i) 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 this 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.

(ii) For each NDC–11, CMS calculates the quotient of total quantity 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, for the year 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) *General.* 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 § 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 this paragraph (a) 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 this paragraph (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 this paragraph (a), 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 this paragraph (a), 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 this paragraph (a), 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 are 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 and 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 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 an NDC–11, as calculated in paragraph (a)(3)(i)(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) Multiplies the total Part B billing units from Part B data for that NDC–11, as calculated in paragraph (a)(3)(i)(C) of this section, by the billing unit to NCPDP conversion ratio (calculated by dividing the product of the standard package size and package quantity for an NDC–11 by the number of billing units per NDC–11 reporting unit for the NDC–11) to determine the PDE equivalent of the total Part units for that NDC–11.

(E) Notwithstanding paragraphs (a)(3)(i)(A) through (D) 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.

(ii) [Reserved]

(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 payment amount under section 1847A(b)(4) of the Act for each HCPCS code, set forth in paragraph (a)(2) of this section, and assigns it to each NDC–11 within that HCPCS code.

(B) [Reserved]

(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 § 429.415(a)(2).

(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)(vi) 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) *Sequestration.* CMS does not apply the sequestration payment adjustment (as defined in § 429.20) 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 (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 § 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 § 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 § 429.425.

(C)(*1*) 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.

(*2*) 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)(i) through (v), 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)(A) 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.

(B) 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 and 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–11s 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 (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 § 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 this paragraph (a)(1) that meet all of 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.

(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 this paragraph (a)(1).

(E) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (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 this paragraph (a)(1).

(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 § 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 this paragraph (a)(2) 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 this paragraph (a)(2); 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 this paragraph (a)(2).

(E) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (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 this paragraph (a)(2) 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 (2) of this section, CMS calculates the applicable percent of the average non-FAMP as follows:

(i) For each NDC–11 of the selected drug as a 30-day equivalent supply (in accordance with the methodology described in § 429.415).

(ii) Across the NDC–11s of the selected drug as a 30-day equivalent supply.

(4) *Average non-FAMP across NDC–11s of the selected drug.* 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 (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.

(B) [Reserved]

(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.

(B) [Reserved]

(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 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)(iii) 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 this paragraph (a)(4)(iv), 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.

(B) [Reserved]

(v) For each NDC–11, after CMS calculates the average non-FAMP per unit for the calendar year (as calculated in paragraph (a)(4)(iii) of this section for the calendar year as set forth in paragraph (a)(2) of this section and as calculated in paragraph (a)(4)(iv) 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.

(B) [Reserved]

(vi) 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)(iv) of this section, and with the applicable percent applied as determined in paragraph (a)(4)(v) of this section by the quotient of total units divided by the total 30-day equivalent supply.

(vii) For each NDC–11, CMS then 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 and multiplies

this quotient by the amount calculated in paragraph (a)(4)(vi) of this section.

(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)(iv) of this section, and with the applicable percent applied as specified in paragraph (a)(4)(v) 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 had—

(i) 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

(ii) 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, 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, calculated using the methodology set forth in § 429.435.

(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, calculated using the methodology set forth in § 429.435.

(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 paragraph (b)(4)(i), (ii), or (iii) of this section, as applicable, and calculates such adjusted ceiling amount as follows:

(i) CMS excludes the average non-FAMP in 2021 identified under section 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(b) or § 429.620(b), such resulting ceiling amount applies as the ceiling.

(ii) If the resulting ceiling amount determined under paragraph (b)(4)(i) of this section is lower than the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410(b) or § 429.620(b), CMS excludes 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 §§ 429.410(b)(2)(ii) and 429.435(a)(2), identified under section 1194(c)(1)(C)(ii)(II) 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(b) or § 429.620(b), such resulting ceiling amount applies as the ceiling.

(iii) If the resulting ceiling amount determined under paragraph (b)(4)(ii) of this section is below the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410(b) 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 (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 (4).

(b) *Timing.* (1) CMS intends to provide the information specified in paragraphs (a)(1), (2), and (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 § 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 paragraph (a)(1), (2), or (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) *General.* 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 paragraph (b)(2) of this section and evidence about the selected drug and therapeutic alternatives specified in paragraph (d)(3) of this section, 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) *Primary Manufacturer requirement to timely report updates.* 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 in this paragraph (e), 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 in this 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.

(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 all of the following:—

(i) Off-label use(s) for potential therapeutic alternatives as defined in § 429.20.

(ii) Prescribing information as approved by the FDA.

(iii) 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.

(iv) Potential therapeutic alternatives in a different pharmacologic class than the selected drug.

(v) 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 the following:

(A) The Net Part D Plan Payment and Beneficiary Liability of the therapeutic alternative.

(B) The MFP of the therapeutic alternative, if applicable.

(C) The WAC of the therapeutic alternative.

(ii) For a therapeutic alternative payable under Part B, the price is the lower of the following:

(A) The ASP of the therapeutic alternative.

(B) The MFP of the therapeutic alternative, if applicable.

(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 (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 (ii) of this section using the methodology described in paragraphs (d)(2)(i) and (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 the following:

(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).

(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 all of the following:

(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.

(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 both of the following:

(A) A CMS-led literature review.

(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 both of the following:

(A) The costs of the selected drug and its therapeutic alternative(s).

(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 all of the following:

(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.

(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)(i) The price resulting from paragraphs (f)(1) and (2) of this section is the initial offer.

(ii) Notwithstanding this paragraph (f)(3), 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 section, 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 this paragraph (a)(1), 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; and

(B) Materials, including pages, slides, charts, and graphs, to facilitate discussion, which must comply with limits on the amount or format of such materials as specified by CMS; and

(ii) CMS may request that the Primary Manufacturer provide copies of any presented or discussed materials before 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).

(2) [Reserved]

(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 this subpart; and

(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 do all of the following:

(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.

(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).

(b) [Reserved]

§ 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) *General.* 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 § 429.135) until termination of the Negotiation Program Agreement in accordance with § 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 § 429.700, and notwithstanding § 429.700(b)(1) and (b)(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) of the Act, 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.* 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 considered disease or 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(a), if any.

(A) If a Primary Manufacturer voluntarily submits information through the process described in § 429.615(a), then CMS may consider off-label use when determining if a new indication has been added for renegotiation eligibility.

(B) [Reserved]

(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(a).

(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 §§ 429.505(b)(2) and (d)(3) and 429.510(e) and (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 (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.

(B) [Reserved]

(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 the factors listed at section 1194(e) of the Act or any other information to support CMS' determination.

(ii) [Reserved]

§ 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), information as specified in paragraphs (b)(1) and (3) of this section must be submitted to CMS, 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) 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 paragraph (b)(1)(ii)(A) 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; and

(ii) Calculates the average non-FAMP amount(s) used in the calculation set forth in paragraph (b)(2) of this section 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)(v)(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.

(2) [Reserved]

(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*) of this chapter 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)(i), 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) *WAC ratio.* 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 (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 (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 labeling and other sources associated with the new NDC as described at paragraph (c)(1) or (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 (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 in this paragraph (c)(4)(i)(B), 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.

(ii) [Reserved]

(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 § 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 paragraph (a) of this section, 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 paragraph (a) of this section 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 paragraph (a) of this section.

(c) *Accrual of civil monetary penalty.* The civil monetary penalty accrues for each day of such violation as set forth in paragraph (a) of this section, 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 paragraph (c) of this section.

§ 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 paragraph (a) of this section.

(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 paragraph (a) of this section 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, 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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