CENTER FOR MEDICARE

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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DATE: September 30, 2025*

TO: Interested Parties

FROM: Chris Klomp, CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: 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

This memorandum provides interested parties with the final Medicare Drug Price Negotiation Program (the "Negotiation Program") guidance for initial price applicability year 2028 and manufacturer effectuation of the maximum fair price (MFP) in 2026, 2027, and 2028. It includes four sections:

A. An introduction.
B. A summary of changes and clarifications to the draft guidance released on May 12, 2025.
C. A summary of the public comments received in response to the draft guidance and the Centers for Medicare & Medicaid Services' (CMS') responses.
D. Final guidance that establishes policies on the topics discussed for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027 and 2028, and a table of contents.

CMS may supplement this guidance with further program instruction to explain how these policies will be implemented for initial price applicability year 2028 and during 2026, 2027, and 2028.

A. Introduction

Sections 11001(c) and 11002(c) of the Inflation Reduction Act of 2022 (IRA) direct the Secretary of the Department of Health and Human Services (hereinafter "the Secretary") to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, on May 12, 2025, CMS issued draft guidance for implementation of the Negotiation Program for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. CMS also voluntarily solicited

* Updated December 16, 2025 to correct a numerical error in footnote 93 on p. 172.

comments on the draft guidance.[1] The 45-day comment period for the draft guidance began May 12, 2025 and concluded June 26, 2025. CMS received 122 timely comment letters in response to the draft guidance, representing a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), trade associations, and wholesalers.

CMS is making public copies of the timely comment letters that CMS received on the CMS IRA website at https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/guidance-and-policy-documents at the same time CMS publishes this final guidance. Comment letters from individuals not representing organizations have the name, address, and contact information of the individual removed for privacy purposes.

After consideration of the comments received, and recently enacted provisions in the "Working Families Tax Cuts Act" (P. L. 119-21), CMS is making certain changes to the policies described in the draft guidance in this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028.[2] When required by law, CMS will develop its policies for 2029 and all subsequent years of the Negotiation Program through notice-and-comment rulemaking. The public will have an additional opportunity to submit comments as part of that rulemaking process, and comments submitted in response to the draft guidance for initial price applicability year 2028 may be considered as part of that rulemaking process.

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[1] The Internal Revenue Service (IRS) is responsible for administering and enforcing the excise tax, not CMS. CMS understands the Department of the Treasury has established regulations that govern the administration of the excise tax (see Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507, available at https://www.federalregister.gov/documents/2024/07/05/2024-14706/excise-tax-on-designated-drugs-procedural-requirements; see also, Notice 2023-52, Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax, available at https://www.irs.gov/pub/irs-drop/n-23-52.pdf. Revenue Procedure 2025-9, available at https://www.irs.gov/pub/irs-drop/rp-25-09.pdf. Excise Tax on Designated Drugs; Notice of Proposed Rulemaking, 90 Fed. Reg. 31, available at https://www.federalregister.gov/documents/2025/01/02/2024-31462/excise-tax-on-designated-drugs.).

[2] For purposes of this document, CMS refers to the "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" as initial guidance for initial price applicability year 2026, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026" as revised guidance for initial price applicability year 2026, "Medicare Drug Price Negotiation Program: Draft 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 (MFP) in 2026 and 2027" as draft guidance for initial price applicability year 2027, "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 (MFP) in 2026 and 2027" as final guidance for initial price applicability year 2027, "Medicare Drug Price Negotiation Program: Draft 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" as draft guidance for initial price applicability year 2028, and "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" as final guidance for initial price applicability year 2028.

CMS is providing a summary of significant comments that it received in response to the draft guidance for initial price applicability year 2028, as well as the agency's responses to those significant comments. Some of the public comments received were outside the scope of draft guidance for initial price applicability year 2028. Such out-of-scope comments are summarized in section C but are not addressed in this final guidance.

B. Summary of Changes and Clarifications in Final Medicare Drug Price Negotiation Program Guidance[3]

CMS appreciates the comments received from interested parties on the draft guidance for initial price applicability year 2028 that was released on May 12, 2025. This section provides a summary of the key changes and clarifications made to the draft guidance based on these comments and other feedback. CMS provides responses to the significant comments received in section C of this final guidance and has made corresponding changes and clarifications to the policies described in the draft guidance for initial price applicability year 2028, as summarized below.

Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2028:

- Use of Medicare Advantage (MA) Data: In section 30 and throughout this final guidance, CMS included the use of MA encounter data for Part B items and services in policies regarding Part B claims. Examples include the calculation of Total Expenditures under Part B (section 30 of this final guidance) and the determination of the 30-day equivalent supply for a selected drug (section 60.2.1.1 of this final guidance).
- Fixed Combination Drugs: CMS is not making a change to the fixed combination drug policy outlined in section 30.1 of this final guidance. However, CMS describes its intent to address this program integrity risk and that it is continuing to consider the appropriate policy to implement in rulemaking beginning initial price applicability year 2029.
- Treatment of Vaccines for Infectious Disease(s): CMS revised section 30.1 of this final guidance to clarify that, for vaccines for infectious disease(s), it will identify a potential qualifying single source drug as all dosage forms and strengths of the vaccine with the same antigen component(s) and the same holder of the Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs. CMS specified that for each unique potential qualifying single source drug that CMS identifies based on its antigen component(s), CMS will use the earliest date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of determining the time eligibility.
- Bona Fide Marketing Utilization Data Sources: CMS revised section 30.1 of this final guidance to include review of average sales price (ASP) data for utilization as a component of CMS' determination of bona fide marketing.
- Orphan Drug Exclusion: CMS revised sections 30.1 and 30.1.1 of this final guidance in accordance with amendments to the Orphan Drug Exclusion enacted in the Working Families Tax Cuts Act.

[3] CMS notes that sections 50, 80, 100, 110, and 120, are not included in the Summary of Changes because CMS did not make significant clarifying edits or changes to these sections.

- Identification of Negotiation-Eligible Drugs: CMS revised section 30.2 of this final guidance to describe use of MA expenditures in the calculation of Total Expenditures under Part B.
- Request for a Biosimilar Delay—High Likelihood Determination: CMS revised section 30.3.1.3 of this final guidance to revise the requirements to demonstrate that patents related to the negotiation-eligible drug that includes the reference product for the biosimilar biological product (the "Biosimilar") are unlikely to prevent the Biosimilar from being marketed before the date specified under the statute, and to include examples of "clear and convincing" evidence of a high likelihood of marketing of the Biosimilar by the required deadline.

Section 40 – Requirements for Manufacturers of Selected Drugs:

- Clarification on a Primary Manufacturer's Decision Not to Enter an Agreement: In section 40.1, CMS clarified the process when a Primary Manufacturer elects to terminate participation in the Manufacturer Discount Program and the Medicaid Drug Rebate Program rather than execute a Negotiation Program Agreement.
- Added Drug Data Processing System (DDPS) Edits Related to MFP Eligibility Not Resolved Within 90 Days: CMS clarified in section 40.4.2.1 of this final guidance the potential notification from Primary Manufacturers to dispensing entities regarding claims with DDPS edits related to MFP-eligibility when such edits are not resolved within 90 days of rejection.
- Justification Code Added to Table 5: In section 40.4.3.1 of this final guidance, CMS added a Justification Code to Table 5 to address scenarios described in section 1193(d)(2) of the Social Security Act ("the Act"). Primary Manufacturers should use this code when transmitting the claim-level payment elements if a claim is determined to be 340B eligible, and the MFP for that claim is lower than the 340B price of the drug.
- Claim Adjustments for Primary Manufacturers Utilizing the Medicare Transaction Facilitator Payment Module (MTF PM): In section 40.4.3.2 of this final guidance, CMS provided additional information for how Primary Manufacturers should respond to adjustments to original claims.
- Transmission of MFP Refund Payments if a Dispensing Entity is Not Enrolled in the MTF Data Module (MTF DM): CMS added language to section 40.4.3.3 of this final guidance that outlines a process for which Primary Manufacturers that have elected to make payments through the MTF PM may elect to pass through MFP refund payments to dispensing entities that are not enrolled in the MTF DM.
- Claim-Level Payment Elements for MFP Refund Payments Made Outside of the MTF PM: CMS revised the claim-level payment elements for MFP refund payments made outside of the MTF PM in Table 6 in section 40.4.4.2 of this final guidance. These changes include separating MFP refund transmission date and time into separate elements and adding another MFP refund amount element to report the amount calculated as the MFP refund.
- Data Elements that Alone Will Not Constitute Sufficient Evidence that a Claim was 340B-Eligible: CMS made a clarifying edit in sections 40.4.5 and 90.2 of this final guidance to align the language describing certain information that alone generally will not constitute sufficient evidence that a claim was 340B-eligible with the claim-level data elements detailed in Table 2 of section 40.4.2.1 of this final guidance.

- Clarification on Termination Procedures for 2026, 2027, and 2028: CMS clarified that if CMS determines a Primary Manufacturer's notice to terminate the Medicare Drug Price Negotiation Program Agreement complies with the requirements in section 40.6 of this final guidance, the Primary Manufacturer's request will constitute good cause for CMS to terminate the Primary Manufacturer's applicable agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and section VII(b) of the Medicaid National Drug Rebate Agreement (NDRA).

Section 60 – Negotiation Process:

- Determination of the 30-Day Equivalent Supply for a Selected Drug: In section 60.2.1.1 of this final guidance, CMS revised the language to state that for each Part B claim, the number of 30-day equivalent supplies will be equal to the "days between service" divided by 30.
- Addition of Wholesale Acquisition Cost (WAC) as a Potential Starting Point: In section 60.3.2 of this final guidance, CMS added WAC for a therapeutic alternative covered under Part D and/or payable under Part B as a possible option for determining the starting point for development of the initial offer.
- Analysis of Selected Drugs with Therapeutic Alternatives: In sections 60.3.3.1 and 60.3.3.2 of this final guidance, CMS clarified that the analyses described are conducted specifically on indications for the therapeutic alternative(s) of a selected drug.
- Collection of ASP Data to Inform Consideration of the Factor Listed at Section 1194(e)(1)(E) of the Act: CMS added a data collection requirement to section 60.3.4 of this final guidance for Primary Manufacturers to submit updated ASP data for the last two sales quarters in calendar year 2025 to ensure that CMS has the most recent ASP to inform the consideration of the factor at section 1194(e)(1)(E) of the Act.
- Negotiation Meetings: In section 60.4.4 of this final guidance, CMS revised the timing of the negotiation meeting period and the procedures for the meetings, including the meeting materials and agenda, for initial price applicability year 2028.
- Additional Price Exchange Opportunities: In section 60.4.5 of this final guidance, CMS revised the deadline by which CMS and Primary Manufacturers may exchange additional written offers and counteroffers for the MFP within the CMS Health Plan Management System ("the CMS HPMS") during the negotiation process for initial price applicability year 2028.
- Issuance of the Final Offer: In section 60.4.6 of this final guidance, CMS revised the deadline by which CMS will provide the final offer to Primary Manufacturers for initial price applicability year 2028.
- Removal of NDC-11 Package Price from the MFP File: In section 60.5 of this final guidance, CMS explained why the NDC-11 package price will be removed from the MFP file. CMS did not receive comments on removal of the NDC-11 package price from the public pricing file.
- Application of the MFP to New National Drug Codes (NDCs), New Drug Applications (NDAs) / BLAs, and to NDCs with Insufficient Prescription Drug Event (PDE), Fee-for-Service (FFS) Part B Claims, and MA Encounter Data for Items and Services, or WAC Data in Calendar Year 2025: In section 60.5.1, CMS clarified the application of MFP for new NDCs of selected drugs.

Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect:

- Removal from the Selected Drug List Before or During Renegotiation, or After a Renegotiated MFP is in Effect: CMS made revisions to clarify the application of section 70 of this final guidance to drugs that may be eligible for selection for renegotiation for initial price applicability year 2028, and drugs that are selected for renegotiation for initial price applicability year 2028 as discussed in section 130 of this final guidance. Additionally, CMS made parallel edits from section 30 to include CMS' review of ASP for utilization as a component of CMS' determination of bona fide marketing.

Section 90 – Manufacturer Compliance and Oversight:

- Monitoring of Access to the MFP in 2026, 2027, and 2028: In section 90.2 of this final guidance, CMS provided further detail on the process CMS will use when determining whether the MFP had been made available by Primary Manufacturers to specific dispensing entities.
- Centralized Intake System for Complaints and Disputes: In section 90.2.2 of this final guidance, CMS provided additional information on the initial threshold review, triage, and outreach that CMS will complete when an issue is received via the centralized intake system for complaints and disputes. CMS also clarified that the initiation of a dispute does not affect the Primary Manufacturer's obligation to make MFP available and transmit the claim-level payment elements within the 14-day prompt MFP payment window.

Section 130 – Renegotiation of a Maximum Fair Price for Initial Price Applicability Year 2028:

- Renegotiation Eligibility for Previously Negotiated Drugs with Part B Utilization: CMS clarified in section 130.1 of this final guidance that Part B utilization may result in a selected drug with an agreed-upon MFP becoming eligible for renegotiation and ultimately selected for renegotiation if such utilization results in the selected drug meeting the criteria described in section 130.1 and 130.2 of this final guidance and pursuant to sections 1194(f)(2) and (f)(3) of the Act, respectively.
- Sources of Information Used to Determine a New Indication: In section 130.1.2 of this final guidance, CMS clarified that CMS may use information from both public and CMS-specific sources to determine whether a new indication has been added to the selected drug.
- Timing Consideration of New Indications for Renegotiation Eligibility: In section 130.1.3 of this final guidance, CMS added that new indications that emerge on or before the submission date of the "Negotiation Program Drug Selection Information Collection Request for Initial Price Applicability Year 2028" (CMS-10844, OMB 0938-1443) (hereinafter the "Drug Selection ICR") will be considered when reviewing a selected drug for renegotiation eligibility for initial price applicability year 2028.
- Criteria for Determining Material Change: In section 130.1.4 of this final guidance, CMS clarified that CMS will consider a change(s) to a section 1194(e) factor for a selected drug to be material if the change(s) would reasonably be expected to meaningfully alter CMS' consideration of that factor within the context of renegotiation offers and counteroffers, including the initial offer, as compared with its consideration of offers,

including the initial offer and, if applicable, counteroffers, during the most recent prior negotiation process rather than considering a material change solely in the context of a section 1194(e)(1) or section 1194(e)(2) adjustment to the initial offer.

- Sources of Information Used to Determine Material Change: In section 130.1.4 of this final guidance, CMS indicated that evidence related to a material change(s) that emerges on or before the submission date of the Drug Selection ICR will be considered when reviewing a selected drug for renegotiation eligibility for initial price applicability year 2028.
- Timing for Consideration of Material Change for Renegotiation Eligibility: In section 130.1.4 of this final guidance, CMS revised guidance to reflect that CMS may use information from both public and CMS-specific sources to determine whether there has been a material change(s) to a section 1194(e) factor of a selected drug.
- Publication of List of Drugs Selected for Renegotiation: CMS clarified in section 130.2 of this final guidance that CMS will publish the list of drugs selected for renegotiation, if any, not later than February 1, 2026 in accordance with section 30.4 of this final guidance.

Appendix A – Definitions for Purposes of Collecting Manufacturer-Specific Data:

- Definitions Related to Research & Development (R&D) Costs: CMS revised the definitions related to R&D costs to remove duplication in the descriptions across the defined terms of direct basic pre-clinical costs, post-Investigational New Drug Application (IND) costs, other allowable costs, and costs of failed and abandoned products related to the selected drug to ensure the permissible costs are sufficiently clear and remove duplication in the descriptions that may cause unintended confusion. CMS also incorporated technical revisions in the definition of "post-IND costs" for consistency with revisions to definitions of R&D Costs and prior Federal financial support in the draft guidance for initial price applicability year 2028 that expanded the collection of R&D costs and prior Federal support to indications that have not been approved by the Food and Drug Administration (FDA) and removed instructions for the time periods of the data reported. CMS removed the word "indications" from the terms defined for consistency with the revisions CMS included for the definitions of these terms in the draft guidance, which expanded R&D costs to include costs for indications that have not been approved by the FDA.
- Definitions Related to Market Data and Revenue and Sales Volume Data: CMS added definitions for the terms of "ASP" and "ASP Unit". Use of this data is discussed in section 60.3.4 of this final guidance and CMS intends to include these in the 30-day revisions to the Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS-10844, OMB 0938-1452)[4] (hereinafter the "Drug Price Negotiation ICR").

Appendix B – List of DDPS Edits Directly Related to MFP Eligibility:

- DDPS Edits Directly Related to MFP Eligibility: CMS updated the list of DDPS edits that CMS identified as directly relating to the determination and verification of MFP

[4] CMS published the ICR for a 60-day comment period in the Federal Register that ended on August 29, 2025. CMS intends to publish a revised version of the ICR for a 30-day comment period in late Fall 2025.

eligibility for the purposes of the Negotiation Program, as referenced in section 40.4.2.1 of this final guidance.

C. Summary of Public Comments on the Draft Medicare Drug Price Negotiation Program Guidance and CMS' Responses

General Comments Related to the Implementation of the Negotiation Program

Comment: Many commenters expressed concern that the draft guidance and the Negotiation Program more broadly would increase uncertainty related to developing new treatments and undermine market dynamics. Some commenters expressed concern that the draft guidance lacked transparency; in particular, these commenters added that CMS is not following an Executive Order to improve transparency of the Negotiation Program and minimize impacts on innovation.[5] And several commenters further asserted that the draft guidance is inconsistent with statute and thus unlawful under *Loper Bright Enterprises et al. v. Raimondo*[6]—in particular, by maintaining the definition of a qualifying single source drug. One commenter recommended CMS reconsider the draft guidance for initial price applicability year 2028 and make sure to meaningfully respond to submitted comments received for that draft guidance. One commenter urged CMS to monitor the impacts of the Negotiation Program on innovation and drug development, and another commenter encouraged CMS to monitor such impacts on the development of personalized medicines for small patient subpopulations.

Response: CMS thanks these commenters for their feedback. The U.S. prescription drug market is the largest in the world—with a track record of fostering innovation. However, patients in the United States generally pay more for prescription drugs than anywhere else in the world.[7] CMS believes 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.[8, 9] CMS also expects 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 FDA for at least 7 years and only biologicals 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. Additionally, in accordance with the Working Families Tax Cuts Act and as described in section 30.1.1 of this final guidance, CMS is implementing amendments to the Orphan Drug Exclusion to expand the eligibility requirements for the Orphan Drug Exclusion and to measure the 7- and

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[5] "Lowering Drug Prices by Once Again Putting Americans First," April 15, 2025, https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first.

[6] See: https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf.

[7] 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.

[8] 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.

[9] *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.

11-year periods described above starting from when a drug or biological product does not or did not meet the criteria for the Orphan Drug Exclusion. With the changes made by the IRA, CMS believes 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. Finally, CMS believes the Negotiation Program will help improve drug affordability for people with Medicare therefore improving access to innovative, life-saving treatments for people who need them.

Additionally, CMS drafted the guidance and is implementing the Negotiation Program consistent with the statute. CMS appreciates the comments received from interested parties on the draft guidance for initial price applicability year 2028 released on May 12, 2025. CMS refers commenters to section B, "Summary of Changes and Clarifications in Final Medicare Drug Price Negotiation Program Guidance" for a summary of key changes and clarifications. CMS also read and responded to all significant comments received timely on the initial guidance for initial price applicability year 2026 and the draft guidance for initial price applicability year 2027 and MFP effectuation for 2026 and 2027. Similar to CMS' process in connection with the publication of the revised guidance for initial price applicability year 2026 and final guidance for initial price applicability year 2027 and MFP effectuation for 2026 and 2027,[10] CMS is making public copies of all timely comments received for the draft guidance on the CMS IRA website at https://www.cms.gov/priorities/medicare-prescription-drug-affordability/medicare-prescription-drug-affordability in conjunction with CMS' publication of this final guidance. Additionally, CMS notes that the agency has pursued implementation in accordance with the statutory requirements of the Negotiation Program. Finally, CMS refers commenters to section C, "Summary of Public Comments on the Draft Medicare Drug Price Negotiation Program Guidance and CMS' Responses," in this final guidance for initial price applicability year 2028 for a summary of comments and CMS' responses.

Comment: A couple of commenters recommended CMS generally minimize the impact the Negotiation Program may have on patient access to prescription drugs. Another commenter expressed concern about the inclusion of drugs payable under Part B into the Negotiation Program for initial price applicability year 2028 and the Negotiation Program's impact on patients and providers. This commenter recommended that CMS keep payment amounts at a level that incentivizes providers to stock and furnish drugs payable under Part B.

Response: CMS thanks these commenters for their input. CMS believes the Negotiation Program will help improve drug affordability for people with Medicare, improving access to innovative, life-saving treatments for people who need them. CMS agrees with the commenters about the importance of ensuring meaningful access to selected drugs. Finally, the commenter's recommendation about payment amount is outside the scope of this guidance. CMS reminds commenters that Primary Manufacturers are required to establish processes to ensure that Part B providers have access to the MFP for the selected drug in accordance with section 1193(a) of the Act.

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[10] See: https://www.cms.gov/files/zip/negotiation-guidance-published-comments.zip and https://www.cms.gov/files/document/public-comments-medicare-drug-price-negotiation-draft-guidance.pdf.

Comment: A commenter stated that 45 days is an insufficient amount of time to provide meaningful comments and engage substantively with CMS given the significant range of new complexities in incorporating drugs payable under Part B into the Negotiation Program. The commenter added that CMS should provide more meaningful opportunities to comment on issues specific to initial price applicability year 2028.

Response: CMS thanks this commenter for their concern and notes that the amount of time provided many interested parties sufficient time to submit thorough and extensive comments. CMS encourages interested parties to direct further feedback, queries, or meeting requests to the IRA mailbox (IRARebateandNegotiation@cms.hhs.gov). CMS intends to address MFP effectuation for Part B in the future, which will provide an additional opportunity for public input.

Comment: A couple of commenters provided input regarding updates in this final guidance and the impact on initial price applicability year 2026. One commenter urged CMS to clearly denote that any significant changes made between the draft and final versions of the guidance are not in effect for initial price applicability year 2026. Another commenter requested that CMS not make changes to manufacturer responsibilities providing access to the MFP for 2026 to ensure that compliance with these requirements is feasible.

Response: CMS thanks these commenters for their input. Policy changes in this final guidance are generally limited to initial price applicability year 2028, except for sections pertaining to manufacturer effectuation of the MFP in 2026, 2027, and 2028 and the formulary successor regulations that apply to 2027 and 2028. CMS has indicated in the applicable section titles and throughout the final guidance when policies apply to 2026, 2027, and 2028. For example, in section 90.2 of this final guidance, CMS describes the following with respect to MFP effectuation policies for 2026, 2027, and 2028: "The MFP effectuation policies established for 2026 and 2027 in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 are final policies that remain in effect for 2026 and 2027. In this final guidance, CMS makes updates and includes supplemental information regarding these policies for 2026 and 2027 and is extending these same policies to 2028 for drugs covered under Part D. For ease of reference, CMS is restating the MFP effectuation sections from the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 in this final guidance so that the changes and updates to those policies can more easily be read in context with the policies in the prior final guidance that CMS is modifying or supplementing. In this section, CMS adds clarifying language regarding the agency's process for determining whether MFP was made available and information that may be considered during case-specific monitoring and investigation activities."

Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2028 (Section 30.1)

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. Many commenters disagreed

with CMS' definition of a qualifying single source drug and asserted that CMS guidance 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. Many of these commenters claimed that the statute defines a qualifying single source drug in reference to a distinct NDA or BLA, and a few 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 Federal Food Drug and Cosmetic Act ("FD&C Act") or section 351(a) of Public Health Service Act ("PHS Act"). One commenter 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.[11]

Some other commenters expressed appreciation for CMS' consistent approach to the qualifying single source drug definition. These commenters believed that CMS' approach aligns with statute, and they supported the current definition. One of these commenters stated that the statute does not require CMS to adhere to the FDA's licensure categories when identifying qualifying single source drugs. A few commenters stated that this policy is critical in preventing manufacturers from gaming the drug selection process and finding inappropriate ways to exclude drug products from the Negotiation Program that might otherwise be eligible and underscored that it is consistent with section 1192(d)(3)(B) of the Act. These commenters specified that this policy will reduce incentives for "product hopping," wherein a manufacturer would obtain a new NDA or BLA based solely on modifications that are modest or minor—and which often do not result in increased efficacy or improved outcomes—in order to effectively reset the 7- or 11-year periods that must pass before a product is eligible as a qualifying single source drug.

Response: Consistent with CMS' response on pages 12 and 13 of the final guidance for initial price applicability year 2027, 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. 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 section 60 of this final guidance, 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

[11] Section 1927(c)(2)(C) of the Act defines a "line extension" as "with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation."

ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries as intended by the law. 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 source drug in reference to a distinct NDA or BLA is inconsistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act. Contrary to the views of some commenters, such section 1192(d)(3)(B) of the Act refers to the aggregation of data "across dosage forms and strengths of the drug, including new formulations of the drug," thereby necessarily establishing that the statutory negotiation procedures apply more broadly than to a distinct NDA or BLA. Unlike the views offered by some commenters, CMS' 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; CMS is 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.

CMS agrees with commenters that complying with the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths, as described in this final guidance, will decrease incentives for pharmaceutical manufacturers to engage in "product hopping." This statutory requirement ensures that products by the same sponsor with the same active moiety / active ingredient are subject to the same processes under the Negotiation Program, and that a manufacturer is therefore limited in its ability to inappropriately exclude from the Negotiation Program drug products that might otherwise be eligible based on modest or minor modifications. Reducing "product hopping" 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. For the above reasons, in this final guidance, CMS maintains the approach described in the draft guidance for initial price applicability year 2028 for identifying potential qualifying single source drugs.

Comment: A few commenters recommended that certain drugs be automatically excluded from the Negotiation Program. A couple of those commenters stated that CMS should immediately exclude, or as one commenter stated, make a "carve-out" exemption, for all medications used for the treatment of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) in the U.S. in order to prevent harm to both persons living with HIV/AIDS and the general population and not include HIV treatments in initial price applicability year 2028 or any future guidance for the Negotiation Program. The other commenter recommended that CMS should not consider Drugs Covered as Additional Preventive Services (DCAPS) to be qualifying single source drugs for which payment is made under Part B since DCAPS are not payable under Part B as drugs and instead are covered and paid for as additional preventive services.

Response: CMS thanks these commenters for their input. The statute does not specify an exclusion for medications used for the treatment of HIV/AIDS or DCAPS. On September 30, 2024, CMS established coverage under Medicare Part B of certain drugs as an additional

preventive service under section 1861(ddd)(1) of the Act for the first time.[12] The current set of drugs covered as DCAPS drugs meets the definition of a potential qualifying single source drug for the purposes of identifying negotiation-eligible drugs in accordance with section 1192(e)(1) of the Act.

Comment: A few commenters stated that influenza vaccines should be excluded from the Negotiation Program with a couple of commenters stating that the time intensity and complexity of the influenza vaccine production process contributes to fragility in the influenza vaccine market, such as a limited number of manufacturers producing these vaccines. A couple of commenters stated that influenza vaccines are not qualifying single source drugs eligible for negotiation because commenters state that the active ingredient(s) are the strain antigens, which vary annually as the strain changes every influenza season. These same commenters stated that multivalent influenza vaccines are comprised of a combination of different active ingredients and should therefore be considered fixed combination drugs and be deemed a new qualifying single source drug. Additionally, these commenters stated that because each new unique active ingredient(s) requires a new FDA approval and constitutes a new qualifying single source drug, the influenza vaccine would never be on the market for 11 years and therefore never meet the timing requirements in accordance with 1192(e)(1)(B)(ii) of the Act.

Response: Nothing in the statute indicates that CMS should categorically exclude vaccines or products with complex and time intensive production processes from being potential qualifying single source drugs nor from the Negotiation Program more broadly. In fact, section 1194(c)(3)(A) of the Act makes clear that vaccines are not categorically excluded from the Negotiation Program. Section 1194(c)(3)(A) of the Act specifies the same applicable percent, for purposes of calculating the ceiling under section 1194(c)(1)(C) of the Act, for vaccines as it does short-monopoly drugs. By expressly specifying the same applicable percent for establishing a ceiling for the MFP of vaccines as it does for short-monopoly drugs, the statute contemplates the selection of vaccines under the Negotiation Program.

As stated in section 30.1 of this final guidance, in accordance with section 1192(e)(1) of the Act, CMS will identify a potential qualifying single source drug as all dosage forms and strengths with the same active moiety or active ingredient and the same holder of an NDA or BLA, inclusive of products that are marketed pursuant to different NDAs or BLAs. CMS will identify the active moiety or active ingredient of the drug using public sources such as RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file. CMS may also consult with FDA as appropriate to, for example, clarify whether a suffix or prefix in an ingredient name represents a genuine difference in active ingredient. CMS clarifies that in the context of vaccines for infectious disease(s), CMS will identify a potential qualifying single source drug on the basis of such vaccines' antigen component(s) as reflected on such vaccines' labeling, as accessed in public sources.

As stated in section 30.1 of this final guidance, to determine the date of licensure for a potential qualifying single source drug that is a biological product with more than one FDA application

[12] See: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection, available at https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310.

number, CMS will use the earliest date of licensure of the initial FDA application number assigned to the BLA holder for the active ingredient (or in the case of fixed combination drugs, for the distinct combination of active ingredients). CMS is aware that some manufacturers of vaccines for infectious disease(s) update the antigen component(s) of their products through supplemental BLAs. For each unique potential qualifying single source drug that CMS identifies based on its antigen component(s), CMS clarifies that it will use the earliest date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of determining time eligibility. Therefore, CMS agrees with the commenters who suggested that a potential qualifying single source drug that is a vaccine for infectious disease(s) that has expenditures during the November 1, 2024 to September 30, 2025 period may not meet the 11-year timing requirement for biological products at section 1192(e)(1)(B)(ii) of the Act if, for example, the supplemental BLA for such potential qualifying single source drug, as identified by its antigen component(s), was issued less than 11 years prior to the selected drug publication date.

Comment: Many commenters stated that CMS' definition of a qualifying single source drug is overly broad and expressed concerns that it will be detrimental to future innovation and patient access to medications and limit manufacturers from researching new formulations or routes of administration, post-approval research, follow-on indications for selected drugs, new products that address unmet medical needs, and orphan drug development. A few of these commenters stated that manufacturers will be disincentivized from investing in improvements to existing products, which can take years to complete and require significant investment if those products will be immediately subject to negotiated pricing. Some of these commenters stated that the definition will limit manufacturers from researching new formulations or routes of administration and a few cited the use of hyaluronidase to facilitate subcutaneous administration as an example of such innovation and new routes of administration. One commenter stated that by aggregating across products with different regulatory histories and development timelines, CMS is creating an ambiguous and unpredictable pricing regime that chills investment in follow-on innovation—particularly in areas such as extended-release formulations, adherence technologies, or delivery mechanisms. This commenter stated that CMS' policy is not transparent and makes it impossible to distinguish the value of discrete innovation. A few commenters emphasized that FDA's regulatory framework is meant to differentiate between products with clinically meaningful differences and recommended that CMS adopt a definition of a qualifying single source drug that recognizes these differences. One of these commenters stated that CMS' over-broad and overly simplistic approach neglects to consider clinically meaningful differences that do not hinge on the product's active moiety / active ingredient and that CMS should adopt a clear case-by-case or multi-dimensional approach to identification of potential qualifying single source drugs that appropriately aligns with FDA statutory authority and clinical expertise. One other commenter stated that they are concerned with CMS' expansive interpretation of a qualifying single source drug and that it is unlawful and risks treating two distinct FDA-approved products intended for entirely different therapeutic areas as the same drug.

Response: CMS thanks these commenters for their input. As discussed in CMS' response on page 14 of the final guidance for initial price applicability year 2027, CMS is committed to recognizing 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 directs readers to section 60.3.3 of this final guidance, which details CMS' approach to adjusting the starting point for an initial offer based on section 1194(e)(2) factors, which includes factors related to clinical benefit as compared to therapeutic alternatives. As further illustrated by section 60.3.3 of this final guidance, the negotiation process aims to reward manufacturers' innovation and improved benefits across patient populations. CMS appreciates the commenters' suggestions for alternate aggregation approaches but will continue to use the process outlined in section 30.1 of this final guidance. For comments on formulations of a drug containing hyaluronidase, CMS directs readers to CMS' response directly below regarding fixed combination drugs, which affirms that CMS will not make a change to the fixed combination drug policy in this final guidance.

Comment: Many commenters responded to CMS' comment solicitation in section 30.1 of draft guidance for initial price applicability year 2028 regarding the aggregation of fixed combination drug products with drug products that contain at least one but not all of the active moiety(ies) / ingredient(s) of that fixed combination product, stating that CMS lacks the statutory authority to make the changes described in the comment solicitation to the current fixed combination drug policy. Many commenters raised concerns that CMS' proposed changes to the fixed combination drug policy do not align with how FDA regulates and reviews the approvals of fixed combination drugs. Many commenters questioned how CMS would apply a consistent definition to the terminology proposed in comment solicitation in the draft guidance, including the terms "biologically active against the disease state" or "clinically meaningful difference," stating that CMS does not have the clinical expertise to make such determinations when evaluating which products should be aggregated. Some commenters supported CMS' consideration of a modification to the fixed combination policy, stating that such a change would 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. A few commenters stated a policy change would potentially harm patients and would likely discourage the innovation of pharmaceutical manufacturers. A few commenters noted that aggregating fixed combination products with single ingredient products did not consider the research and development time and costs that it is required to bring a fixed combination drug to market. A couple of commenters noted that a change of policy is unpredictable and would be administratively complex for manufacturers and disagreed with the process that CMS had outlined for making such a policy change. A couple of commenters highlighted what they describe as the intersection, and potential for tension, of this proposed policy with the Orphan Drug Exclusion policy which the commenters describe as raising questions about the treatment of fixed combination drugs. A few commenters provided examples of fixed combination drugs that have benefits related to clinical efficacy or simplified dosing schedules in the treatment of opioid use disorder or HIV and theorized on how a change to the fixed combination drug policy might negatively impact drug development in those areas. One commenter noted that there could be a misalignment with the proposed fixed combination drug policy with Part D formulary inclusion policies by reducing plans leverage in formulary design and potentially increasing costs.

Response: CMS thanks the commenters for their feedback on how the existing fixed combination drug policy could impact negotiation eligibility and selection of drugs payable under Part B and how CMS might consider grouping some 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. CMS agrees with the concerns cited by commenters that manufacturers may use CMS' existing fixed combination drug policy to avoid aggregation and therefore selection for negotiation by making minor changes to an existing drug. Due to the complexity and scope of this issue as noted above in stakeholder comments, CMS believes additional time would be necessary to develop objective policy criteria if CMS were to finalize such a policy, and thus will not make a change to the fixed combination drug policy in this final guidance. CMS intends to address this program integrity risk and is continuing to consider the appropriate policy to implement in rulemaking beginning in initial price applicability year 2029.

For initial price applicability year 2028, CMS will maintain its approach to fixed combination drugs which states that if a drug is a fixed combination drug [13] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs. A product containing only one (but not all) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. Section 30.1 of this final guidance details how CMS intends to treat fixed combination drugs and gives an example to illustrate the application.

Comment: One commenter asked CMS for clarification on the distinction between co-formulated drugs and co-packaged drugs. The commenter asked whether a drug with two active moieties would be considered a fixed combination drug for purposes of the Negotiation Program if the two active moieties are not co-formulated but rather are present in separate dosage forms that are sold in a single package. The commenter provided an example and asked whether the total expenditures for the co-packaged product would be calculated at the co-packaged level or at the level of the individual moieties contained within the co-packaged product.

Response: For purposes of the Negotiation Program in initial price applicability year 2028, if a drug (including a co-packaged drug) contains two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs, whether such drug is co-formulated or co-packaged. All formulations of this distinct combination offered by the same NDA / BLA holder will be considered as one potential qualifying single source drug. As noted above, CMS intends to address fixed combination drugs in rulemaking beginning in initial price applicability year 2029 and may address co-packaged drugs at that time.

Comment: Many commenters asserted that the distinct time periods for when a drug and a biological product will be eligible for negotiation are arbitrary and that CMS should implement the Negotiation Program so that, for any drug or biological product to qualify as a qualifying single source drug, the same number of years must have elapsed since the drug or biological product was approved or licensed, respectively. A few of these commenters specifically recommended increasing the time that must have elapsed between approval by the FDA and

[13] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 C.F.R. § 300.50.

eligibility as a qualifying single source drug for drug products from the current 7 years to 11 years to align with biological products. Some of these commenters believed that the shorter time period for small molecule drugs skews innovation away from these types of drugs and towards biologics because of the additional time allowed for manufacturers to recover their investments. A few of these commenters provided statistics suggesting that this is already occurring. One commenter urged CMS to use its administrative authority to align the time periods for drug products and biological products, whereas a few commenters acknowledged statutory limitations preventing CMS from making such a change and urged CMS to work with Congress to align the time periods. A couple of commenters stated their support for adhering to the current statutory framework. One of these commenters noted that if small-molecule drugs were extended from 7 years to 11 years, more than half of the drugs CMS negotiated in initial price applicability year 2026 would not have been eligible for negotiation, continuing to expose our nation's seniors to unaffordable prices. The other commenter recommended shortening the current years until eligibility as a qualifying single source drug from 7 years (drug products) or 11 years (biological products) to 5 or 8 years, respectively, as this would reduce the waiting period and would help reduce drug prices sooner while still allowing manufacturers to recover their costs from research and development efforts.

Response: CMS thanks these commenters for their feedback and suggestions. As discussed in CMS' response on page 15 of the final guidance for initial price applicability year 2027, section 1192(e)(1)(A)(ii) of the Act states that for a drug product to be considered a qualifying single source drug, at least 7 years must have elapsed since the drug product was approved by the FDA.[14] 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.[15] CMS is implementing the Negotiation Program in accordance with these statutory requirements.

Comment: One commenter provided feedback on CMS' treatment of biological products whose applications were previously submitted as NDAs and approved under section 505 of the FD&C Act but subsequently deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, pursuant to section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed and marketed as biological products under section 351 of the PHS Act (hereinafter, "deemed biologics"). The commenter stated that CMS adopted a new interpretation of biological products without any administrative process and that changing the interpretation for initial price applicability year 2027 from what was used to select drugs in initial price applicability year 2026 is improper because it conflicts with FDA's prior findings as to approval dates for deemed biologics, i.e., the date of original NDA approval. The commenter stated that federal law empowers FDA to approve drugs and, in

[14] For drug products, to determine the date of approval for a potential qualifying single source drug with more than one FDA application number, section 30.1 of this final guidance specifies that CMS will use the earliest date of approval of the initial FDA application number assigned to an NDA for the active moiety for which the manufacturer is the holder of the NDA.

[15] For biological products, to determine the date of approval for a potential qualifying single source drug with more than one FDA application number, section 30.1 of this final guidance specifies that CMS will use the earliest date of licensure of the initial FDA application number assigned to a BLA for the active ingredient for which the manufacturer is the holder of the BLA.

so doing, to determine their date of licensure and that CMS lacks the authority to deviate from such findings.

Response: CMS thanks this commenter for their feedback and input. CMS clarifies that CMS' policy for deemed biologics is an implementation of sections 11001 and 11002 of the IRA. CMS believes that the policy in section 30.1 of this final guidance 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 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.[16] 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[17] 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, 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[18] and via the draft guidance for initial price applicability year 2028.

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

[17] For a biological product with an approved application under section 505(c) of the FDC&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.

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

Bona Fide Marketing (Sections 30.1, 60.7, 70, and 90.4)

Comment: One commenter requested CMS publish the names, or the number, of drugs not selected for negotiation due to a determination by CMS of bona fide marketing.

Response: CMS thanks the commenter for the suggestion. Consistent with prior initial price applicability years, CMS will not publish for initial price applicability year 2028 the names of the qualifying single source drugs removed due to a determination of bona fide marketing in accordance with section 30.1 of this final guidance. This approach is consistent with the policy for exclusions from drug selection in sections 30.1.1 through 30.1.3 of this final guidance and a request for a biosimilar delay in section 30.3.1 of this final guidance.

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. These 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." One commenter stated that the statute does not address generic drug or biosimilar distribution agreements as relevant to whether a generic or biosimilar is being marketed as the statute does in other contexts (e.g., a request for a biosimilar delay). One commenter stated that the Federal Trade Commission (FTC) would regulate any areas of marketing concern. A few commenters raised concerns about the impact of a bona fide marketing determination 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 removed from the selected drug list. A few commenters expressed support for the approach, including the ongoing monitoring of selected drugs removed from selection.

Response: Consistent with CMS' response on page 20 of the final guidance for initial price applicability year 2027, 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, CMS 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, CMS is aware of situations in which a manufacturer of a brand name drug or biologic has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar, where the generic drug or biosimilar manufacturer agrees to limit

production or distribution of the generic drug or biosimilar, such that only a nominal quantity of product is allowed to enter the market. The result is a lack of meaningful price competition, and in that circumstance the generic drug or biosimilar is not "marketed" within the meaning of that term as it is used in the IRA. Given the Negotiation Program is targeted at single source drugs and biologics 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 CMS performs its function of making the determination whether a generic or biosimilar is being marketed. Accordingly, CMS maintains the approach in this guidance of determining if the manufacturer of the generic/biosimilar is engaged in bona fide marketing of the generic/biosimilar.

Comment: A few 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 few other commenters shared support for the bona fide marketing review. One 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. Another commenter thanked CMS for acknowledging that in the absence of a limiting agreement a product with "relatively low" sales may be considered marketing, but the commenter requested that CMS consider "any" such sales be considered marketed. Another commenter stated that CMS should not overly rely on PDE data because the commenter states PDE data may not contain the entire universe of relevant data for all drugs that might be a qualifying single source drug.

Response: CMS thanks commenters for sharing their specific observations of the market and feedback on potential scenarios for review. Consistent with CMS' responses on page 21 of the final guidance for initial price applicability year 2027, CMS reiterates that the determination whether a generic drug or biosimilar is being bona fide marketed on an ongoing basis is a totality-of-the circumstances inquiry that will not necessarily turn on any one source of data, including PDE data. Further, as stated with additional detail in CMS' response immediately above, 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 and not just when there are "any" sales of the generic drug or biosimilar as suggested by a commenter.

Comment: A couple of commenters shared their perspectives about the interplay of the definition of a qualifying single source drug and bona fide marketing. Specifically, one commenter suggested that CMS' "broad" aggregation policy for a qualifying single source drug paired with CMS' determination of when bona fide marketing is met through PDE and Average Manufacturer Price (AMP) data results in de facto agency discretion to determine the product's exclusivity period. Alternatively, another 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.

Response: CMS thanks the commenters for their feedback. Regarding a commenter's assertion that CMS' aggregation policy and its bona fide marketing determinations results in de facto agency discretion to determine the product's exclusivity period, we respectfully disagree. The identification of qualifying single source drugs under the Negotiation Program is not a determination of the regulatory exclusivity periods for drugs and biological products. With respect to a commenter's concern that competition on older formulations could result in a qualifying single source drug avoiding selection or being removed from the list, CMS acknowledges 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. CMS is finalizing the policy for bona fide marking for initial price applicability year 2028 as described in the draft guidance. As stated in section 30.1 of this final guidance, if any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar products that CMS determines are approved or licensed, as applicable, and marketed based on the process described in this final guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028.

Comment: A couple of commenters thanked CMS for sharing examples of potential qualifying single source drugs with at least one approved generic drug or licensed biosimilar with bona fide marketing. These commenters also shared feedback on the examples provided. One commenter raised concerns that the examples were "subjective" and do not provide sufficient predictability to manufacturers of the bona fide marketing standard. One commenter disagreed with the third example—according to this comment, this example would result in the wrong outcome where a particular biosimilar has recently launched, e.g., 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: CMS thanks commenters for their feedback. The examples provided in section 30.1 of this final guidance are for illustrative purposes only to provide interested parties with some instances of how certain factors might weigh in favor of, or against, a determination 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, as stated with additional detail in CMS' response above, 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, would not be considered bona fide marketed because there is no current distribution of the biosimilar and there are potential barriers to its future distribution. However, CMS reiterates, as stated in section 30.1 of this final guidance, that CMS' ultimate determination of any particular drug will be based on the totality of the circumstances and not on the presence, or absence, of any single factor.

Comment: A couple of commenters requested additional information from CMS about the notification process to the public, Part D plan sponsors, and manufacturers when a selected drug is removed from the list of selected drugs. One commenter asked if public notice beyond the CMS website will be provided and another commenter suggested CMS provide public notice via the CMS HPMS. Additionally, a few commenters raised concerns about the interplay of prompt notice of deselection or removal of a selected drug and the impact on formulary coverage, for example, including if and when removal by a Part D sponsor of a selected drug from a formulary is permitted.

Response: CMS thanks commenters for their questions. Consistent with section 70 of this final guidance, CMS will provide public notice by publishing the relevant information on the CMS website when a selected drug is removed from a selected drug list before or during negotiation, or after an MFP is in effect after CMS determines the statutory criteria in section 1192(c) of the Act for generic or biosimilar competition are met for the selected drug. CMS will consider alerting interested parties about this updated information using its regular channels for the Negotiation Program, including the CMS HPMS for manufacturers and plans.

Responses to comments regarding Part D formulary inclusion of selected drugs, including the formulary inclusion exception successor regulation for 2027 and 2028, are discussed in the comment summaries and responses for sections 110 and 110.1 of this final guidance.

Comment: Some commenters suggested that if a generic drug or biosimilar is determined to be bona fide marketed after the negotiation period ends but prior to the initial price applicability year 2028, the MFP should never apply to this selected drug. One commenter provided text revisions to section 70 of the draft guidance for initial price applicability year 2028 to remove a selected drug when a generic drug or biosimilar is marketed after the end of the negotiation period and before the MFP takes effect.

Response: Consistent with our responses on page 131 of the final guidance for initial price applicability year 2027, section 1192(c) of the Act requires that each negotiation-eligible drug included on the selected drug list with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) of the Act are met, unless CMS makes such a determination before or during the negotiation period. CMS interprets this requirement such that a drug included on the selected drug list published for initial price applicability year 2028 will remain a selected drug for initial price applicability year 2028 unless CMS determines on or before November 1, 2026 (that is, on or before the end of the Negotiation Period for the initial price

applicability year 2028) that a generic drug or biosimilar product for the selected drug has been approved for marketing by the FDA, and that bona fide marketing exists for the generic drug or biosimilar product; if CMS so determines, the MFP would not apply for initial price applicability year 2028 and the selected drug would cease to be a selected drug on January 1, 2029. If CMS determines between November 2, 2026 through March 31, 2028, for a drug selected for initial price applicability year 2028, that bona fide marketing exists for the generic drug or biosimilar, the MFP would apply for initial price applicability year 2028 and the selected drug would cease to be a selected drug on January 1, 2029. If CMS makes this determination between April 1, 2028 and March 31, 2029, then the selected drug will cease to be a selected drug on January 1, 2030, and the MFP will apply for 2028 and 2029. These circumstances are summarized in section 70 in Table 9 of this final guidance.

Comment: One 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 2027, if a generic or biosimilar is approved and marketed by March 31, 2027, the MFP is no longer applicable beginning January 1, 2028, and the selected drug should not be eligible for renegotiation for initial price applicability year 2028.

Response: CMS confirms, consistent with the response on page 131 of the final guidance for initial price applicability year 2027, that if CMS determines between November 2, 2025 through March 31, 2027, for a drug selected for initial price applicability year 2027, that bona fide marketing exists for the generic drug or biosimilar, the MFP would apply for initial price applicability year 2027 and the selected drug would cease to be a selected drug on January 1, 2028. In other words, the selected drug remains a selected drug and MFP applies for initial price applicability year 2027; the selected drug ceases to be a selected drug on January 1, 2028.

Additionally, CMS has revised section 70 of this final guidance to specify if CMS determines bona fide marketing exists for a drug selected for initial price applicability years 2026 or 2027 prior to the publication of the selected drug list (which includes drugs selected for renegotiation for initial price applicability year 2028), a drug selected for initial price applicability years 2026 or 2027 is not eligible for renegotiation as specified in section 1194(f)(5) of the Act. After the publication of the selected drug list including drugs selected for renegotiation for initial price applicability year 2028, the timeline for removal of the drug selected for renegotiation from the selected drug list following generic drug or biosimilar approval and marketing, and the application of the renegotiated MFP follows the same timeline as drugs selected for negotiation for initial price applicability year 2028.

Further as included in revisions to section 70 of this revised guidance, regardless of when a drug is removed from selection for renegotiation for initial price applicability year 2028, the requirements for application of the originally negotiated MFP must be separately determined based on the price applicability year that the drug was originally selected for negotiation. For drugs selected for negotiation for initial price applicability year 2026, the MFP remains in effect in accordance with the table provided on page 166 of the revised guidance for initial price applicability year 2026. For drugs originally selected for negotiation or initial price applicability year 2027, the MFP remains in effect as specified in Table 9 of this final guidance.

Comment Solicitation on Data Sources for Utilization Review

Comment: A few commenters responded to CMS' solicitation for comment in section 30.1 of the draft guidance for initial price applicability year 2028 regarding which, if any, additional data sources may include timely utilization data for drugs payable under Part B and/or covered under Part D. A couple of these commenters suggested that CMS use all available data sources (e.g., AMP, ASP, Medicaid State Drug Utilization Data (SDUD), and/or data from a nationally representative and commercially available database). These commenters also suggested other sources including: commercial claims providers; pharmaceutical distributor ordering platforms; pharmacy dispensing records; IQVIA; the FDA Orange Book for safety, effectiveness, and marketing status; and Part D claims. Additionally, one commenter suggested that manufacturers should be permitted to submit additional data as needed to demonstrate that the generic or biosimilar has entered the market.

Response: CMS thanks 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. In consideration of the comments received in response to CMS' comment solicitation, CMS revised section 30.1 of this final guidance to specify that CMS, in addition to PDE and AMP data for utilization review, CMS will review ASP data available for the sales quarters of the fourth quarter of 2024 through the third quarter of 2025 (e.g., the 12-month period beginning October 1, 2024 and ending September 30, 2025). CMS believes this additional source is necessary for drugs payable under Part B. Additionally, CMS may consider additional data sources to review utilization; however, data may not be available in these additional data sources for all drugs. As available, CMS may consider SDUD and/or data from a nationally representative and commercially available database. CMS may review these additional data sources for utilization for drugs payable under Part B and/or covered under Part D for the most recent 12-month period for the applicable data source, when available to CMS. The utilization review is in addition to the review of the additional relevant factors under a holistic inquiry as specified in section 30.1 of this final guidance (and additionally discussed for removal from the selected drug list in section 70 of this final guidance and monitoring for bona fide marketing in section 90.4 of this final guidance). The revisions to the utilization data review for bona fide marketing specified in section 30.1 of this final guidance are applicable to sections 60.7, 70, and 90.4, as specified in these sections of final guidance. CMS will also continue to consider these suggestions in CMS' policy development for this issue in future rulemaking.

Comment: A few commenters also noted specific concerns that the data, when it is pulled for purposes of a CMS determination of bona fide marketing for drug selection or removal of a drug from selection, may not include the full scope of evidence for bona fide marketing because of delayed timing of initial uptake for biosimilars and generics. A few commenters also raised concerns that marketing volume and related data are affected by uncontrollable market dynamics and lagging system processes. Specifically, one of these commenters stated that lags in CMS' Medicare Hospital Outpatient Prospective Payment System (OPPS) and OPPS addenda files are not in a manufacturer's control, which can lead to a disincentive to prescribe a product and in turn impact the bona fide marketing. Another commenter mentioned delays in Part D formulary listings. One other commenter stated that data sources may not reflect commercial availability in particular for low-volume or specialty medicines.

Response: CMS thanks commenters for raising their concerns. As specified in section 70 of this final guidance, a determination 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 bona fide marketing. We direct commenters to the additional relevant factors specified in section 70 of this final guidance, which include, for example, whether the generic drug or 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 a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar, as articulated further in section 90.4 of this final guidance.

Orphan Drug Exclusion from Qualifying Single Source Drugs (Section 30.1.1)

Comment: Many commenters asked CMS to specify that the 7- or 11-year periods that must elapse prior to eligibility as a qualifying single source drug would begin on the date the Orphan Drug Exclusion ceases to apply to a drug or biological product. That is, a drug or biological product could not become a qualifying single source drug until 7 or 11 years had passed between the date on which the drug or biological product, respectively, loses eligibility for the Orphan Drug Exclusion and the selected drug publication date. Some commenters stated that, because the term "qualifying single source drug" is defined to expressly exclude drugs that qualify for the Orphan Drug Exclusion, the best interpretation of the statute is that the product is entirely exempt from the qualifying single source drug definition and all its requirements. These commenters also asserted that such interpretation would align with the intent of the Orphan Drug Exclusion and mitigate the extent to which it may disincentivize rare disease drug development. In contrast, another commenter acknowledged that CMS is statutorily required to measure the 7- and 11-year periods starting from the date of the drug or biological product's approval or licensure date.

Some commenters raised concerns with the policy that, to be considered for the Orphan Drug Exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition 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 or condition. These commenters raised concerns that narrowly exempting only single-indication orphan drugs from the definition of a qualifying single source drug undermines incentives for post-approval research and threatens innovation for rare disease treatments. A couple of commenters asserted that CMS should interpret section 1192(e)(3)(A) of the Act such that drugs or biological products with multiple orphan drug designations (for multiple rare diseases or conditions) that are approved only for indications within the scope of a single rare disease or condition would qualify for the Orphan Drug Exclusion. A couple of commenters acknowledged that CMS does not have the authority to change the statutory requirement and expressed their support for legislation to amend the statutory language. A few commenters expressed their general recommendation that CMS should re-evaluate its interpretation of the Orphan Drug Exclusion to maximize incentives for the development of orphan drugs. In contrast, one commenter wrote that exempting additional orphan drugs with designations for multiple uses would further chip away at the list of drugs eligible for negotiation, resulting in more high-cost drugs for Medicare enrollees.

Response: CMS appreciates these commenters sharing their perspectives. On July 4, 2025, the Working Families Tax Cuts Act was signed into law. Section 71203(a)(2) of the Working Families Tax Cuts Act amended section 1192(e)(1)(3)(A) of the Act to describe a drug that qualifies for the Orphan Drug Exclusion as a drug 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) 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). Section 71203(a)(3) of the Working Families Tax Cuts Act also added new section 1192(e)(4) of the Act, which describes the treatment of former orphan drugs. In accordance with section 71203(b) of the Working Families Tax Cuts Act, the amendments made in section 71203(a)(3) of the Working Families Tax Cuts Act 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.

Accordingly, CMS is revising section 30.1.1 of this final guidance in accordance with these amendments. To be considered for the Orphan Drug Exclusion for initial price applicability year 2028, 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). Pursuant to section 1192(e)(4) of the Act, if, as of the date of a drug or biological product's earliest approval or licensure identified under section 1192(e)(1)(A)(ii) or 1192(e)(1)(B)(ii) of the Act and described in section 30.1 of this final guidance, such drug or biological product met or meets the criteria for the Orphan Drug Exclusion, as described in section 1192(e)(3)(A) and section 30.1.1 of this final guidance, CMS will measure the 7- and 11-year periods described in sections 1192(e)(1)(A)(ii) and 1192(e)(1)(B)(ii) of the Act, respectively, starting from the first day after such earliest 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 will 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. For orphan drug designations withdrawn on or after August 12, 2013, the FDA Orphan Drug Product designation database includes the date of such withdrawal. For orphan drug designations withdrawn prior to August 12, 2013, CMS will use August 12, 2013 as the date on which the orphan drug 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. Because these amendments to the Orphan Drug Exclusion apply with respect to initial price applicability years beginning on or after January 1, 2028, nothing in this section 30.1.1 of final guidance modifies CMS' implementation of the Orphan Drug Exclusion with respect to initial price applicability years 2026 and 2027, the status of selected drugs that were selected with respect to initial price applicability years 2026 and 2027, or a Primary Manufacturer's obligation to make any agreed-upon MFP available with respect to such selected drugs, including in 2028.

Comment: A few 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, with a couple of these commenters stating

that CMS cannot rely on FDA's databases because those databases principally track orphan exclusivity rather than orphan drug designation. Commenters expressed appreciation that CMS will consult with FDA as needed but 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: CMS appreciates these comments. CMS believes 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. CMS reviews designations and approved indications to determine whether the indication falls within a designation. Further, CMS will consult with FDA if needed. CMS acknowledges commenters' request to have the opportunity to submit supporting documentation regarding orphan drug designations but believes that is unnecessary at this time.

Plasma-Derived Product Exclusion from Qualifying Single Source Drugs (Section 30.1.3)

Comment: One commenter stated that CMS should adhere to the statutory language describing the plasma-derived product exclusion at section 1192(e)(3)(C) of the Act. They recommended that CMS continue to look to multiple sources when determining if a potential qualifying single source drug qualifies for the plasma-derived product exclusion, including the drug's approved label and FDA resources, such as the Approved Blood Products list. They also recommended CMS use FDA's Cellular and Gene Therapy Products website[19] to ensure that other plasma-derived products are appropriately captured in this exclusion.

Response: CMS thanks this commenter for the comments and feedback. As stated in CMS' response on page 23 of the final guidance for initial price applicability year 2027, CMS continues to believe that referring to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[20] and databases such as FDALabel[21] and the FDA Online Label Repository[22] are the best ways to identify plasma-derived products for the purpose of implementing the Plasma-Derived Product Exclusion in a consistent manner. CMS confirms that cellular and gene therapies are not categorically ineligible for the Plasma-Derived Product Exclusion described in section 1192(e)(3)(C) of the Act, which applies the exclusion to biological products derived from human whole blood or plasma. As described by FDA, cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications. As further described by FDA, human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use.[23] Cellular and gene therapies will be assessed for the Plasma-Derived Product Exclusion using the same criteria applicable to other biological products.

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[19] See: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-genetherapy-products.
[20] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[21] FDALabel: https://nctr-crs.fda.gov/fdalabel/ui/search.
[22] FDA Online Label Repository: https://labels.fda.gov/.
[23] See: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products.

Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2028 (Section 30.2)

Comment: One commenter recommended adding more drugs to the list of those eligible for negotiation as currently only the high spending drugs are selected each year. This commenter stated that there are very expensive drugs for patients that are not in the top 10, for initial price applicability year 2026, or top 15, for initial price applicability year 2027, which were selected for negotiation.

Response: CMS thanks this commenter for their feedback and suggestion. As stated in section 30.2 of this final guidance, in accordance with sections 1192(a) and 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2028 is a qualifying single source drug 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 and as described in section 30.3 of this final guidance, in accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 15 (or all, if such number is less than 15) negotiation-eligible drugs for negotiation for initial price applicability year 2028.

Comment: A few commenters expressed concern with CMS' use of total gross covered prescription drug costs to identify and rank negotiation-eligible drugs to determine Total Expenditures under Part D. These commenters all stated concerns that excluding price concessions and other rebates from gross covered prescription drug costs will result in CMS identifying and ranking negotiation-eligible drugs without regards to manufacturer rebates or discounts that Part D plans currently secure on these same products. A couple of commenters suggested CMS revert to the regulatory definition that was in effect when the Negotiation Program was enacted defining "gross covered prescription drug costs" as a price net of rebates. One of the other commenters suggested that using gross drug costs to determine Total Expenditures under Part D and net drug costs to determine Total Expenditures under Part B results in a bias towards and overweighting of drugs covered under Part D, which is exacerbated by CMS including expenditures associated with beneficiaries enrolled in Medicare Advantage in Total Expenditures under Part D but not in Total Expenditures under Part B. This commenter recommended that CMS incorporate data on Medicare Advantage expenditures into the calculation of Total Expenditures under Part B. Additionally, all of these commenters suggested using net drug costs for Part B and Part D to determine Total Expenditures for drug selection as that would result in a more accurate reflection of costs for drugs with high Medicare expenditures. One additional commenter inquired if Total Expenditures under Part D include amounts paid when Medicare is not the primary payer.

Response: CMS thanks these commenters for their feedback and suggestions. As stated in CMS' response on page 23 of the final guidance for initial price applicability year 2027, CMS first notes that any suggestion that CMS amend the regulatory definition of "gross covered prescription drug costs" at 42 C.F.R. § 423.308 is outside the scope of this final guidance. CMS acknowledges the commenters' concern about the impacts of excluding price concessions and other rebates when identifying and ranking negotiation-eligible drugs. Consistent with the approach discussed in CMS' response on pages 23 and 24 of the final guidance for initial price

applicability year 2027, in identifying and ranking the negotiation-eligible drugs for initial price applicability year 2028, CMS will use Total Expenditures under Part D, which are defined at section 1191(c)(5) of the Act as "total gross covered prescription drug costs," as defined in section 1860D-15(b)(3) of the Act. Section 1860D–15(b)(3) of the Act defines "gross covered prescription drug costs" in relevant part as "the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered Part D drugs during the year and costs relating to the deductible." The term is also defined in the Part D regulations at 42 C.F.R. § 423.308 as, in part, "those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year." As discussed in the Contract Year 2024 Final Rule (see 88 Fed. Reg. 22120, 22259-22263 (Apr. 12, 2023)), costs directly related to the dispensing of covered Part D drugs are most logically calculated as the accumulated total of the negotiated prices that are used for purposes of determining payment to the pharmacy or other dispensing entity for covered Part D drugs. Consistent with this policy, CMS will calculate Total Expenditures under Part D for purposes of the Negotiation Program using PDE data and will not consider any rebates or other price concessions not reflected in the negotiated price of the drug on the PDE to identify and rank negotiation-eligible drugs. CMS acknowledges the concern about the use of gross drug costs to determine Total Expenditures under Part D and net drug costs to determine Total Expenditures under Part B but reiterates that it is calculating such total expenditures in accordance with the definition of "total expenditures" at section 1191(c)(5) of the Act. In response to the comment raising concerns about the use of expenditures associated with beneficiaries enrolled in MA in the calculation of Total Expenditures under Part D but not in the calculation of Total Expenditures under Part B, CMS directs readers to the discussion below and in section 30.2 of this final guidance. In response to the one commenter inquiring whether Total Expenditures under Part D include amounts paid when Medicare is not the primary payer, the process of identifying Part D high spend drugs described in section 1192(d)(1)(A) of the Act is discussed in section 30.2, in which CMS will identify PDE data for each 11-digit National Drug Code (NDC-11) of a qualifying single source drug for dates of service during the 12-month period beginning November 1, 2024 and ending October 31, 2025 in which the data includes payments when Medicare is not the primary payer. This PDE data includes PDE records in instances when CMS is not the primary payer.

Comment: One commenter expressed support for the policy in the draft guidance for initial price applicability year 2028 to exclude expenditures for a drug or biological product that is bundled or packaged into the payment for another service when calculating Total Expenditures under Part B. Another commenter asked that CMS consider how it might, within the existing statutory framework, include bundled drugs that are billed separately (such as end-stage renal disease drugs) in its calculation of Total Expenditures under Part B, as doing so could present opportunities for significant program savings. Another commenter requested clarification on how CMS will determine if a drug or biological product is bundled or packaged into the payment for another service in order to exclude those expenditures, and if a line-level claim in the carrier fee-for-service file has a Healthcare Common Procedure Coding System (HCPCS) code for a specified drug, is it assumed that the payment associated with that line of the claim is not bundled or packaged into the payment for another service.

Response: CMS appreciates these comments. As described in section 30.2 of this final guidance, CMS will exclude expenditures for a drug or biological product that are bundled or packaged into the payment for another service when calculating Total Expenditures under Part B, as required by section 1191(c)(5) of the Act. CMS will only exclude expenditures for these billing and payment codes when they are bundled or packaged; that is, CMS will not exclude any expenditures for a drug that can be bundled or packaged into the payment for another service when it is separately paid. CMS has 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. CMS will exclude such separately billed claims. CMS notes that allowed charges in FFS Part B claims are zero for billing and payment codes when they are bundled or packaged. Therefore, the expenditures associated with the claim line in such data for a drug that is bundled or packaged would not be included in Total Expenditures under Part B. CMS can identify such claims for billing and payment codes that are not bundled or packaged into the payment for another service because they typically have allowed amounts greater than zero and, in circumstances in which it is required, include an "AY" modifier.

Comment: Many commenters suggested that CMS should account for expenditures on drugs payable under Part B and administered to MA enrollees when identifying Part B high spend drugs. These commenters explained 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. They expressed concern that the policy in draft guidance to calculate Total Expenditures under Part B of Title XVIII of the Act using Part B claims data would therefore skew the negotiation-eligible drug list toward drugs covered under Part D and away from drugs payable under Part B.

A few of these commenters asserted that including spending on drugs provided to MA enrollees is the best reading of the statute, arguing that the Act makes clear that Part B benefits received through MA plans are benefits received "under" Part B, and that Congress intended to treat drugs payable under Part B in the same way as drugs covered under Part D. A couple other commenters argued that CMS should not include Medicare spending on drugs provided to both fee-for-service Medicare beneficiaries and MA enrollees in the calculation of Total Expenditures under Part B because the better reading of the statute is that this spending is excluded. They asserted 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. One of these commenters also viewed the exclusion in section 1191(c)(5) of the Act of expenditures for a drug or biological product that are bundled or packaged to require that MA units are excluded from total expenditures under Part B since CMS makes capitated payments to MA plans on a per member per month basis.

A few commenters offered input on the data and methodology CMS could use to calculate MA expenditures under Part B. A couple of commenters recommended that CMS use MA encounter data to identify units of a drug at the NDC-11 level and then assign a dollar value to these encounters by applying the fee-for-service methodology for payment, such as, for example, that is described at section 1847A of the Act. One of these commenters acknowledged that MA encounter data lags behind Part B claims data and recommended that CMS either use MA

encounter data from an earlier period or require submission of MA encounter data on a more rapid basis. One commenter suggested that CMS could extrapolate the MA expenditure spend by multiplying Medicare fee-for-service spending by the ratio of total Medicare enrollment over the fee-for-service-only population. Another commenter did not recommend a specific methodology but requested that CMS not require any new reporting requirements for MA plans.

Response: CMS thanks these commenters for their suggestions. In response to the commenters, CMS agrees that MA expenditures for drugs payable under Part B and administered to MA enrollees should be accounted for and included in Total Expenditures under Part B. CMS also agrees that by leaving that data out, roughly half of total spending on drugs payable under Part B would be left out because of the number of enrollees in MA plans. Therefore, CMS has updated this final guidance to include MA encounter data for drugs payable under Part B (hereinafter "MA encounter data for Part B items and services") when calculating the Total Expenditures under Part B of Title XVIII of the Act.

CMS agrees with the commenters stating that the statute supports including MA encounter data for Part B items and services. Section 1192(d)(1)(B) of the Act defines a negotiation-eligible drug as including 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." Likewise, section 1192(b)(1)(A) of the Act states that "the Secretary shall rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under Part B and D of title XVIII." Total expenditures under Part B is best understood as including MA expenditures for drugs payable under Part B, as section 1852(a)(1) of the Act requires MA plans to provide to enrollees the "benefits under the original [M]edicare [FFS] program option," which includes, as relevant here, drugs payable under Part B. CMS notes further that including MA expenditures for drugs payable under Part B is consistent with the statutory directive in section 1191(c)(2)(B) of the Act that a "maximum fair price eligible individual," includes individuals "enrolled under part B of title XVIII, including [individuals] enrolled in an MA plan under part C of such title, if payment may be made under part B for such selected drug." CMS therefore agrees with commenters stating that exclusion of MA expenditures for drugs payable under Part B from the computation of Total Expenditures for drugs payable under Part B would not capture the complete or most accurate Total Expenditures for drugs payable under Part B.

However, CMS notes that MA encounter data for Part B items and services does not include the actual amount paid by the MA plan sponsor. Due to this gap in MA encounter data for Part B items and services, CMS agrees with commenters that CMS may best estimate MA expenditures for drugs payable under Part B by establishing an approach that uses 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 Medicare Fee-for-Service (FFS). We describe our methodology for this approach in section 30 of this final guidance.

Comment: One commenter asked whether Total Expenditures under Part B include amounts paid when Medicare is not the primary payer. This commenter also asked whether Total

Expenditures for drugs payable under Part B includes beneficiary deductible payments in addition to Medicare payment and beneficiary coinsurance.

Response: CMS will use FFS Part B data to calculate the total allowed charges (meaning the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item and service) for purposes of determining Total Expenditures under Part B. FFS Part B data includes claims for payments when Medicare is not the primary payer. For CMS' approach to MA expenditures, we refer readers to the preceding response and the approach described in section 30 of this final guidance.

Comment: One commenter asked whether PDE records with a value of "0=Not specified (missing values are also possible)" will be excluded from the calculation of Total Expenditures under Part D and asserted that such values make up roughly 15 percent of the records in the PDE file for 2023.

Response: As CMS described in draft guidance for initial price applicability year 2028 and this final guidance, CMS will only use PDE records with a compound code field equal to "1=Not a Compound" when calculating Total Expenditures under Part D. CMS disagrees with the commenter that PDE records with a value of "0=Not Specified" make up roughly 15 percent of PDE records for 2023. CMS has found that, in recent years, the "0=Not Specified" field typically accounts for less than 0.05 percent of PDE records, and the vast majority (more than 99 percent) of PDE records are populated with "1=Not a Compound."

Comment: A few commenters provided their views on whether and how CMS should combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs. A couple of commenters stated that CMS' proposal to combine such expenditures is inconsistent with the statute and recommended that CMS instead rank negotiation-eligible drugs according to their separate spending under Part B or Part D. Another commenter raised their concern about incentives for manufacturers to develop products with split utilization across Medicare Part B and Part D to evade selection for the Negotiation Program by keeping expenditures below the threshold for inclusion on the Part B high spend drug list or Part D high spend drug list, even if the drug's combined total expenditures would be large enough to place it on the combined Part B and Part D list. This commenter recommended that CMS develop a step in the drug selection process where CMS sums utilization for the same product across Part B and Part D before the calculation of total expenditures and the ranking of drugs across Part B and Part D.

Response: CMS thanks these commenters for sharing their perspectives. CMS disagrees with the commenters who stated that the policy 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 Part B and Part D. Such statutory language directs CMS to combine Total Expenditures under Part B and Part D when ranking negotiation-eligible drugs. CMS acknowledges the commenter's concern that manufacturers may be incentivized to split utilization across Medicare Part B and Part D. However, section 1192(b)(1)(A) of the Act directs CMS to combine Total Expenditures under Part B and Part D when ranking negotiation-eligible

drugs. CMS therefore declines to combine Total Expenditures under Part B and Part D before ranking negotiation-eligible drugs, as suggested by the commenter.

Small Biotech Exception (Section 30.2.1)

Comment: A few commenters asked CMS to establish a dispute resolution process in implementing the Small Biotech Exception (SBE). A few commenters asked CMS to provide flexibility and maintain communication with companies throughout the SBE submission process to ensure complete and accurate data submissions.

Response: CMS declines at this time to create a dispute resolution process for the SBE. Consistent with CMS' response on page 24 of the final guidance for initial price applicability year 2027, 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, CMS believes that there is enough time during the submission window for manufacturers to provide the relevant data to support their application for the exception and declines to use a dispute resolution process for a manufacturer to supplement a submission. As stated in section 30.2.1 of this final guidance, CMS may request additional information from the Submitting Manufacturer as necessary to make a determination with respect to an SBE request.

Comment: One commenter stated that if a drug has received an SBE and the manufacturer's circumstances have not changed in a material way, the manufacturer should not have to re-apply for an SBE in subsequent years.

Response: Consistent with CMS' response on page 25 of the final guidance for initial price applicability year 2027, CMS' determination that a given qualifying single source drug qualifies for the SBE for a given initial price applicability year, including initial price applicability year 2027, does not mean that this drug will continue to qualify for the SBE for a future initial price applicability year. CMS must provide separate information collection requests for each of these initial price applicability years because of different statutory requirements across these years, including the limitation for certain acquisitions for an SBE starting with initial price applicability year 2027 and the inclusion of selected drugs payable under Part B starting in initial price applicability year 2028.

Comment: One commenter stated that treating drugs payable under Part B and covered under Part D as a single qualifying single source drug would have negative impacts on the SBE because large manufacturers might qualify for the SBE for such a drug.

Response: CMS thanks this commenter for their feedback. As stated in section 30.1 of this final guidance and further explained in CMS' response above, and consistent with the aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act, a potential qualifying single source drug will include all dosage forms and strengths with the same active moiety / active ingredient and the same holder of a NDA / BLA, inclusive of products that are marketed pursuant to different NDA(s) / BLA(s). Therefore, in cases when different dosage forms and strengths, as well as different formulations, containing the same active moiety / active ingredient may be payable under Part B or covered under Part D, CMS will aggregate such

dosage forms and strengths or formulations under the same potential qualifying single source drug.

Section 1192(d)(2)(A) of the Act states that a negotiation-eligible drug will not include a qualifying single source drug that meets the criteria in either section 1192(d)(2)(a)(i) of the Act or section 1192(d)(2)(a)(ii) of the Act. For initial price applicability year 2028, and as described in more detail in section 30.2.1 of this final guidance, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the criteria for a drug payable under Part B *or for* a drug covered under Part D. CMS will make separate determinations with respect to the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"), and the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track").

To be eligible for an SBE for the Part D Track, the Total Expenditures during 2021 under Part D for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and (2) equal to at least 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 Coverage Gap Discount Program (CGDP) Agreement in effect on December 31, 2021. To be eligible for an SBE for the Part B Track, the Total Expenditures during 2021 under the Part B for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid 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.

Selection of Drugs for Negotiation for Initial Price Applicability Year 2028 (Section 30.3)

Comment: A couple of commenters requested greater transparency into the process of selecting drugs for negotiation. One of these commenters recommended that, well in advance of the selected drug publication date, CMS should notify manufacturers of drugs that CMS intends to select and provide each manufacturer an opportunity to dispute such intended selection. This same commenter recommended that CMS provide the same notification and opportunity to dispute to each manufacturer of at least the next five drugs that would be selected if one or more of the drugs CMS intended to select were found ineligible for selection. This commenter also recommended for CMS to make publicly available the Medicare expenditure data it is using in its identification of negotiation-eligible drugs for the selection years, as the data in the Medicare spending dashboards is the only data that is currently publicly available. They stated that their understanding that this is not the source for CMS' determination of negotiation-eligible drugs. The other commenter also stated that manufacturers do not have access to the same data that CMS has and suggested that CMS provide more detail on how expenditures are actually aggregated and drugs are ranked, as well as reasons why high expenditure drugs are excluded.

Response: CMS thanks the commenters for sharing their perspectives. The statute requires that CMS publish the selected drug list no later than February 1, 2026 for initial price applicability year 2028. Similar to CMS' response on pages 26 and 27 of the final guidance for initial price applicability year 2027, CMS believes that disclosing to manufacturers whether their drug is a

selected drug before this 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 February 1, 2026. For example, section 1192(d)(1)(A) of the Act requires that CMS identify negotiation-eligible drugs for initial price applicability year 2028 using Total Expenditure data during the most recent 12-month period for which data are available prior to February 1, 2026. As discussed in section 30 of this final guidance, Total Expenditures under Part D will be calculated using PDE data for dates of service between November 1, 2024 and October 31, 2025. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service during this 12-month period that is available to CMS by December 1, 2025. The complexity of the data analyses and quality checks that must then be performed on the data forecloses the possibility of notifying manufacturers that their drug is a selected drug or providing a dispute process as suggested by commenters prior to the publication of the selected drug list for initial price applicability year 2028. CMS appreciates feedback received on the Medicare Spending Dashboards. Similar to CMS' response on page 26 and 27 of the final guidance for initial price applicability year 2027, these dashboards allow for a longer claims runout to provide time for claims to be submitted, processed, and finalized than is possible for the data that CMS is statutorily required to use to identify and rank negotiation-eligible drugs. To provide transparency and more timely data to interested parties, CMS plans to release quarterly Part B and Part D drug spending datasets in the near future.[24]

CMS is taking additional steps to promote transparency in the Negotiation Program. As described in section 30.4 of this final guidance, CMS will also publish a list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D, as described in section 30.3 of this final guidance, and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable. Additionally, CMS will publish the list of drugs selected for renegotiation, if any, no later than February 1, 2026, as described in section 130.2.2 of this final guidance.

Biosimilar Delay (Section 30.3.1)

Comment: A couple of commenters suggested that CMS provide greater transparency with the requirements to delay the inclusion of a negotiation-eligible drug that includes the reference product for biosimilar. Specifically, one commenter urged CMS to have more open communication with manufacturers so that they can better understand the likelihood of drug selection and appropriately anticipate the likelihood of biosimilar approval launch timelines for the biosimilar of a selected drug. Additionally, a few commenters requested that CMS provide advance notice of a reference product's potential or actual selection, to the Primary Manufacturer and/or the manufacturer of the biosimilar, including for example, providing advance notice to a Primary Manufacturer of potential selection at least one quarter before publication of the selected drug list. The commenters suggested that the pre-selection notification period would permit manufacturers of the biosimilar to inquire if a particular Reference Drug is likely to be included on the selected drug list and properly prepare any delay request or raise any concerns. One

[24] See: https://www.cms.gov/blog/cms-drug-spending-dashboards-and-inflation-reduction-act, https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard, and https://data.cms.gov/tools/medicare-part-d-drug-spending-dashboard.

commenter suggested that CMS automatically delay selection of a reference product if a request for a biosimilar delay is submitted in order to provide CMS adequate time to evaluate the request. Finally, a couple of commenters requested that CMS provide the underlying data used for the basis of qualifying single source drug and negotiation-eligible drug determinations. One commenter also requested CMS publish a list of all reference products for the requests that were submitted.

Response: CMS thanks the commenters for their suggestions. Consistent with CMS' response to similar comments on page 27 of the final guidance for initial price applicability year 2027, this final guidance 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 has been set as close to the selected drug publication date as is administratively feasible. CMS adopted this timeline under the authority granted to it in section 1192(f)(1)(B)(ii) of the Act to set the time, form, and manner of Biosimilar Delay requests, and has exercised this authority to establish a timeline (which is described in sections 30.3.1 and 30.3.1.1 of the final guidance) 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 CMS 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.

Finally, 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, CMS reiterates the response provided to similar comments on page 22 of 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 30.3.1.1 of this final guidance, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request of CMS' determination regarding such request on or after the date that the selected drug list for initial price applicability year 2028 is published, but not later than February 28, 2026. CMS will also notify each Primary Manufacturer of the reference Drug (the "Reference Manufacturer") named in a successful Initial Delay Request and will identify the Reference Drug that would have been a selected drug, absent the successful Initial Delay Request. Further, CMS will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2028, absent successful Initial Delay Requests, as part of publishing the selected drug list no later than February 1, 2026.

Comment: A couple of commenters asked CMS to allow submissions of requests as close as reasonably possible to the publication of selected drugs to ensure that decisions are informed by the most recent developments. These commenters also suggested CMS accept supplemental and late-breaking information that may impact CMS' determination. One commenter supported the use of the January 15, 2026 date for updating CMS on the status of the Biosimilar's application for licensure because of the importance of providing the most up-to-date information to CMS prior to drug selection.

Response: CMS thanks commenters for this feedback. Consistent with the response to the comments immediately above, 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. As noted by one of the commenters, CMS already includes an additional date for updating CMS on the status of the Biosimilar's application for licensure in instances where updates since the submission of the request for the biosimilar delay may satisfy the eligibility criteria.

Comment: A couple of commenters requested that CMS clarify what types of agreements are considered to "incentivize" a Biosimilar Manufacturer to request a delay or otherwise disqualify a Biosimilar from eligibility. One of these commenters also suggested that an agreement should only disqualify a Biosimilar if the agreement explicitly requires the submission of an Initial Delay Request by the Biosimilar Manufacturer from the manufacturer of the reference product. One commenter supported CMS' review of the requirements regarding agreements to address what the commenter referred to as "pay for delay" arrangements between the manufacturers.

Response: CMS thanks the commenters for these questions. Consistent with CMS' responses on page 29 of the final guidance for initial price applicability year 2027 and pages 21 and 25 of the revised guidance for initial price applicability year 2026, CMS reiterates 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. CMS confirms 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. However, if CMS determines that the agreement has the characteristics described in section 1192(f)(2)(D)(iv) of the Act, then CMS cannot provide a Biosimilar Delay.

Comment: A couple of commenters requested that CMS create a dispute resolution process for CMS' determination that a Biosimilar does not qualify for the biosimilar delay.

Response: CMS thanks these commenters for their recommendations. CMS declines 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, CMS believes that there is enough time during the submission window for manufacturers to provide the relevant data to support their

application for the exception and declines to use a dispute resolution process for a manufacturer to supplement a submission.

Comment: One commenter asked CMS to clarify if CMS intends the phrase "reference product included in the Reference Drug" to mean the same as "presentation included in the Reference Drug," and, if so, the commenter requests CMS to revise the term in the guidance. This commenter stated that use of "reference product" is inconsistent with FDA and industry terminology. This commenter suggested the term CMS used in the draft guidance for initial price applicability year 2028 appears to be intended to capture presentations (e.g., dosage form, strength, route of administration) in the BLA, but, if CMS intends otherwise, the commenter requests CMS clarify use of "reference product."

Response: As specified in section 30.3.1.1 of this final guidance, and consistent with other uses of "reference product" in the Act (e.g., section 1192(e)(1(B) regarding biosimilars that are licensed and marketed), the reference product refers to a biological product that is included in the negotiation-eligible drug as defined in section 30.1 of this final guidance and is the reference product for a Biosimilar. CMS clarifies that the commenter's characterization of "presentations" is different than FDA's use of the term "presentation". CMS declines to revise the term(s) used in this final guidance because "reference product," as discussed in this response, is consistent with the statutory term used to discuss the delay of selection for a biosimilar and other uses of the term in the statute.

Comment: A couple of commenters asked CMS to clarify how CMS determines if the Biosimilar is "operationally ready".

Response: In section 30.3.1.3 of this final guidance and for purposes for an Initial Delay Request, CMS specifies that, consistent with 1192(f)(1)(B)(ii) of the Act, CMS will assess if the Biosimilar Manufacturer is operationally ready by reviewing 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 February 1, 2028; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. The Biosimilar Manufacturer should demonstrate this component of the "clear and convincing evidence" requirement within the statutorily-required documentation specified in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act.

Further progress in operational readiness is also considered for purposes of an Additional Delay Request, as discussed further in the response to the comment about "a significant amount of progress" below and in section 30.3.1.4 of this final guidance.

Comment: A couple of commenters asked CMS to clarify what meets the requirements to be "clear and convincing evidence" of a "significant amount of progress" to successfully determine an Additional Delay Request. A couple of commenters shared feedback on specific evidence for an Additional Delay request. One commenter suggested that the Biosimilar Manufacturer be required to share evidence, only when new evidence was available, to reduce the Biosimilar

Manufacturer's burden in submission of the request. Some specific examples suggested by commenters as examples of clear and convincing evidence of a significant amount of progress for an Additional Delay Request included: the first cycle of FDA review of the Biosimilar remains ongoing and FDA has issued a complete response letter to the Biosimilar Manufacturer denying the Biosimilar but the Biosimilar Manufacturer has resubmitted the BLA.

Response: As discussed in section 30.3.1 of this final guidance, CMS did not grant any Initial Delay Requests for initial price applicability year 2027; therefore, Additional Delay Requests are not relevant for initial price applicability year 2028. However, CMS is providing more information about the Additional Delay Request process within this final guidance to respond to previous comments requesting information about this topic and CMS will provide more information in rulemaking applicable to future initial price applicability years.

Sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act specify the documentation CMS must rely on to determine if the Biosimilar Manufacturer demonstrates that there is clear and convincing evidence of a high likelihood that the Biosimilar will be marketed by the High Likelihood Deadline. In section 30.3.1.3 of this final guidance, CMS specifies that to establish clear and convincing evidence CMS will look for the Biosimilar Manufacturer to demonstrate, within this documentation, both that: (1) patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) the Biosimilar Manufacturer will be operationally ready to market the Biosimilar.

As discussed in section 30.3.1.4 of this final guidance, CMS will use a holistic review of the documentation submitted by the Biosimilar Manufacturer with the Additional Delay Request, including the statutorily-required documentation specified in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act to demonstrate the clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, and to determine 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. Specifically, CMS is looking to see that the Biosimilar Manufacturer has made affirmative progress towards being operationally ready to market the Biosimilar by the High Likelihood Deadline. Therefore, it would not be sufficient for a Biosimilar Manufacturer to only provide CMS with new information when available, as some commenters suggested, as CMS must holistically review the required documentation to determine if there is clear and convincing evidence of significant progress from CMS' initial review. To conduct this new review, similar to CMS' initial review for a determination of an Initial Delay Request, CMS will consider 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 February 1, 2028; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. However, for an Additional Delay Request, CMS is also comparing such actions, activities, and milestones in comparison to the Biosimilar Manufacturer's affirmative progress, holistically, since CMS reviewed such information for purposes of the successful Initial Delay Request for the Biosimilar.

Comment: A few commenters requested that CMS clarify what patents would be considered "related to the Reference Product." Additionally, commenters asked CMS to clarify if a carved-out patent-protected indication is not applicable to the Biosimilar.

Response: CMS thanks commenters for questions. Under section 1192(f)(1)(A) of the Act, the Reference Drug at issue for the Biosimilar Manufacturer's request for a biosimilar delay 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 by FDA or accepted for review. Accordingly, a patent related to the reference product is a patent that would be related to the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by FDA or accepted for review. As specified in section 30.3.1.3 of this final guidance, 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 would not be considered to be "applicable to the Biosimilar."

Comment Solicitations on Patent Documentation
Comment: Many commenters responded to CMS' request for comments regarding additional or alternative evidence that may demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline. These commenters generally suggested that CMS should permit use of additional or alternative evidence to demonstrate a high likelihood of marketing. Some of these commenters suggested that CMS rely on documentation of industry-recognized milestones in a patent dispute to demonstrate clear and convincing evidence of a high likelihood of marketing, for example, that the court has issued neither preliminary injunction nor permanent injunction preventing launch within the relevant time period. A couple of these commenters suggested CMS should consider that issuance of the notice of first commercial marketing from the Biosimilar Manufacturer to the Reference Product sponsor no later than 180 days before first marketing as evidence of a high likelihood of marketing. Additionally, some of these commenters suggested that CMS had broad authority to consider any evidence from the Biosimilar and/or Reference Product Manufacturer under section 1192(f)(1)(B)(ii)(II) of the Act, and such evidence might include press statements, investor meetings/reports, and corporate director statements.

Some commenters also provided responses to CMS' request for comments on whether CMS should consider public-facing statements in which the Biosimilar Manufacturer asserts that ongoing patent disputes will be resolved within the relevant time period for the High Likelihood Deadline. A couple of these suggested that because a Biosimilar Manufacturer or a Reference Product Manufacturer must provide information in the statutorily-required documentation based on fiduciary and legal requirements of the originating documentation, that CMS could reasonably rely on a statement from a fiduciary representative that the Biosimilar would be marketed by the High Likelihood Deadline. Commenters also suggested CMS consider as evidence, for example, that a Biosimilar Manufacturer certifies that no valid patents will be infringed once the Biosimilar is launched, an executive summary of a law firm's assessment of the asserted patents' invalidity and non-infringement, and a Biosimilar's market entry forecast by an industry-leading analytics firm based on data-driven forecast of anticipated market entry based on tracked litigation and mapping of the patent landscape.

Finally, a few commenters responded to CMS' request for comments on whether investments in operationalization efforts, or other Biosimilar Manufacturer activity, may be evidence that demonstrates a patent dispute will be resolved or not prevent marketing of the Biosimilar by the High Likelihood Deadline. These commenters supported CMS' use of additional evidence to demonstrate operational readiness. Commenters provided a variety of suggestions for documentation that would demonstrate operational activity, including: investor disclosures with plans to market, or the manufacturing schedule submitted to FDA for the Biosimilar indicates that commercial lots of the Biosimilar are expected to be produced before the end of the relevant period; the Biosimilar Manufacturer has not stated in its disclosures to investors or in filings to the Securities and Exchange Commission (SEC) (e.g., Forms 10-K or 10-Q), that it will not market the Biosimilar by the High Likelihood Deadline; the Biosimilar Manufacturer has not withdrawn its BLA; the Biosimilar Manufacturer is not in arrears for any user fees due under section 744H of the FD&C Act for the BLA; and that no manufacturing facility where the Biosimilar is made or processed has a classification of Official Action Indicated. A couple of commenters also suggested that CMS consult and make determinations in conjunction with the FDA. One commenter noted that given the interplay of the biosimilar development timeline and the statutory requirements for a request for a biosimilar delay and drug selection (e.g., a drug may be selected for negotiation after 11 years, but a BLA may not be approved until 12 years after the Reference Product's licensure) that CMS should consider earlier markers of a high likelihood of licensure. Specifically, one of these commenters suggested the FDA could advise CMS on whether the Biosimilar Manufacturer has held a Biological Product Development Type 4 Meeting that occurs prior to filing of a BLA with the FDA or has undergone a manufacturing facility inspection. The commenter suggested FDA advisement would be also helpful for determinations of a "significant amount of progress" for an Additional Delay Request.

Response: CMS thanks commenters for their feedback. CMS appreciates commenters' concerns that the current items a Biosimilar Manufacturer may use to demonstrate patent barriers are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline in section 30.3.1.3 of this final guidance may prevent certain manufacturers from eligibility for the biosimilar delay, for example, if the litigation on patents related to the Reference Product is ongoing. In response to similar concerns raised by commenters in previous years, CMS reiterates that CMS remains bound by the statutory constraints that the Biosimilar Manufacturer must provide "clear and convincing evidence," to be found in the documentation specified in sections 1192(f)(1)(B)(ii)(I)(bb) and (III)[25] of the Act that the Biosimilar has a high likelihood to be marketed by the High Likelihood Deadline. Despite the potentially unpredictable nature of the litigation process, CMS recognizes that representatives of a manufacturer have fiduciary obligations as company representatives and legal disclosure requirements under the Securities

[25] 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 (e.g., 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 biological product.

Act of 1934 for publicly traded companies. Therefore, CMS believes that it is consistent with section 1192(f)(1) of the Act and CMS policy at section 30.3.1.3 of this final guidance, for the items that demonstrate patents related to the Reference Drug are unlikely to prevent a Biosimilar from being marketed before the High Likelihood Deadline, to add to item (2) that a Biosimilar Manufacturer may demonstrate that neither a court nor the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) has adversely ruled against the Biosimilar Manufacturer's legal 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 clearly specified a launch date for the Biosimilar that is a calendar date before the High Likelihood Deadline; further, the launch date must not be contingent on the outcome of pending litigation. CMS believes that the revision is also responsive to commenters' suggestions to consider a Biosimilar Manufacturer's affirmative actions towards production, and demonstration of the lack of any negative actions thwarting progress. Additionally, CMS revised item (1) to read that "there *will be* no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar," instead of "there *are* no unexpired patents…" to account for patents related to the Biosimilar that may expire after submission of the request is required but before the High Likelihood Deadline.

CMS declines 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. CMS does not believe that this information alone is "clear and convincing." Additionally, CMS disagrees with commenters' suggestions that the statute permits CMS to consider an attestation as evidence separate from the specified documentation in the statute. Further, in response to commenters' suggestions to use any evidence as acceptable evidence under section 1192(f)(1)(B)(ii)(II) of the Act, CMS notes that this provision applies only after CMS has first reviewed the information submitted in accordance with sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act and CMS determines that additional information is needed from the Biosimilar Manufacturer.

Finally, as requested by commenters and to provide transparency regarding examples of the type of information CMS may identify as "clear and convincing evidence" in the documentation required at 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, CMS includes examples of evidence in section 30.3.1.3 of this final guidance. Specifically, as described in section 30.3.1.3 of this final guidance, these examples could include: (1) the listing of a signed legal 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 FTC or 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 legal 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 specifies a 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, and (3) 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 examples are illustrative but alone may not always constitute "clear and convincing evidence" of a high likelihood of marketing.

Publication of the Selected Drug List (Section 30.4)

Comment: Some commenters were in favor of CMS publishing a list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D by February 1, 2026, for initial price applicability year 2028. The commenters all noted that this would provide transparency and allow manufacturers and interested parties to better anticipate which drugs will be selected in future initial price applicability years. One of the commenters recommended that CMS clearly state that the list is for informational purposes only and potentially subject to change in future years in order to avoid any confusion. One of the commenters suggested that CMS publish the list of negotiation-eligible drugs, and potentially the list of selected drugs, sooner than the February 1 deadline required by statute, as soon as December or January. This same commenter suggested that CMS promote transparency by publishing information on the drugs ranked in the top 50 spend in its published list for a given initial price applicability year, but were excluded on the basis of the orphan drug exclusion or, at a minimum, by publishing the number of drugs that were excluded under the orphan drug exclusion. One commenter was opposed to publication of the top 50 negotiation-eligible drugs ranked by combined Total Expenditures under Part B and Part D at all, noting that publishing such a list is not required by statute. The commenter raised concerns that this list could lead to plans proactively adjusting formulary placement of drugs that are likely to be selected, and that generics and biosimilars for drugs that appear on the top 50 list will be less likely to come to market.

Response: CMS thanks the commenters for their support and feedback. CMS agrees that publishing the list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D, as described in section 30.3 of this final guidance, and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable, will promote transparency into the drug selection process. CMS affirms that, with the exception of the top 15 drugs on this list, which are the selected drugs for initial price applicability year 2028, the list of up to 50 top negotiation-eligible drugs will be published for informational purposes only. 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 are not static, and this list is therefore not intended to predict or replicate the selected drug list for future initial price applicability years. In response to the commenter who requested that CMS publish information about drugs that would have been included in the negotiation-eligible drug list but for the Orphan Drug Exclusion, CMS reminds the commenter that the Orphan Drug Exclusion is an exclusion from the definition of a qualifying single source drug under section 1192(e) of the Act. CMS therefore does not assess whether a potential qualifying single source drug that qualifies for the Orphan Drug Exclusion would have become a negotiation-eligible drug absent the Orphan Drug Exclusion.

In response to the commenter who suggested that CMS publish the list of negotiation-eligible drugs, and potentially the list of selected drugs, sooner than the February 1 deadline, as discussed in CMS' response on page 26 of the final guidance for initial price applicability year 2027, CMS believes that committing to publishing the selected drug before this 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 February 1. Similarly, CMS believes that committing to publishing the list of negotiation-eligible drugs before this date is also operationally infeasible due to the same reasons.

CMS acknowledges the one commenter's concerns that the publication of the up to 50 top negotiation-eligible drugs could impact formulary placement of certain drugs or generic and biosimilar entry. CMS directs readers to section 110 of this final guidance for further information about CMS' policies on formulary inclusion and intent to monitor Medicare Part D plans' compliance with all applicable formulary requirements and treatment of drugs. CMS believes that publishing the list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable, provides important transparency under the Negotiation Program.

Requirements for Manufacturers of Selected Drugs (Section 40)

Comment: One commenter asked CMS to not hold Primary Manufacturers liable for any violations of Secondary Manufacturers with respect to making the MFP accessible to eligible entities and that CMS should sign separate agreements with Secondary Manufacturers.

Response: As discussed in CMS' response on page 35-36 of 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 an Agreement with "the manufacturer" of a selected drug, where "the manufacturer" is the NDA / BLA holder as described in section 40 of this final guidance. 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).

Confidentiality of Proprietary Information
Comment: A few 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 access that include use by CMS staff only on a "need-to-know" basis. Another commenter shared examples of other CMS programs, such as the Medicaid Drug Rebate Program (MDRP), with systems that include multilayered privacy and security protections to safeguard sensitive manufacturer data, including pricing information. One commenter noted that CMS does not specify a data destruction schedule for the data submitted through the Negotiation Program.

Response: CMS thanks the commenters for their comments on safeguarding data submitted by manufacturers. Consistent with CMS' response starting on page 37 of the final guidance for initial price applicability year 2027, CMS reaffirms its commitment to protect sensitive and confidential data submitted by Primary Manufacturers and continues 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, CMS 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. CMS includes below the information previously provided in response to similar comments received for initial price applicability years 2026 and 2027 and CMS believes this information is both adequate to detail the protocols and safeguards used in handling manufacturer-submitted data and, as discussed in further detail below, 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, Box.[26] Box provides a secure way to share content and improve collaboration both within CMS and with our partners. 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 personally identifiable information (PII), protected health information (PHI), and agency sensitive information. Inviting collaborators through named email addresses of authorized individuals is the preferred method for this collaboration to ensure the confidentiality and integrity of the content being shared.

The CMS HPMS adheres to all applicable policies, procedures, controls, and standards required by the Department of Health and Human Services (HHS)/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

[26] If CMS specifies an alternative secure location to Box, CMS will provide updated instructions and information to Primary Manufacturers.

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 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 (e.g., 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.

Comment: One commenter acknowledged the Negotiation Program's confidentiality policies as described in section 40.2.1 of the draft guidance for initial price applicability year 2028, including Exemptions 3 and 4 of the Freedom of Information Act (FOIA), but asked CMS to confirm if the Negotiation Program also maintains the confidentiality of information protected against disclosure under all other federal price reporting law and policy.

Response: Consistent with our response on page 34 of the revised guidance for initial price applicability year 2026, 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. CMS is 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 process. For initial price applicability year 2028, as described in section 40.2.1 of this final guidance, 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

U.S.C. § 1905 requires executive branch employees to protect trade secrets and certain other information. CMS understands 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, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this final guidance.

Comment: A couple 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. One of these commenters suggested CMS publish aggregate or de-identified data summaries and create a petition process to reconsider redacted information. When the statute is silent regarding confidentiality or disclosure of a particular piece of information, another of these commenters suggested CMS solicit comment on the data element in question to weigh the benefit of disclosure versus risk of potentially sensitive market information.

Response: Consistent with our responses on pages 36 and 129 of the final guidance for initial price applicability year 2027 and page 68 of the revised guidance for initial price applicability year 2026, CMS is committed to a negotiation process that is transparent and respects confidentiality of proprietary information. CMS appreciates the need to balance transparency in the negotiation process with the need to maintain the confidentiality of certain information, including manufacturers' proprietary data. As discussed in section 60.6 of this final guidance, CMS 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 CMS publishes as part of the public explanation of the MFP and any other public documents related to the MFP and negotiation process will abide by the confidentiality policy described in section 40.2 of this final guidance and will redact proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law.

Providing Access to the MFP in 2026, 2027, and 2028 (Section 40.4 and 90.2)

Comment: One commenter expressed concern that pharmacies would be reimbursed by Part D plan sponsors and PBMs below the MFP for selected drugs. The commenter requested that CMS ensure Part D plan sponsors and PBMs reimburse pharmacies at the MFP, plus a dispensing fee, and without pharmacy price concessions. This commenter also asserted that the IRA does not expressly prohibit the Secretary from ensuring that pharmacies are not reimbursed less than the MFP for selected drugs and that the amended definition of negotiated price does not include price concessions. One commenter suggested that CMS require that plan reimbursement for selected drugs include an enhanced dispensing fees for selected drugs to cover increased operating costs of pharmacies related to dispensing selected drug.

Response: CMS thanks these commenters for their recommendations. CMS expects 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.

CMS will closely monitor for whether further programmatic adjustments are needed to address any contrary practices that emerge. As described in section 60.1 of this final guidance, CMS interprets 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. As noted in CMS' response to a similar comment on pages 39-40 of the final guidance for initial price applicability year 2027, 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 such drug. CMS is not establishing requirements for dispensing fees for selected drugs at this time but will monitor complaints and audits related to this issue. CMS encourages plan sponsors to work with pharmacies to ensure adequate and fair compensation for dispensing selected drugs.

Furthermore, CMS intends to closely monitor plan reimbursement for selected drugs including pharmacy price concessions, and as described in section 110 of this final guidance, monitor plan compliance with other requirements (e.g., the formulary inclusion requirement under section 1860D-4(b)(3)(I) of the Act).

Comment: Some commenters expressed support for CMS' centralized approach to facilitating data and payment through the MTF DM and MTF PM, arguing that this centralized structure promotes standardization, predictability, and reduces operational burden on stakeholders responsible for implementing these programs while asserting that there are currently no private market solutions that offer the MTF's end-to-end capabilities. A few commenters recommended that CMS should maintain and invest in the MTF infrastructure during the initial years of implementation to avoid unnecessary administrative burden for manufacturers, pharmacies, and plans, with one commenter citing the potential cost and complexity of developing independent systems. Another one of these commenters stated that several entities are working to develop private market solutions, though none of these solutions will be able to transmit MFP refund payments from manufacturers to dispensers before mid-2026 at the earliest. One commenter requested that CMS ensure that dispensing entities are not financially burdened through additional fees if a private market alternative is developed and leveraged in place of the MTF.

A few commenters suggested that any future private market solution for the MTF should serve as an alternative to rather than a replacement for the MTF PM. A couple of commenters recommended that CMS wait until initial price applicability year 2028 concludes before seeking feedback on private market alternatives for MFP effectuation. One commenter expressed that CMS' policies related to MFP effectuation, including use of the MTF, are operationally complex and will be less efficient and more expensive than existing private market solutions. This commenter requested CMS explore alternatives to the MTF, including by relying on existing data flows, and refrain from imposing barriers to interested parties through new complex requirements. One commenter urged CMS to explore a private market solution because the commenter disagreed with the shortened PDE submission window for selected drugs. A couple of commenters shared specific data platforms that they believe could offer alternatives to the MTF in the private market.

Response: CMS thanks these commenters for their suggestions related to the request for input regarding potential private market solutions that could offer an alternative to the MTF and the

extent to which interested parties perceive a need for ongoing MTF support over time. At this time, Primary Manufacturers and dispensing entities that have entered into network pharmacy agreements with Part D plan sponsors will be required to enroll in the MTF DM, and we expect that Primary Manufacturers will use the MTF platform (including the voluntary MTF PM) to support access to the MFP for a selected drug starting January 1, 2026. CMS plans to continue to support MTF operations through 2028 and intends to monitor potential private sector alternative solutions for sharing verified data or for routing MFP refund payments from manufacturers to dispensing entities.

Comment: One commenter recommended CMS allow plans to negotiate rates for selected drugs that are lower than the MFP, rather than being required to adopt the MFP.

Response: 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. CMS has not prohibited plans from negotiating rates for selected drugs that are lower than the MFP.

Comment: One commenter asserted that the IRA required CMS to ensure prospective access to the MFP for selected drugs. One commenter recommended that CMS support a strategy for manufacturers to prospectively provide access to the MFP rather than providing access to the MFP through the retrospective MTF process. A few of commenters stated that, if required by a manufacturer to purchase retrospectively, pharmacies would have to purchase the drugs at a higher price and be exposed to financial shortfalls until receiving the MFP refund retrospectively. One of these commenters asserted that this process would lead to more independent pharmacies going out of business. A couple of commenters requested that CMS remove the retrospective access to the MFP framework from the guidance and adopt a framework for prospective access to the MFP. One commenter requested that in future initial price applicability years, CMS should explore an MFP effectuation process that occurs upstream in the payer process and does not place financial constraints on pharmacies. One commenter recommended CMS consider the use of voluntary claims identifiers for selected drugs prospectively purchased at the MFP.

Response: CMS appreciates the perspectives shared by these commenters. As CMS stated in response to similar comments on page 43 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, a Primary Manufacturer may provide access to the MFP prospectively or retrospectively. In section 40.4 of this final guidance, CMS maintains that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. Recognizing that there may be advantages and disadvantages to both approaches, CMS encourages Primary Manufacturers and dispensing entities to work together to reach agreements as to whether the dispensing entity will access the MFP prospectively or retrospectively for a given MFP-eligible claim. As described in sections 40.4.2 and 40.4.3 of this final guidance, the MTF will support Primary Manufacturers and dispensing entities using either option. Specifically, the MTF will support data exchange and optional payment facilitation for Primary Manufacturers using the MTF's optional payment facilitation functionality, provide a process for Primary Manufacturers

to document retrospective MFP refunds made outside of the MTF's optional payment facilitation functionality, and provide a process to exclude MFP refunds on claims when the prospective approach was used. In response to concerns that dispensing entities would be exposed to financial shortfalls until receiving the MFP refund retrospectively, CMS is committed to the goal of assuring prompt payment to dispensing entities, consistent with other prompt pay rules in Part D, and is requiring the Primary Manufacturer to transmit payment of an amount that provides access to the MFP within 14 days of the MTF transmitting to the Primary Manufacturer data elements confirming an individual is eligible for the MFP. Please refer to sections 40.4 and 90.2 of this final guidance for more information. Additionally, section 40.4.2.2 of this final guidance describes a process for dispensing entities to self-identify as dispensing entities that anticipate material cashflow challenges because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and section 90.2.1 of this final guidance describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns for such dispensing entities in their MFP effectuation plans.

Comment: One commenter requested CMS publicly report metrics on pharmacy enrollment and other aspects of the MTF DM and PM rollout before initial price applicability year 2026 and publish more detailed information on the MTF testing scope and timeline process.

Response: CMS thanks the commenter for this suggestion. CMS is committed to continued stakeholder engagement as preparations for MFP effectuation in 2026 continue, including providing information and support for stakeholders during enrollment, onboarding, and testing of the MTF. CMS anticipates continuing to release pertinent information on a regular basis through our dedicated MTF webpages, listservs, and monthly stakeholder calls. CMS is dedicated to working closely with those stakeholders most directly involved in 2026 MFP effectuation (namely, Primary Manufacturers with selected drugs for initial price applicability year 2026 and the entities dispensing those drugs) on MTF enrollment, onboarding, and testing prior to January 1, 2026.

Comment: A few commenters provided feedback on the MTF development process, including requests related to meeting cadences with CMS to work on solution development and implementation, to request direct engagement with the MTF PM, and to provide feedback on the testing schedule for the MTF, among other topics

Response: CMS thanks these commenters for their comments. MTF development continues to proceed on schedule, and throughout the MTF development process, CMS has remained committed to continuing engagement with manufacturers during development, onboarding, and testing of the MTF ahead of the effective date for MFPs of selected drugs for initial price applicability year 2026 and will continue this engagement with manufacturers as the MTF is implemented and additional manufacturers and selected drugs are added as part of future initial price applicability years. Specifically, CMS has hosted and continues to host monthly manufacturer calls, which include a time set aside for question and answer and discussion with manufacturers. CMS has hosted individual technical working sessions with initial price applicability year 2026 Primary Manufacturers and has routinely answered technical questions submitted via email. Manufacturer end-user testing began in July and is proceeding with routine testing phases, office hours, and individual manufacturer engagement through Fall 2025, which

will incorporate additional testing of both the MTF DM and MTF PM. CMS is routinely publishing new information on MTF development as it is available, including published development milestones, Interface Control Documents, FAQs, and support resources (including videos and user guides with technical instructions).

Comment Solicitation on a Fact-Based Assessment When Determining Whether a Primary Manufacturer Provided Access to the MFP

Comment: CMS received some comments in response to CMS' comment solicitation in section 90.2 of the draft guidance for initial price applicability year 2028, regarding CMS' plan to undertake a fact-specific assessment when determining whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug. One commenter expressed concern that the factors CMS considers for its fact-specific assessment are overly broad, particularly the factor of "whether the retrospective refund amount…is sufficient to account for commercially reasonable costs the dispensing entity is likely to encounter in the supply chain." Other commenters echoed similar concerns, asking for clarification on "commercially reasonable costs" and asserting that factor should be limited to statutory obligations. One commenter warned that the commercially reasonable costs criterion may provide incentives for abusive practices and manipulation by supply chain entities. A couple of other commenters stated that "commercially reasonable costs" should include all costs to dispense, and pharmacies should not be expected to dispense MFP drugs below their full and complete costs to acquire and dispense.

Response: CMS thanks these commenters for their feedback. In response to the concerns raised, and as a result of efforts by CMS to build out the operational process for assessing whether or not the MFP has been made available, CMS has provided additional detail on the approach outlined in this final guidance that CMS will use when evaluating whether or not a Primary Manufacturer has provided access to the MFP to a dispensing entity as part of general oversight activities and when making case-specific determinations with respect to whether MFP was made available in specific circumstances. First, CMS describes in section 90.2 of this final guidance that, in the absence of information available to CMS indicating otherwise, CMS will consider WAC to be an appropriate proxy for a dispensing entity's acquisition cost when monitoring and assessing compliance with a Primary Manufacturer's obligation to effectuate the MFP. Therefore, in the absence of information indicating otherwise, CMS will consider provision of the standard default refund amount (SDRA) (defined as WAC minus the MFP) to meet the Primary Manufacturer's obligation to make MFP available.

Additionally, CMS has provided additional information on the process that CMS will use when engaged in a case-specific determination as to whether the Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug when reviewing cases as a result of a complaint, an audit, or other compliance monitoring or investigations. CMS will consider contextual information available to the agency, including, as applicable: the invoice amount from the dispensing entity (if available); documentation maintained by the Primary Manufacturer supporting its MFP refund amount (as described in section 40.4.3.1 of this final guidance); the MFP refund amount provided by the Primary Manufacturer, based on the amount indicated in the "Total MFP Refund Amount" field on the Primary Manufacturer's claim-level payment elements, where available, or as determined based on other supporting documentation

in the event the claim-level payment elements are deemed to be inaccurate; other documentation regarding the dispensing entity's actual acquisition costs such as documentation of an arrangement for prospective purchase at the MFP or other alternative arrangement evidencing acquisition cost (e.g., establishment of an agreed-upon proxy for MFP refund calculation as described in section 40.4.1 of this final guidance); and the commercial reasonableness of costs incurred by the dispensing entity related to the procurement of the selected drug (if available). Supply chain costs would be considered as part of CMS' review of the commercially reasonable costs incurred by the dispensing entity related to the procurement of the selected drug, if available.

Comment: CMS received a couple of comments regarding the type of information that may be considered when assessing whether or not the MFP has been made available. One commenter argued that pharmacies should not be forced to submit invoices for any reason and urged CMS to clarify that manufacturers may not request pharmacy invoices for drugs purchased through a wholesaler. This commenter also requested clarification that manufacturers should not use pricing data from other pharmacies or pricing metrics such as Predictive Acquisition Cost (PAC), Maximum Allowable Cost (MAC), or National Average Drug Acquisition Cost (NADAC) when determining acquisition cost for a specific dispensing entity. Another commenter requested clarification that complaint submissions without evidence will not be accepted.

Response: CMS thanks these commenters for their input. CMS provides relevant content in section 90.2 of this final guidance, and encourages dispensing entities to review accounts receivable to assess whether the Primary Manufacturer has accurately paid all claims the dispensing entity believes are MFP eligible. While CMS encourages dispensing entities and manufacturers to work together to resolve any discrepancies, this guidance does not require that pharmacies provide manufacturers with invoices during this process. As described in section 90.2.1 of this final guidance, should a dispensing entity submit a complaint for review and investigation by CMS, CMS may require supporting documentation (e.g., invoices, purchase orders) in the course of assessing the complaint. CMS does not intend to make such documentation directly available to manufacturers (though information shared by the dispensing entity may be used by the agency in making a determination as to MFP availability and calculating civil monetary penalties (CMPs), which will be disclosed to Primary Manufacturers); CMS refers these commenters to the Privacy Statement included in the Drug Price Negotiation Program Complaint and Dispute Intake Form[27] that notes, among other things, that "information transmitted in [the complaint and dispute intake] form will be stored in a secure environment and only accessible by authorized users."

As described in section 90.2 of this final guidance, as part of a fact-based assessment to determine whether MFP was made available, CMS may request additional information from relevant parties, including dispensing entities, to further its inquiry. There will likely also be circumstances, such as where a dispensing entity is filing a complaint related to MFP availability, where documentation may be provided as part of the complaint. Section 90.2.2 of this final

[27] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that dispensing entities will be required to provide. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

guidance describes that such complaints "should include supporting documentation, such as an open accounts receivable demonstrating that the Primary Manufacturer did not provide access to a price for the selected drug that is equal to or less than the MFP." The Drug Price Negotiation Program Complaint and Dispute Intake Form[28] includes a section for Supporting Documentation, as well as further examples of supporting documentation. Finally, in the Medicare Transaction Facilitator Data Module User Agreement for Dispensing Entities, which all dispensing entities sign when they enroll in the MTF DM, Section II contains responsibilities for dispensing entities to maintain records that the dispensing entity may create or receive in connection with the MTF, to make these records available upon request by CMS for the purpose of audits, investigations, verifications, inspections and examinations, and to cooperate with all compliance activities in which CMS shall engage pursuant to applicable guidance and regulations.

In completing the fact-based assessment regarding MFP availability, CMS anticipates that information on acquisition cost will be needed from the dispensing entity. As outlined in the Drug Price Negotiation Program Complaint and Dispute Intake Form published in the MTF Information Collection Request package,[29] dispensing entities will have the opportunity to submit supporting documentation to aid in CMS' investigation during their submission of a complaint. CMS notes that when assessing whether a manufacturer has effectuated the MFP, CMS will only be able to make determinations based on the information available to CMS and deemed to be reliable; CMS anticipates dispenser-provided information may play an important role in that process. In this instance, where a complaint does not provide any supporting documentation when filed, as part of the threshold review of the complaint described in section 90.2.2 of this final guidance, CMS plans to reach out to the complainant and provide an opportunity to submit supporting documentation or additional information as to why supporting documentation is unavailable.

Comment: One commenter requested that CMS clarify that pharmacies should not be required to submit private contractual agreements between pharmacies and manufacturers.

Response: CMS thanks this commenter for their input. Table 5, in section 40.4.3.1 of this final guidance, explains that invoice documentation of the drug sold at or below MFP, an outside agreement between the Primary Manufacturer and dispensing entity establishing prospective purchasing of the selected drug at or below MFP, or an alternative arrangement between the Primary Manufacturer and dispensing entity that established an agreed-upon proxy for MFP refund calculation are examples of the type of documentation that should be maintained to substantiate the reporting of a claim-level payment element indicating that the dispensing entity and the manufacturer have established prospective purchasing or other alternative arrangement documenting acquisition of a selected drug at a price other than WAC. Questions 11-14 of the

[28] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that dispensing entities will be required to provide. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

[29] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that dispensing entities will be required to provide. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan[30] include questions about alternative arrangements, including space for a Primary Manufacturer to describe the nature of alternative arrangements and any planned alternative arrangements that may not already be established. The Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan also states that, "CMS may request copies of these contracts, including, without limitation, in response to complaints from dispensers regarding lack of MFP availability, or as part of routine audits or investigations related to MFP availability. In addition, if the NPIs [National Provider Identifiers] of affected dispensing entities are not contained within the contracts, CMS may request documentation to support any instances of a Primary Manufacturer declining to pay a claim for a specific NPI based on an alternative arrangement." This final guidance describes the requirement that Primary Manufacturers provide CMS with copies of alternative arrangements upon request. CMS may ask a dispensing entity in the course of investigating a complaint to provide a copy of any alternative arrangements with a Primary Manufacturer, if they are able to do so. When making compliance determinations, CMS will only be able to make determinations based on the information available to CMS at the time, and CMS' assessment of the reliability of that information, and in certain cases may not be able to make a determination in the absence of specific documentation, such as a copy of an alternative arrangement.

Comment Solicitation on the Effectuation of the MFP for Drugs Payable Under Part B
Comment: CMS received feedback from many commenters on a range of issues related to the effectuation of the MFP for drugs payable under Part B. These comments included topics such as Part B providers' participation with the MTF, an SDRA for drugs payable under Part B, claim-level data elements for drugs payable under Part B, how processes should differ from what is outlined for drugs covered under Part D, alternatives to the MTF, identification of 340B-eligible claims, timing of CMS providing more details related to MFP effectuation for drugs payable under Part B, access concerns, and engaging interested parties as CMS continues to develop policy on these issues.

Some commenters recommended CMS update policies related to MA Part B encounter data submission to help ensure efficient MFP effectuation of selected drugs payable under Part B or requested clarity around MFP effectuation for individuals enrolled in MA plans.

Response: CMS thanks these commenters for their suggestions related to the request for input regarding the effectuation of the MFP for drugs payable under Part B. CMS intends to provide detailed policy on providing access to the MFP for selected drugs payable under Part B in the future and will consider these comments and recommendations for this issue in CMS' policy development.

[30] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that Primary Manufacturers will be required to provide. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

Retrospective Refund (Section 40.4.1)

Comment: A few commenters provided feedback opposing the retrospective refund model discussed in section 40.4.1 of the draft guidance for initial price applicability year 2028, noting that they preferred a prospective MFP purchase model, where a dispensing entity would acquire the drug at the MFP cost, as opposed to a retrospective refund model, citing the potential financial strain that a retrospective refund model placed on dispensing entities. Additionally, a few commenters provided considerations for CMS on how to improve MFP effectuation in a retrospective refund model, highlighting recommended changes to the 14-day prompt MFP payment window and considerations for providing the dispensing entities with access to the MFP more quickly.

Response: CMS appreciates the perspectives shared by these commenters. CMS reiterates that a Primary Manufacturer may provide access to the MFP prospectively or retrospectively. In section 40.4 of this final guidance, CMS maintains that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. Recognizing that there may be advantages and disadvantages to both approaches, CMS encourages Primary Manufacturers and dispensing entities to work together to reach agreements as to whether the dispensing entity will access the MFP prospectively or retrospectively for a given MFP-eligible claim. As described in sections 40.4.3 and 40.4.4 of this final guidance, the MTF will support Primary Manufacturers and dispensing entities using either option. Regarding MFP refund payment timing, CMS will apply the standards set forth in current Part D prompt pay reimbursement regulations regarding payment by plan sponsors to pharmacies to Primary Manufacturers for their transmission of MFP refunds for selected drugs. That is, CMS will require that a Primary Manufacturer transmit a payment of an amount that provides access to the MFP to pharmacies, mail order services, and other dispensing entities within 14 days. The 14-day prompt MFP payment window provides Primary Manufacturers with the same 14-day timeframe to transmit payment as applies for Part D plan sponsors under existing Part D prompt pay rules. Additionally, section 40.4.2.2 of this final guidance describes a process for dispensing entities to self-identify as dispensing entities that anticipate material cashflow challenges because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window.

Comment: Some commenters provided feedback supporting the use of WAC as a standardized pricing metric in the calculation of the SDRA and cited that WAC offered a reliable refund amount for both dispensing entities and manufacturers. One commenter noted that CMS should clarify that the WAC price used in the calculation of the SDRA should be the amount at the time of adjudication and not the WAC price at the time the MFP refund is transmitted. Some commenters requested that CMS state that the MFP refund amount cannot exceed the SDRA and that the use of WAC as a standardized pricing metric in the SDRA calculation should be required to effectuate MFP refund payments. One commenter did not support a WAC-based calculation, stating that acquisition cost is often lower than WAC because of discounted pricing available to providers through Group Purchasing Organization (GPO) contracting. One commenter asked that CMS impose a timeline of six months within which manufacturers must notify pharmacies of

changes to WAC (as the SDRA) in advance, so that pharmacies may financially plan for the impact of the WAC change.

Response: CMS appreciates commenters' feedback regarding the use of WAC to calculate the SDRA. In section 40.4.1 of this final guidance, CMS states that the MTF DM will use WAC, as published in pharmaceutical pricing database compendia on the date of service of the Part D claim, as the standardized pricing metric to calculate the SDRA. CMS maintains that WAC is the best option to calculate the SDRA because WAC is a widely available pricing metric, published and regularly updated in common pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process, and does not require the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates between parties. CMS believes using WAC to calculate the SDRA generally best approximates the acquisition costs of dispensing entities and offers a reliable refund amount for both manufacturers and dispensing entities that agree to use such a standardized pricing metric. CMS notes that the inclusion of WAC as a standardized pricing metric in the calculation of the SDRA as outlined in section 40.4.2 of this final guidance is informational and that the Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines some other amount is appropriate and sufficient to make the MFP available. As such, CMS is not establishing requirements regarding the timing and reporting of WAC to pharmaceutical pricing database compendia by Primary Manufacturers.

Comment: Some commenters provided feedback that CMS should consider the SDRA to be a "true default" and that manufacturers should not be required to issue refunds above the calculated and provided SDRA as reported on the claim level data elements described in section 40.4.2 of the draft guidance for initial price applicability year 2028. Additionally, some other commenters noted that manufacturers should not be required to reimburse at an amount above the SDRA if the dispensing entity requests such reimbursement and that CMS should clarify that the MFP refund payment amount should be capped at an amount no higher than the SDRA. One commenter noted that the MFP refund amount should be negotiated and agreed upon between the manufacturer and the dispensing entity if it is an amount other than the SDRA.

Response: CMS thanks these commenters for their feedback. CMS reiterates the obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP rests with the Primary Manufacturer, as required under section 1193(a)(3) of the Act. A Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines some other amount is appropriate to make the MFP available. When assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug, absent information available to CMS indicating otherwise, CMS will consider provision of the SDRA (which is equal to WAC minus the MFP) to meet the Primary Manufacturer's obligation to make MFP available. CMS encourages interested parties to review section 90.2 of this final guidance for information regarding CMS' approach to monitoring and making determinations regarding provision of access to the MFP. If a dispensing entity believes that it has not received a retrospective refund payment that effectuates the MFP, CMS recommends the dispensing entity remediate with the manufacturer directly. If remediation between the parties cannot be carried out, Primary Manufacturers and dispensing entities may

use the complaints process within the complaint and dispute system, as described further in section 90.2.2 of this final guidance.

Comment: A few commenters expressed concerns that using the dispensing entities' actual acquisition cost as a determinant in the evaluation for assessing MFP effectuation is problematic particularly because it may contain costs that are passed on from supply chain trading partners that the manufacturer should not be responsible for reimbursing. Further, commenters requested that CMS should clarify that manufacturers are not responsible for costs passed on to dispensing entities from supply chain trading partners. A couple of commenters noted that requiring manufacturers to reimburse dispensing entities at actual acquisition cost could result in gaming among supply chain trading partners to artificially inflate MFP refund payments. One commenter recommended that CMS track which dispensers or types of dispensers are claiming acquisition costs above WAC and specify what documentation is required by a dispensing entity when claiming an acquisition cost above the SDRA.

Response: The Primary Manufacturer is ultimately responsible under the statute for establishing and paying the appropriate MFP refund amount to ensure access to the MFP. CMS believes that allowing a Primary Manufacturer flexibility to determine its preferred methodology for calculating its MFP refund payments aligns with the Primary Manufacturer's statutory obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP, as required under section 1193(a)(3) of the Act. CMS outlines in section 90.2 of this final guidance its process for evaluating whether a manufacturer has made MFP available.

Regarding the comments related to supply chain fees and the gaming concerns of trading partners inflating acquisition cost to increase MFP refund payments, in section 90.2 of this final guidance, CMS describes its process for determining whether the MFP has been provided in specific cases. As reflected in section 90.2 of this final guidance, this determination process includes an assessment of the commercial reasonableness of costs incurred by the dispensing entity related to the procurement of the selected drug. Primary Manufacturers may consider CMS' process for determining whether the MFP has been provided when determining an MFP refund amount that sufficiently meets their statutory obligation. As outlined in section 90.2 of this final guidance, when assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug, absent information available to CMS indicating otherwise, CMS will consider provision of the SDRA (which is equal to WAC minus the MFP) to meet the Primary Manufacturer's obligation to make MFP available.

MTF Data Facilitation (Section 40.4.2)

Comment: Many commenters expressed concern with the 14-day prompt MFP payment window. Some commenters stated that the payment window does not provide enough time for manufacturers to process the expected volume of MFP claims accurately and thoroughly. One commenter suggested the prompt payment window should exclude weekends and holidays. A couple of commenters recommended using timelines between 30 days and 38 days. One commenter stated that the 14-day prompt MFP payment window is not mandated by statute. A few commenters stated that the 14-day prompt MFP payment window is too long and could cause cash flow concerns for dispensing entities. One commenter recommended the payment

window begin within 14 days of the dispensing entity adjudicating the claim with the plans or PBMs, rather than beginning when the MTF sends the claim-level data elements to the Primary Manufacturer. A couple of commenters suggested allowing dispensing entities and manufacturers to agree on a different prompt MFP payment window if payment is not being made through the MTF PM.

Response: CMS thanks these commenters for their input. Section 1193(a)(3) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to pharmacies, mail order services, and other dispensing entities that dispense the selected drug to MFP-eligible individuals described in section 80 of this final guidance. Consistent with CMS' response on pages 50 and 51 of the final guidance for initial price applicability year 2027, CMS will apply the standards set forth in current Part D prompt pay reimbursement regulations regarding payment by plan sponsors to pharmacies to Primary Manufacturers for their transmission of MFP refunds for selected drugs. That is, CMS will require that a Primary Manufacturer transmit payment of an amount that provides access to the MFP to pharmacies, mail order services, and other dispensing entities within 14 days. The 14-day prompt MFP payment window provides Primary Manufacturers with the same 14-day timeframe to transmit payment as applies for Part D plan sponsors under existing Part D prompt pay rules. This timely MFP refund payment will support dispensing entities to continue efficient operations and prevent undue financial hardship. Additionally, section 40.4.2.2 of this final guidance describes a process for dispensing entities to self-identify as dispensing entities that anticipate material cashflow challenges because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and section 90.2.1 of this final guidance describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns for such entities in their MFP effectuation plans.

The 14-day prompt MFP payment window begins when the MTF DM sends the claim-level data elements to the Primary Manufacturer. While this may result in MFP refund payments in excess of 14 days from time of claim submission by the dispensing entity to the Part D plan sponsor, this policy allows CMS to include claim-level data elements that have been twice validated for an individual's MFP-eligibility by the Part D plan and by DDPS and ensures the Primary Manufacturer has the minimum necessary information to effectuate the MFP so no additional validation of MFP-eligibility of an individual needs to be performed. CMS finalized in rulemaking a change effective in contract year 2026 to shorten the current 30-day window for plans to submit initial PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities.

Sections 40.4.3 and 40.4.4 of this final guidance outline that the MTF PM facilitation of retrospective payment is voluntary for Primary Manufacturers, and that dispensing entities and Primary Manufacturers may reach an agreement outside of the MTF PM to make MFP refund payments, regardless of whether the Primary Manufacturer is using the MTF PM; however, the 14-day prompt MFP payment window still applies.

Comment: A couple of commenters expressed appreciation for the ability of dispensing entities to indicate that they expect to experience material cashflow concerns. One commenter suggested criteria for dispensing entities to qualify for having material cashflow concerns. One commenter

expressed appreciation for shortening the window for Part D plans to submit initial PDE records into the DDPS system from 30 days to 7 days which could expedite MFP refund payments to dispensing entities. Some commenters stated concern with holding manufacturers responsible for mitigating dispensing entities' cashflow challenges, with a couple of commenters noting that there is no statutory basis for such responsibility. A few commenters suggested using a model where CMS pre-funds a pool from which refunds are promptly paid to dispensing entities to mitigate cashflow concerns, similar to the model used for the Manufacturer Discount Program (MDP).

Response: CMS appreciates this feedback. As discussed in section 40.4.2.2 of this final guidance, CMS will allow dispensing entities to self-identify as anticipating material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. At this time, CMS did not specify other criteria by which dispensing entities qualify for such designation. This information will be provided to Primary Manufacturers to assist in the development of their MFP Effectuation Plans. Consistent with section 1193(a)(5) of the Act and as described in section 90.2.1 of this final guidance, CMS will require Primary Manufacturers to include their approach to mitigating material cashflow concerns in their MFP Effectuation Plans. CMS agrees timely movement of funds is important and appreciates that prefunding would offer advantages. The IRA did not include an appropriation to 'prefund' MFP refund payments. In accordance with section 1193(a)(3)(A) of the Act, it is the sole responsibility of the Primary Manufacturer to provide dispensing entities access to the MFP for selected drugs.

Comment: A couple of commenters suggested that all PDE records for selected drugs should be passed to the Primary Manufacturer regardless of the presence of DDPS edits that are not listed in Appendix B of this final guidance. A couple of commenters requested that all DDPS edits, including those not listed in Appendix B of this final guidance, should be resolved before sending to Primary Manufacturers.

Response: CMS thanks these commenters for their input. As discussed in section 40.4.2 of this final guidance, CMS will receive PDE records for all claims for selected drugs with an MFP dispensed to MFP-eligible individuals during a price applicability period. Data elements for a PDE record will not be sent to the Primary Manufacturer until the PDE record can be verified as reflecting that a selected drug was dispensed to an MFP-eligible individual. As discussed in section 40.4.2 of this final guidance, CMS will use the list of DDPS edits in Appendix B of this final guidance in determining whether to transmit a PDE record to a Primary Manufacturer. In cases where DDPS edits directly relate to the determination and verification of MFP eligibility for the purposes of the Negotiation Program, such as missing NDCs or dispensing entity identifiers, the MTF will not send these claims to the Primary Manufacturer for MFP refunds until those issues are resolved.

MTF Payment Facilitation (Section 40.4.3)

Comment: Some commenters expressed concern or provided comment related to the financial burdens of the MFP effectuation process on dispensing entities, with a couple of commenters expressing concerns with how MFP refund payments are effectuated. Commenters requested that

CMS work collaboratively with the pharmacy and provider community to establish mitigation strategies to avoid cash flow disruptions. Some commenters provided feedback related to the methods described in section 40.4.3 of the draft guidance for initial price applicability year 2028 that interested parties can consider in addressing the cash flow concerns of dispensing entities. Some commenters requested that CMS "prefund" MFP refund payments from manufacturers to dispensing entities through the MTF and a few commenters recommended that CMS consider modeling the MFP refund payment process after CGDP. A couple of commenters shared feedback related to CMS prohibiting the charging of fees or the placement of administrative burden on dispensing entities by interested parties in the MFP effectuation process. One commenter requested that CMS leverage its statutory authority to pre-fund a "MFP" discount pool to mitigate pharmacy cashflow concerns. Another commenter recommended that CMS utilize an approach utilizing a "pass through" of CMS pre-funded MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication with manufacturers invoiced at a later date.

Response: CMS appreciates this feedback. Consistent with CMS' previous response on pages 78-79 of the final guidance for initial price applicability year 2027, CMS agrees that timely movement of funds is important and appreciates that prefunding would offer advantages. However, the IRA did not include an appropriation to 'prefund' MFP refund payments. In accordance with section 1193(a)(3)(A) of the Act, it is the sole responsibility of the Primary Manufacturer to provide dispensing entities access to the MFP for selected drugs. CMS notes that there are distinct differences in the agency's role outlined in statutory requirements for the Negotiation Program and the agency's role outlined in statutory requirements for CGDP under section 1860D-14A of the Act. CMS reiterates that the goal of the MTF PM is to provide an efficient and unified payment flow through the connection of statutorily affected parties where a payment flow does not currently exist today.

In addition to requiring Primary Manufacturers to transmit MFP refund payments within the 14-day prompt MFP payment window, CMS finalized in rulemaking a change effective in contract year 2026 to shorten the current 30-day window for plans to submit initial PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities.

As described in section 40.4.2.2 of this final guidance, during MTF DM enrollment, CMS is asking dispensing entities to self-identify whether they are a dispensing entity that anticipates having material cashflow concerns due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. This information will be provided to Primary Manufacturers to assist in the development of their MFP effectuation plans, as described in section 90.2.1 of this final guidance. Consistent with section 1193(a)(5) of the Act, CMS requires Primary Manufacturers to include their approach to mitigating material cashflow concerns in their MFP effectuation plans. In section 40.4.3 of this final guidance CMS outlines considerations for interested parties to consider when addressing pharmacies that have identified as having material cash-flow concerns.

As stated in section 40.4.3 of this final guidance, neither Primary Manufacturers nor dispensing entities shall have to pay any fees to the MTF PM in connection with the pass through of MFP refund payments, including but not limited to user fees or transaction fees, as CMS intends to

bear the cost of operationalizing the MTF PM for 2026, 2027, and 2028. As outlined in section 40.4.3 of this final guidance, regardless of whether the MFP refund is passed through the MTF PM or outside of the MTF PM, neither Primary Manufacturers nor their contracted entities shall charge any transaction or other fees to dispensing entities for the pass through of the MFP refund to the dispensing entity.

Comment: Many commenters requested clarification on different aspects of how credits and debits will be managed by the MTF credit/debit ledger system. One commenter requested visibility into the credit and debit ledger for accounting purposes. A couple of commenters requested that CMS clarify that a record of full reversals will be provided to the manufacturer and that CMS transmit the record to the manufacturer first before applying a full reversal of the previously paid amount. A couple of commenters requested that CMS clarify that any adjustments that occur to claim data within the 14-day prompt MFP payment window restart the payment window based on the transmission of the adjusted record. A couple of commenters requested that CMS provide access to the credit/debit ledger system after termination from the Negotiation Program or termination from MTF PM participation. One commenter requested that the MTF PM maintain a balance of credits and debits for payments made outside of the MTF PM as well as for payments made through the MTF PM.

Response: CMS thanks these commenters for their input. In response to interested parties' requests for additional clarity on how reversals and adjustments will be addressed by Primary Manufacturers that elect to pass payment through the MTF PM, section 40.4.3.2 of this final guidance describes how MFP refund payments will be reconciled using a credit/debit ledger system for claims that are reversed or require payment adjustment for Primary Manufacturers that pass payment through the MTF PM. CMS clarified in section 40.4.3.2 of this final guidance that for full reversals, the MTF DM will issue a record to the Primary Manufacturer indicating that a full reversal has occurred on a claim. Further, in the case of a credit accrual in the MTF PM as a result of the issuance of a full reversal after the claim-level payment elements have been transmitted, a receipt file will be issued to the Primary Manufacturer to provide notice of the accrued credit, unless no MFP refund payment was authorized, in which case the credit amount would be equal to zero. In response to comments related to the expectations for timing of the transmission of claim-level payment elements on adjusted claims, CMS reiterates in section 40.4.3.2 of this final guidance that each set of claim-level data elements is required to be responded to within the 14-day prompt MFP payment window, regardless of whether a new adjusted set of claim-level data elements is issued before the claim-level payment elements of the original claim are transmitted by the Primary Manufacturer. That is, the 14-day prompt MFP payment window for an original claim is not reset when an adjusted set of claim-level data elements is issued, and both the original and adjusted set of claim-level payment elements have different and unique 14-day prompt MFP payment windows that are based on the date of transmission of the associated claim-level data elements to the Primary Manufacturer. CMS believes that this aligns with the policy described in section 40.4.2.1 of this final guidance, that Primary Manufacturers are required to transmit claim-level payment elements "for each claim identified in the claim-level data elements".

For Primary Manufacturers that pass payments through the MTF PM, the ledger will operate two pathways for reconciliation, the first pathway being an automatic credit to be applied for a

reversal record indicated by receipt of a PDE reversal record from DDPS, and the second pathway being an indication on the claim-level payment elements, as described in section 40.4.3.1 of this final guidance, that a previously transmitted set of claim-level payment elements requires an adjustment as determined by the Primary Manufacturer in its provision of access to the MFP. In both pathways, a credit, if applicable, will be applied for that Primary Manufacturer at the dispensing entity NPI-level that the MFP-eligible claim originated from, and to which selected drug the MFP refund payment was made. Credits will then be netted out of future MFP refund payments on the selected drug to the credited dispensing entity for Primary Manufacturers that choose to pass payment through the MTF PM. Regarding visibility into credits and debits at termination, in section 40.4.3.2 of this final guidance, CMS outlines that CMS, or its designated contractor, will provide the Primary Manufacturer with an accounting of any outstanding credits remaining in the credit/debit ledger system as of the date of termination, at a time and in a manner to be described by CMS in upcoming guidance or technical instruction. Lastly, as stated in section 40.4.3.2 of this final guidance, CMS intends that dispensing entities and participating Primary Manufacturers will be able to view the status of available credits and MFP refunds through their MTF portal and further technical specifications will be outlined in technical guidance.

The MTF will not maintain a credit/debit ledger for transactions that occur between interested parties outside of the MTF PM, whether because a Primary Manufacturer that has elected to participate in the MTF PM and a dispensing entity have a mutually agreed-upon process for MFP effectuation outside of the MTF PM, or because the Primary Manufacturer chooses to not utilize the MTF PM at all. For payments not passed through the MTF PM, section 40.4.4 of this final guidance outlines the Primary Manufacturer's responsibility to indicate on the claim-level payment elements reversals and adjustments to previously paid claims; however, the MTF will not maintain balances of credits or debits for such Primary Manufacturers. The Primary Manufacturer will be responsible for establishing a generally accepted accounting principles (GAAP) compliant system to account for adjustments and reversals to previously paid MFP refunds.

Comment: A couple of commenters provided feedback related to the receipt file that CMS intends to provide to manufacturers participating in the MTF PM. A few commenters noted that CMS should clarify that manufacturers are not responsible for technical failures of the MTF PM in effectuating payments.

Response: CMS thanks these commenters for their feedback. CMS will consider suggestions related to the receipt file as we continue to develop the technical specifications of the files and reports that are exchanged between interested parties. Regarding the comments related to MTF PM technical failures, section 100.1 of this final guidance notes that CMS will take into consideration when determining a Primary Manufacturer's CMP liability, technical failures related to transmission of payments outside of the Primary Manufacturer's control as well as other factors for consideration as evidenced by the Primacy Manufacturer in the Primary Manufacturer's response to CMS' Notice of Potential Noncompliance.

Comment: A couple of commenters requested the addition of a Justification Code to Table 5 in section 40.4.3.1 of draft guidance for initial price applicability year 2028 that is dedicated to

addressing specific scenarios where the 340B price of a selected drug is greater than the MFP. According to the commenters, the intent of having this code is to communicate that a reduced MFP refund payment is being made because of (1) the claim being determined to be 340B eligible and (2) the 340B price being greater than the MFP. The commenters believe that Justification Code "2" is too broad to capture this circumstance.

Response: In response to commenters' request, CMS has added a Justification Code to Table 5 in section 40.4.3.1 of this final guidance to address the scenario described. Justification Code "8", "Amount Other than Standard Default Refund Amount Transmitted – Section 1193(d)(2) Scenario", has been added to the available list of codes. Primary Manufacturers should use this code when transmitting the claim-level payment elements if a claim is determined to be 340B eligible, and the MFP for that claim is lower than the 340B price of the drug.

Comment: Some commenters provided feedback regarding technical specifications that they would like to see incorporated into the MTF payment facilitation framework. A couple of commenters provided feedback related to the handling of unclaimed funds, seeking clarification for how unclaimed funds will be handled and how the return of unclaimed funds will be communicated to Primary Manufacturers. Some commenters noted their support for the MTF PM and the proposed retrospective refund process.

Response: CMS is contracting with the MTF Contractor to administer the functions described in this final guidance with respect to the MTF PM. CMS expects specifications related to the functionality, interface, and technical specifications of the MTF PM to develop in partnership with the MTF Contractor and expresses gratitude to the commenters sharing thoughts and recommendations for features they would like to see related to the operation of the MTF PM. CMS will consider these recommendations as technical development with the MTF Contractor evolves.

Regarding unclaimed funds, CMS describes in section 40.4.3 of this final guidance the process and will reiterate here that all unclaimed funds for payment provided through the MTF PM will be returned to the Primary Manufacturer, CMS will not accrue any interest on unclaimed funds, and any disputes related to unclaimed funds will be reconciled directly between the Primary Manufacturer and the dispensing entity. CMS intends to provide further clarification through technical instructions as the MTF PM contractor develops the operational considerations for the processing of unclaimed funds for Primary Manufacturers that utilize the MTF PM.

Comment: A couple of commenters provided feedback that manufacturers should not be required to participate in the MTF PM. One commenter noted that Primary Manufacturers should not be responsible for the payments of Secondary Manufacturers. CMS received a couple of comments reinforcing the commenters' concerns that Primary Manufacturers must participate in the MTF PM, stating, "Allowing manufacturers not to participate in the MTF PM could potentially require pharmacies to negotiate alternative and unique payment arrangements with each manufacturer. Such scenario would be unduly burdensome and costly for pharmacies."

Response: CMS thanks these commenters for their feedback. Primary Manufacturers have a statutory obligation to effectuate the MFP, and as described in sections 40.4 and 90.2 of this final

guidance, Primary Manufacturers are required to establish a process to ensure the MFP is made available to MFP-eligible individuals and dispensing entities. While section 1193(a)(3) of the Act places the obligation on Primary Manufacturers to provide access to the MFP to dispensing entities, it does not expressly specify how Primary Manufacturers must make MFP accessible. Therefore, participation in the MTF PM is voluntary for Primary Manufacturers. A Primary Manufacturer may elect to use the MTF PM to pass through MFP refund payments to dispensing entities. CMS declines the suggestion to make participation in the MTF PM mandatory.

Comment: A few commenters requested that dispensing entity enrollment in the MTF be mandatory, and that Primary Manufacturers only be responsible for facilitating payments through the MTF PM if that is how the Primary Manufacturer has elected to effectuate the MFP to dispensing entities to avoid having to develop standalone processes with dispensing entities outside of the MTF PM.

Response: In the CY 2026 Parts C&D Final Rule[31] and as codified at 42 C.F.R. § 423.505(q), CMS requires Part D plan sponsors to include in their network pharmacy agreements a provision requiring dispensing entities to be enrolled in the MTF DM. Dispensing entity enrollment in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and sending electronic remittance advices (ERAs) or remittances, facilitating continued access to selected drugs that are covered Part D drugs, and ensuring accurate Part D claims information and payment. Further, CMS added language to section 40.4.3.3 of this final guidance that outlines a process by which Primary Manufacturers that have elected to make payments through the MTF PM may elect to pass through MFP refund payments to dispensing entities that are not enrolled in the MTF DM.

Nonduplication with the 340B Ceiling Price (Section 40.4.5 and 90.2)

Comment: Many commenters requested that CMS provide greater clarity on how manufacturers should identify 340B claims, expressing opposition to the 340B nonduplication approach that CMS described in the draft guidance for initial price applicability year 2028 and stating that it creates operational and compliance challenges and risks for supply chain entities. One commenter recommended that CMS expressly affirm that manufacturers may develop and rely on their own good-faith nonduplication methodologies and confirm that reasonable, auditable approaches, when thoughtfully designed and consistently implemented, will be deemed sufficient for compliance. The commenter raised concerns that manufacturers may face legal risk despite acting in good faith to fulfill their obligations for nonduplication between the 340B ceiling price and the MFP. One commenter stated that an identification mechanism that is voluntary for 340B covered entities will not serve as a realistic solution because, they asserted, covered entities have no compelling reason to report their 340B claims and that CMS should rely on civil monetary penalties as an enforcement framework. A couple of commenters recommended CMS prohibit identification of 340B units after a period of time in order to avoid duplication of discounts.

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[31] CMS, Final Rule, "Medicare and Medicaid Programs: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," April 15, 2025 (90 Fed. Reg. 15834). See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.

Response: CMS thanks these commenters for their input and acknowledges the concerns expressed. As explained in section 40.4.5 of this final guidance, CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim and will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP. CMS reiterates the requirement for the Primary Manufacturer to transmit payment of an amount that provides access to the MFP within 14 days of the MTF DM sending the data elements verifying the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturer. CMS also notes that nothing in this guidance modifies a manufacturer's statutory obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. Nothing in this guidance alters a manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the 340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11. Accordingly, CMS expects manufacturers to work with dispensing entities, covered entities and their 340B Third Party Administrators (TPAs), and other prescription drug supply chain stakeholders to facilitate access to the lower of the MFP and the 340B ceiling price consistent with their statutory obligations.

Comment: Many commenters recommended that CMS require the use of claims modifiers for 340B claims, a few of these commenters suggesting that CMS could enforce this requirement via Part D plan contracts or by conditioning receipt of MFP refunds and Part D payment on the dispensing entity's appropriate use of either a 340B or non-340B modifier. Another commenter requested that, if CMS does not require affirmative 340B and non-340B claim modifiers, CMS and Health Resources and Services Administration (HRSA) jointly state that dispensing entities must provide manufacturers with claim-level data for all 340B-eligible claims with respect to selected drugs for which an MFP is in effect. In contrast, one commenter opposed any policy that would require the use of 340B claims modifiers, stating that a point-of-sale modifier is incompatible with the virtual inventory system used by pharmacies as part of the 340B Program. This commenter noted that dispensing entities may be unable to make the necessary determinations at the point-of-sale, therefore limiting submission of these codes in a timely manner. One commenter referenced an analysis on the usage of 340B modifiers and remarked that 340B claim modifiers are not reliable, even when required. One commenter noted that even if an identifier is added to a claim, it could be removed at some point when the data transfers between entities including pharmacies, third-party administrators, and pharmacy benefit managers. One commenter noted that dispensing entities would be unlikely to use the modifier as this would provide plans with insight into which claims are 340B claims and the plan could reimburse the dispensing entity at a lower rate than it otherwise would. One commenter requested that CMS report how many claims that pass through the MTF DM include the 340B indicator.

Many commenters recommended that CMS create—or facilitate the creation of—a 340B claims "clearinghouse" that could identify units subject to a 340B discount and ensure nonduplication of the MFP and 340B ceiling price in addition to or instead of requiring a claim modifier. One commenter stated that the clearinghouse would enable covered entities (or TPAs acting on their behalf) to retrospectively submit 340B claims data, and data from the clearinghouse could be shared with the manufacturer so they could provide the difference between the MFP and the

340B price to the covered entity for 340B-eligible claims. A few commenters noted that the Oregon Medicaid program has successfully implemented this model for the purpose of nonduplication of 340B discounts and Medicaid rebates, and this approach has eased provider burden while allowing for retrospective claim identification. One commenter stated that if the clearinghouse is not established, CMS should develop a standardized process for manufacturers to coordinate with TPAs. One commenter stated that if CMS has concerns about mandating covered entities to report data to a clearinghouse, it could make submission to the clearinghouse voluntary. By contrast, a few commenters suggested that CMS work with the Health Resources and Services Administration (HRSA) to establish penalties for covered entities that do not submit claims data to the clearinghouse in a specified timeframe. Another commenter suggested that CMS create a conduit within the MTF to facilitate the direct transfer of 340B claims data from covered entities to manufacturers and assist in nonduplication of 340B and MFP claims. One commenter argued that any clearinghouse would only be effective for government-paid claims because commercial 340B claims would not be identified by the clearinghouse and it would therefore create additional fragmentation in the system. Another commenter stated that covered entities should report all 340B sales, not just Medicare sales to a clearinghouse and that manufacturers should be able to receive 340B claims data from the clearinghouse to verify that the total number of 340B claims reported by each covered entity match the 340B discounts provided to that covered entity on each drug. A few commenters noted that this clearinghouse could also be used to remove units that covered entities identified as 340B eligible from the Medicare Part D Drug Inflation Rebate Program.

Response: CMS thanks these commenters for their recommendations. In response to the recommendations for and against the use of a Part D claim modifier for 340B claims, CMS acknowledges feedback that requiring such a modifier has the potential to pose operational challenges, increase administrative burden, and may not always be accurate. Consistent with CMS' response on page 60 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS is not pursuing a policy at this time to require the use of such a modifier and reiterates that use of the 340B submission clarification code described in section 40.4.2.1 of this final guidance is optional for dispensing entities based on current National Council for Prescription Drug Programs (NCPDP) standards. In response to the commenters who recommended that CMS create a 340B claims "clearinghouse" that could collect data on 340B-eligible claims that would be used for nonduplication of the MFP and 340B ceiling price, CMS appreciates the detailed insight provided by commenters. CMS will not, at this time, assume responsibility for such 340B ceiling price and MFP nonduplication functions, whether through a "clearinghouse" or through other means, but will monitor this approach and will continue to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under section 1193(d)(1) of the Act into MTF processes in the future. For example, CMS is considering ways to incorporate asynchronous 340B data into MTF processes in the future.

Comment: A couple of commenters argued that the 340B Drug Pricing Program relies on the ability of covered entities to purchase covered outpatient drugs upfront at the 340B ceiling price, and that under a retrospective 340B rebate model, which these commenters claim will likely result from the approach to nonduplication of the 340B ceiling price and MFP detailed in the

draft guidance, covered entities will be harmed by CMS' decision to not take an active role in nonduplication. One of the commenters explained that under a 340B rebate model, covered entities would be required to purchase drugs at a much higher price and wait for a refund rather than receiving the 340B price at the time of purchase, which has not been authorized by HRSA outside of a very narrow exception for AIDS Drug Assistance Programs (ADAPs). One commenter stated that the statutory requirement to provide access to the MFP in a nonduplicated amount to the 340B ceiling price does not mean that manufacturers can delay providing access to 340B pricing. A couple of commenters requested that CMS impose a timeline, such as a 14-day window, for manufacturers to pay the difference between the MFP and the 340B ceiling price if manufacturers seek to meet their nonduplication requirements by selling drugs at the MFP to 340B covered entities. A couple of commenters stated that the draft guidance for initial price applicability year 2028 has no mechanism for manufacturers to report that they effectuated the 340B price if it is lower than the MFP. One commenter requested that CMS clarify that, when the manufacturer has made the 340B ceiling price available to the covered entity and later determines the MFP is lower than the 340B ceiling price, the manufacturer may offer the difference between the 340B ceiling price and the MFP to the dispensing entity, such as a contract pharmacy, to make the MFP available. One commenter recommended CMS clarify that if a claim is identified as 340B-eligible, but the manufacturer does not pay the 340B discount, then the dispenser is, at a minimum, owed the MFP refund payment.

Some commenters urged CMS to support the 340B rebate models pending HRSA approval, arguing that if CMS does not assume responsibility for nonduplication between the 340B ceiling price and the MFP and also imposes barriers on implementing the rebate model, manufacturers will likely be required to pay duplication of discounts. One commenter stated that the replenishment model removes an effective means to track later purchases or to ensure that manufacturers are not subject to duplication of discounts, which the commenter asserts occurs in the Medicaid space and will grow under the implementation of the IRA. This commenter argued that the only way to ensure manufacturers are not providing duplication of discounts is to transition to make the 340B price available to covered entities as a rebate. The commenter stated concerns with CMS' statement that it is considering ways to incorporate asynchronous 340B data into MTF processes in the future because they interpreted that this statement may indicate that CMS supports post transaction identification of 340B units using the virtual inventory system. A couple of commenters expressed that incorporating asynchronous data into MTF processes is important because it could help manufacturers comply with nonduplication of the MFP and 340B ceiling price by identifying 340B claims that may not be initially identified. One commenter suggested a data platform that interested parties can use to facilitate a 340B rebate model and implement nonduplication with the MFP, arguing that interested parties could use the platform to access claim and rebate information which could provide transparency to all parties. One commenter requested CMS allow maximum flexibility for manufacturers to develop and rely on private market solutions to the de-duplication issue.

One commenter stated that if Primary Manufacturers sell drugs prospectively at the MFP, covered entities could use virtual inventory systems that are used for 340B-eligible drugs to track drugs purchased at the MFP and dispense only to MFP-eligible individuals.

Response: CMS thanks these commenters for the feedback. CMS reiterates that nothing in this final guidance modifies a manufacturer's continued responsibility for statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to offer the 340B ceiling price to eligible entities. CMS also reiterates the requirement for the Primary Manufacturer to transmit payment of an amount that provides access to the MFP within 14 days of the MTF DM sending the data elements verifying the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturer. CMS acknowledges that HRSA has announced the availability of a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to all covered entities.[32] The HRSA 340B Rebate Model Pilot Program is outside of the scope of this final guidance. Nothing in this guidance alters a manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the 340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11.

The Primary Manufacturer has the opportunity to indicate in their reporting of claim-level payment elements that it is not paying an MFP refund for specified claim-level data elements because it reasonably believes the claim is a 340B-eligible claim (as defined in section 40.4.5 of this final guidance). If a Primary Manufacturer pays an MFP refund through the MTF PM and later verifies the claim was processed at the 340B price and the 340B ceiling price is lower than the MFP, the Primary Manufacturer may use the credit/debit ledger system described in section 40.4.3.2 of this final guidance to apply a credit equal to the MFP refund payment initially made, or it may effectuate nonduplication of the 340B ceiling price and the MFP outside of the MTF's processes. CMS anticipates that the credit/debit ledger system maintained by the MTF (or any similar system maintained by a Primary Manufacturer not participating in the MTF PM or by a Primary Manufacturer that participates in the MTF PM but has a mutually agreed-upon method with a dispensing entity for effectuating the MFP outside of the MTF PM) will help support nonduplication of the MFP and 340B ceiling price. CMS has also added a Justification Code (Code "8") to Table 5 in section 40.4.3.1 of this final guidance, which allows manufacturers to communicate in the claim-level payment elements that a reduced MFP refund payment is being made because a claim is determined to be 340B eligible and the MFP for that claim is lower than the 340B price of the drug. Additionally, dispensing entities can indicate on the claim that a 340B drug was used when a drug is dispensed using drugs purchased at the 340B price, to prevent duplication of the 340B ceiling price and the MFP.

Comment: One commenter requested specific guidance regarding the agency that will have enforcement authority with respect to 340B claim verification and dispute resolution, given the recent restructuring of the HHS. A couple of commenters noted that CMS should take accountability over duplication of discounts between the 340B ceiling price and the MFP if the 340B program moves under CMS' jurisdiction. The commenter noted that if HRSA does not move under CMS' jurisdiction in the future, CMS must work closely with HRSA to address the challenges related to the 340B ceiling price and MFP duplication of discounts. One commenter recommended CMS create a complaint and dispute process for 340B identification if CMS acquires oversight of the 340B program. One commenter recommended CMS coordinate closely with HRSA to ensure that 340B rebate guidance is finalized to allow flexibility for manufacturers

[32] See: https://www.govinfo.gov/content/pkg/FR-2025-08-07/pdf/2025-14998.pdf.

to develop and rely on private market solutions to comply with nonduplication of the 340B ceiling price and the MFP.

One commenter stated that CMS asserts that effectuating the 340B price falls under HRSA's purview, not that of CMS, but that construct should not apply in situations involving refunds to effectuate the 340B price for drugs purchased at the MFP, since the entire MFP effectuation system is outside of HRSA's purview.

Response: CMS appreciates the feedback from interested parties on this topic. Consistent with CMS' response on page 65 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS reiterates that CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim. CMS reiterates that nothing in this guidance modifies a Primary Manufacturer's statutory obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. Nothing in this guidance alters a Primary Manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the 340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11. CMS will monitor the extent to which MFP is made available where appropriate, and CMS will also monitor the extent to which the manufacturer faces challenges with nonduplication between the 340B ceiling price and the MFP.

Comment: One commenter requested that CMS clarify the language used in footnote 77 of the draft guidance for initial price applicability year 2028. The commenter argued that the footnote stated that section 340B(a)(1) of the PHS Act imparts authority to the manufacturers to make any determinations regarding the proper identification of 340B-eligible patients. The commenter asserted that the current 340B eligibility determination for individuals is discussed in section 340B(a)(5)(B) of the PHS Act, however, it only refers to the covered entity's responsibility in patient eligibility determination, while footnote 77 of draft guidance suggested a manufacturer privilege of patient 340B eligibility determination. The commenter argued that the footnote could create confusion or conflict between manufacturers and health centers about determining 340B eligible individuals.

Response: CMS thanks this commenter for the input. Footnote 77 of the draft guidance for initial price applicability year 2028 included the language, "CMS does not determine nor verify 340B eligibility and expects manufacturers and covered entities to continue to be responsible for statutory obligations pursuant to section 340B(a)(1) of the PHS Act regarding proper identification of 340B-eligible patients and covered outpatient drugs dispensed to such patients." The footnote refers not only to proper identification of 340B-eligible patients but also covered outpatient drugs dispensed to such patients. CMS is clarifying that this language indicates that manufacturers have statutory obligations related to offering the 340B ceiling price on covered outpatient drugs to eligible covered entities. CMS is not suggesting which entity determines a patient's 340B eligibility. CMS has also clarified the last sentence of the footnote in section 40.4.5 of this final guidance to more broadly refer to section 340B of the PHS Act rather than the specific obligations pursuant to section 340B(a)(1) of the PHS Act.

Comment: A few commenters stated that the draft guidance for initial price applicability year 2028 provides Primary Manufacturers with excessive latitude with respect to 340B nonduplication, and therefore, providers will be in a position where a Primary Manufacturer does not provide access to either the 340B price or the MFP. These commenters raised concerns that provider access to appropriate pricing could therefore hinge on burdensome complaint and dispute resolution processes and refund payments to providers would be excessively delayed. One commenter recommended that CMS provide financial support to providers as complaints and disputes are being resolved and require Primary Manufacturers to provide MFP refunds promptly unless the Primary Manufacturer is certain of and can provide documentation that the claim was identified as 340B-eligible and the 340B ceiling price was lower than the MFP. Another commenter recommended that Primary Manufacturers' nonduplication plans are shared with covered entities so that covered entities can prepare and share any concerns with the Primary Manufacturers in advance. One commenter recommended that CMS require Primary Manufacturers to share the documentation the Primary Manufacturer provides to CMS related to 340B eligibility determinations, stating that such documentation may be useful to providers should potential complaints or disputes emerge.

Response: CMS thanks these commenters for sharing their perspectives and concerns. As described in section 40.4.5 of this final guidance, the Primary Manufacturer is required 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 section 1193(d)(1) of the Act only applies 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 this final 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 further in section 90.2 of this final guidance. CMS refers the commenter who requested that CMS provide financial support to providers as complaints and disputes are being resolved to section 90.2.2 of this final guidance and the policy therein stating that the initiation of a dispute on a claim does not negate the Primary Manufacturer's statutory responsibility to make the MFP available to the dispensing entity for an MFP-eligible claim subject to a dispute.

As described in section 90.2.1 of this final guidance, some information from manufacturer MFP effectuation plans will be made available to dispensing entities through the MTF user interface, and all Primary Manufacturers' plans must include description(s) of the types of documentation and data they anticipate collecting, maintaining, and delivering to CMS, if requested, for the purposes of auditing and compliance with the requirement to make the MFP available. Information about the Primary Manufacturer's process regarding nonduplication of 340B claims is provided in Section 4, Question 6, of the Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form. This section and question will be collected solely for CMS' use for program monitoring and oversight and will not be made public. That is, the Primary Manufacturer's response to this question will not be shared with dispensing entities or

other stakeholders. CMS reiterates that nothing in this final guidance modifies a manufacturer's continued responsibility for statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to offer the 340B ceiling price to eligible entities, nor the federal agencies responsible for enforcing requirements under section 340B(a)(1) of the PHS Act and section 1193(d)(2) of the Act.

Comment: A few commenters requested that HHS exercise enforcement discretion with respect to Primary Manufacturers' nonduplication efforts if the Primary Manufacturer can demonstrate it has engaged in reasonable, good faith efforts with a covered entity to fulfill the manufacturer's obligations under section 1193 of the Act and section 340B(a)(1) of the PHS Act, as applicable, or if compliance is inhibited by factors outside of the manufacturer's control. One commenter requested clarity on the dispute resolution process, including clarity on which federal agency will be responsible for adjudicating complaints related to nonduplication with the 340B price and how disputes related to a 340B rebate model would be resolved. One commenter recommended CMS provide clear guidance for complaints and disputes related to 340B nonduplication that can be handled at the claim level.

Response: CMS thanks these commenters for their feedback. Consistent with CMS' response on page 62 of the final guidance for initial price applicability year 2027, the complaint and dispute system will be set up with two "tracks" within one overall system – one track for complaints and one track for disputes. The disputes process established in section 90.2.2 of this final guidance is intended to cover specific, identifiable challenges to a technical aspect of the MTF and process and is not intended to address 340B compliance concerns. Primary Manufacturers have the option to indicate in their report of claim-level payment elements if they did not pay an MFP refund on a particular claim because they identified it as a 340B claim and the 340B ceiling price is lower than the MFP. To account for the instance in which a Primary Manufacturer believes it provided an MFP refund through the MTF PM on a claim that had already been made available at a lower 340B ceiling price after the MFP refund had been processed (i.e., the manufacturer provided a duplication of discounts), the MTF's crediting functionality within the credit/debit ledger system will be available to enable the Primary Manufacturer to reconcile these duplications retroactively. The MTF DM will provide functionality for Primary Manufacturers to submit instructions for the MTF to apply a credit for the previously provided MFP refund in these scenarios such that Primary Manufacturers will have access to functionality to address duplicated discounts retroactively if needed.

The complaint process will be available to the public as well as Primary Manufacturers and dispensing entities, regardless of their degree of participation in any aspect of the MTF and will encompass any issues that do not qualify as disputes. A dispensing entity may submit a complaint to the MTF that the MFP was not made available, including with respect to claims that the Primary Manufacturer claimed were subject to section 1193(d)(1) of the Act based on the Primary Manufacturer's reported claim-level payment elements. CMS may investigate complaints related to MFP effectuation, including to assess whether an MFP refund was owed rather than the exception in section 1193(d)(1) of the Act applying. CMS intends to limit investigations and findings in such circumstances to (1) whether the MFP is lower than the 340B price; and (2) if so, whether the MFP was made available. As part of that investigation, 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. If CMS determines that the MFP should have been made available for the claim and was not, CMS will follow the process established in section 100.1 of this final guidance. Regarding the commenters' requests that manufacturers be held harmless in certain cases, CMS refers this commenter to sections 100 and 100.1 of this final guidance. Section 100 of this final guidance states that 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. Section 100.1 of this final guidance states that, upon discovery and confirmation of a Primary Manufacturer's failure to make MFP available, CMS intends to send the Primary Manufacturer a Notification of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS intends to establish a process in which the Primary Manufacturer will have 10 business days to respond to the Notice of Potential Noncompliance to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration. CMS intends to consider the materials provided by the Primary Manufacturer when determining the Primary Manufacturer's CMP liability, including any technical failures outside the control of the Primary Manufacturer related to the transmission of payment.

Comment: One commenter noted that, although CMS makes clear that using an NPI on its own would be insufficient to identify a claim as 340B, the claim-level data elements from the MTF DM include the NPI for prescribers and hospitals. The commenter requested clarification on whether using both NPIs in combination would be sufficient for concluding that a claim was 340B-eligible. This commenter strongly opposed identification of 340B-eligiblity based on a combination of NPIs. One commenter supported CMS' policy regarding the minimum manufacturer documentation demonstrating that a claim is 340B-eligible.

Response: CMS appreciates the support and feedback. In response to the commenter who requested clarification on the sufficiency of certain information for concluding that a claim was 340B-eligible, CMS clarifies that the claim-level data elements included in Table 2 of final guidance for initial price applicability year 2027, as well as in draft and final guidance for initial price applicability year 2028, do not include the hospital NPI. CMS believes this commenter may be referring to the Service Provider ID, which identifies the dispensing entity, and Prescriber ID claim-level data elements. In this final guidance, CMS has made clarifying revisions in sections 40.4.5 and 90.2 of this final guidance to align the language used in such sections with the data elements listed in Table 2. CMS affirms that neither the Service Provider ID nor the Prescriber ID alone will constitute sufficient evidence that a claim was 340B-eligible. The Primary Manufacturer is responsible for performing appropriate verifications to validate the 340B-eligibility of a claim. Absent details on specific analyses that a Primary Manufacturer may use to implement a 340B nonduplication approach, CMS is unable to confirm whether the Service Provider ID and Prescriber ID could be used together with other data sources as sufficient evidence that a claim was 340B-eligible.

Negotiation Factors (Section 50)

Comment: One 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 IRA directs CMS to consider information "submitted by the manufacturer" in relation to the factors listed in section 1194(e)(1) of the Act but the statute does not dictate how CMS should weigh or consider that information.

Response: CMS respectfully disagrees with this comment. 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." CMS believes this indicates that the information for section 1194(e)(1) factors must come from the manufacturer of the selected drug.

Comment: A few commenters expressed concern with the deadline for manufacturer submissions of manufacturer-specific data (as described in section 1194(e)(1) of the Act), and a couple of these commenters recommended CMS permit manufacturers to submit the required information after the March 1, 2026 deadline. One commenter suggested CMS broadly allow a manufacturer to supplement a timely submission if new information of relevance to the negotiation process becomes available after the submission deadline or otherwise for good cause shown. A couple of commenters suggested that interested parties should be provided a longer deadline to section 1194(e) data, including through the duration of the public engagement sessions.

Response: CMS thanks the commenters for their input. Pursuant to sections 1194(b)(2)(A) and 1193(a)(4)(B) of the Act, Primary Manufacturers must submit the manufacturer-specific data described in sections 1193(a)(4)(A) and 1194(e) of the Act to CMS by March 1, 2026 for initial price applicability year 2028. Consistent with CMS' response on page 104 in the final guidance for initial price applicability year 2027, CMS will use data submitted by the Primary Manufacturer and other interested parties when developing the initial offer for a selected drug along with CMS analyses and assessments of evidence as described in section 60.3 of this final guidance. Further, 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, 2026, it is not feasible to extend the timeframe for the submission of information under section 1194(e)(2) of the Act. CMS is abiding by the statutory deadlines in this final guidance. As described in section 60.4.1 of this final guidance, interested parties will have several opportunities to provide additional section 1194(e)(2) information after the March 1, 2026 deadline.

Comment: A few commenters encouraged CMS to gather input from a variety of types of stakeholders. A couple of these stakeholders suggested CMS prioritize input from certain interested parties, including clinicians. A couple of these stakeholders also raised concerns that the current written submission process was challenging for certain interested parties and that CMS should provide multiple pathways to provide feedback that are tailored to specific groups of stakeholders, including those with audio-visual or physical challenges. One of these commenters also suggested modifying the information collection so that it required no greater than an eighth grade reading level and recommended making the information collection available

in languages other than English. Additionally, this commenter suggested CMS collect voluntary demographic information to better understand who is using the written submission process.

Response: CMS thanks commenters for their feedback. The initial price applicability year 2028 negotiation process provides multiple opportunities for any interested party to share their feedback, including clinicians. The Drug Price Negotiation ICR collects written information on the factors that are described in section 1194(e)(2) of the Act and is divided into sets of questions that may be applicable to different types of stakeholders, such as those with clinical-focused experience, patients and caregivers, those with research-focused backgrounds, and manufacturers. CMS encourages commenters to provide feedback on revisions to the Drug Price Negotiation ICR for initial price applicability year 2028, and notes that the proposed optional form for the public does include a request for submitters to identify their respondent type and for patients and caregivers to optionally provide certain demographic information. CMS continues to take suggestions regarding translations and alternative collection methods into consideration for future initial price applicability years. As discussed in section 60.4.1 of this final guidance and in response to other comments about opportunities for public input above, interested parties will also have opportunities to provide input orally to CMS through public engagement events.

Comment: Many commenters requested CMS provide additional information regarding how CMS uses the information submitted in the negotiation process. A few commenters suggested such information would improve efficiency in the manufacturer's process to collect and submit the required data because the manufacturer could better identify the relevant data. A few other commenters requested CMS clarify its use of written versus oral information shared about the section 1194(e)(2) factors.

Response: CMS directs commenters to section 60.3 of this final guidance and responses to comments about this section, which concern how CMS uses the section 1194(e) data in developing an initial offer and, if any, counteroffers.

Comment: One commenter suggested that CMS streamline the information by not requesting a manufacturer to submit data available publicly or via other federal agencies.

Response: Consistent with CMS' response to similar comments received in relation to the collection of section 1194(e)(1) data for initial price applicability years 2026 and 2027, CMS maintains that although some of the information may be available through other sources, CMS may not be able to ensure that such data are complete or up to date, and, ultimately, CMS believes that the Primary Manufacturer is best positioned to provide the requested data. Furthermore, CMS section 1194(e)(1) of the Act requires that manufacturers submit information required under this section to CMS for purposes of the Negotiation Program.

Comment: One commenter requested that CMS clarify whether Primary Manufacturers are obligated to continually update their data submissions or only if it becomes clear to the manufacturer that the information submitted was incorrect based on information available at the time of submission or if the data changes (e.g., a Medicaid best price restatement). The commenter raised concerns about the interplay of the requirement to update data with the reporting of data for renegotiation.

Response: As stated in section 50.1 of this final guidance, a Primary Manufacturer must submit updates to the Primary Manufacturer's data submitted under sections 1193(a)(4)(A) and 1194(e)(1) of the Act to CMS if the data was restated due to requirements of the government entity that initially receives and oversees processing of such data, which as the commenter provides, includes revisions to Medicaid best price under 42 C.F.R. § 447.510. 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 (see section 130.3.1 of this final guidance) and the required submission of section 1194(e)(1) data to CMS for drugs selected for renegotiation (see section 130.3.2 of this final guidance), which cover different reporting periods. The reporting requirements in section 50.1 of this final guidance apply to data submitted for negotiation and renegotiation.

Comment: Some commenters urged CMS not to use any metrics of cost-effectiveness or "cost per generic health metric" because the metric and/or the underlying data or assumptions used to develop the metric may be discriminatory. One commenter requested clarification as to whether CMS would use any cost effectiveness metrics. A few commenters supported CMS' decision not to use Quality-Adjusted Life Years (QALYs) when assessing section 1194(e)(2) factors. One commenter supported CMS' consideration of studies that have content relevant to the negotiation process even if the study uses QALYs. One commenter urged CMS to consider the effects that indirectly using metrics like the QALY could have on patients. One commenter urged CMS not to use cost-effectiveness assessments when reviewing a selected drug. One commenter supported the use of health measures that do not violate the prohibition of discriminatory measures in section 1194(e)(2) of the Act, noting studies that include such metrics may provide valuable information on the selected drug.

Response: CMS appreciates these commenters' feedback on cost effectiveness measures. Consistent with our response on page 85-86 of the final guidance for initial price applicability year 2027, CMS reaffirms that QALYs will not be used in the Negotiation Program. CMS 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. In response to feedback received on whether any measures may be permissible under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act, CMS states in section 50.2 of this final guidance that CMS 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 may be 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.

Comment: Some commenters disagreed with CMS' decision to remove the requirement for respondents to the Drug Price Negotiation ICR for initial price applicability year 2028 to indicate whether their submission contains information from studies that use measures or methods that treat 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

and the request that respondents provide a short description of any cost-effectiveness measures included in the research they are submitting, and how they believe the data avoids treating 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. A few of these commenters stated without this requirement, the submitter would not need to disclose if the evidence submitted included discriminatory measures. A few other commenters stated that removal of this requirement jeopardizes transparency in the information shared with CMS and used by CMS in the negotiation process. One commenter supported the decision to remove this requirement because the commenter said it may provide a barrier to submission for respondents unfamiliar with the concept(s).

Response: CMS thanks commenters for their feedback. Consistent with the response to the comments about the use of cost-effectiveness measures provided immediately above and in accordance with section 50.2 of this final guidance, CMS reiterates that QALYs will not be used in the Negotiation Program. Nonetheless, CMS reviews, and will continue to review, measures included in studies submitted by respondents through the Drug Price Negotiation and Drug Selection ICRs. CMS determines, and will continue to determine, if it is appropriate under section 1194(e)(2) of the Act for CMS to consider the information submitted. Section 50.2 of this final guidance discusses the criteria CMS will follow when considering the validity and rigor of the section 1194(e)(2) evidence submitted by interested parties in response to the Drug Price Negotiation and Drug Selection ICRs. Further, CMS directs commenters to section 60.6.1 of this final guidance where CMS discusses publication of the explanation of the MFP, which 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 for initial price applicability year 2028.

Comment: A few commenters requested that CMS provide further detail on study design and evidence prioritization in the Negotiation Program, including but not limited to details related to acceptable modes of data collection, whether outcome adjudication is required for all endpoints in all studies, and approaches to stratifying subgroups of interest. A few commenters suggested that CMS prioritize real-world evidence. One commenter suggested that CMS balance manufacturer-submitted evidence with unpublished data. One commenter suggested that CMS prioritize data submitted by sources other than the Primary Manufacturer. One commenter requested that CMS indicate that Artificial Intelligence (AI)/Machine Learning (ML)- and Large Language Model (LLM)-derived real-world data is acceptable as part of the submission of data under section 1194(e)(2) of the Act.

Response: CMS appreciates commenters' feedback. Section 50.2 of this final guidance describes how CMS will consider evidence and how CMS will prioritize such evidence. Specifically, section 50.2 of this final guidance states that CMS will review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this final guidance) when considering available evidence about alternative treatments to the selected drug. When reviewing the data submissions from the public and manufacturer (including the examples of data above) as well as literature from CMS' review, CMS intends 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. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., 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. CMS believes the above approach will ensure the integrity of the contributing data within the negotiation process.

Comment: One commenter recommended using the European Society for Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale (ESMO-MCBS)[33] in the assessment of section 1194(e)(2) factors for cancer products. Another commenter suggested that CMS consider using a quality framework applicable to both structured and unstructured data, including the ISPOR SUITABILITY Checklist,[34] Flatiron Health's Validation of Accuracy for LLM/ML-Extracted Information and Data (VALID) framework,[35] the ISPOR PALISADE Checklist,[36] and the ISPOR HARmonized Protocol Template to Enhance Reproducibility of Hypothesis Evaluating Real-World Evidence Studies on Treatment Effects (HARPER) framework.[37] One commenter recommended that CMS consult subject matter experts on real-world data quality and methods for mitigating bias in real-world data.

Response: CMS appreciates the suggestion to use the ESMO-MCBS to assess section 1194(e)(2) factors for cancer products as well as the suggestion to review the ISPOR SUITABILITY Checklist, Flatiron Health's VALID framework, the ISPOR PALISADE Checklist, and the ISPOR HARPER framework to inform real-world data evaluation. CMS will 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. CMS also appreciates the suggestion to consult with subject matter experts on real-world data quality and bias and notes that section 50 of this final guidance indicates that CMS will consult with subject matter experts and clinicians when considering available evidence about alternative treatments to the selected drug.

Comment: One commenter supported allowing any interested party to submit data and evidence to CMS about therapeutic alternatives to drugs selected for negotiation, as information from members of the public, including manufacturers, Medicare beneficiaries, their caregivers,

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[33] 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.

[34] Fleurence RL, Kent S, Adamson B, et al. Assessing real-world data from electronic health records for health technology assessment: the SUITABILITY checklist: a good practices report of an ISPOR Task Force. *Value Health*. 2024;27(6):692-701.

[35] Estevez M, Singh N, Dyson L, et al. Ensuring Reliability of Curated EHR-Derived Data: The Validation of Accuracy for LLM/ML-Extracted Information and Data (VALID) Framework. *arXiv.* 2025.

[36] Padula WV, Kreif N, Vanness DJ. Machine learning methods in health economics and outcomes research—the PALISADE Checklist: a Good Practices Report of an ISPOR Task Force. *Value Health*. 2022;25(7):1063-1080.

[37] Wang SV, Pottegård A, Crown WH, et al. HARmonized Protocol Template to Enhance Reproducibility of Hypothesis Evaluating Real-World Evidence Studies on Treatment Effects: A Good Practices Report of a Joint ISPE/ISPOR Task Force. *Value Health.* 2022; 25(10):1663–1672.

academic experts, clinicians, and other interested parties, can play an important role in informing negotiation.

Response: CMS appreciates this commenter's feedback and agrees that robust public input can provide important information on the selected drug and its therapeutic alternatives.

Comment Solicitation on "Forward-looking" Market Data
Comment: Many comments responded to CMS' request for comments on the collection of "forward-looking" market data for the selected drug. Many commenters expressed concern with the type of data suggested in the draft guidance for initial price applicability year 2028. Specifically, these commenters stated that data capturing future projections of costs and/or revenue is not permissible under or consistent with the statute at section 1194(e)(1)(E) of the Act. One commenter stated that CMS' proposal to include forward-looking data in the scope of the factor described at section 1194(e)(1)(E) of the Act is to skew the manufacturer-data towards a lower initial offer. Additionally, some of these commenters stated the data is variable, dynamic, and that the evolving nature of the data would not be consistent with the Primary Manufacturer's requirement to certify that the data submission is "complete and accurate." Additionally, one commenter stated that given the speculative nature of the data, the data is considered highly confidential by manufacturers and CMS should not take on the risk of needing to protect this type of data. A few commenters also stated that additional data will increase manufacturer burden, may require manufacturers to establish new processes to obtain the information, and is inconsistent with CMS' otherwise stated intention to streamline the ICRs. A few commenters also observed that it may be challenging to provide appropriate directions to collect the data intended by CMS. Other commenters supported collection of forward-looking market data but cautioned CMS that the data may be manipulated and less reliable because it is speculative. Some of these commenters suggested CMS require and/or consider third-party sources, such as SEC disclosures, to support the data. One of these commenters also suggested CMS consider data and best practices used by other health authorities. One commenter suggested that if CMS collects this type of data to specify the data is associated with only the selected product because costs are not static and may increase with investments.

Response: CMS thanks commenters for their suggestions related to additional data to be collected and considered under section 1194(e)(1)(E) of the Act. CMS will consider these comments in CMS' policy development for this issue in future rulemaking.

Establishment of a Single MFP for Negotiation and Renegotiation Purposes (Section 60.1)

Comment: Many commenters responded to CMS' request for comments on whether it should take an alternative approach to negotiating the single price for the selected drug—for example, on a per-unit basis rather than a 30-day equivalent supply basis, or on the basis of a days' supply less than 30 days—for drugs for which a 30-days' supply is not representative of the typical use of such drug (for example, drugs that have only one formulation and are indicated for administration once in a course of treatment, or drugs that are typically administered daily for a short period such as two weeks). Some of the commenters opposed the use of a 30-day equivalent supply, especially if it were to be applied to drugs payable under Part B. One commenter opposed using a per unit approach to replace an approach based on 30-day equivalent

supply and suggested an alternative approach of using price per course of treatment. A few other commenters expressed concern with CMS' approach 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, and severity-based variation. One of these commenters stated that any methodology should be flexible to accommodate the clinical disease state and treatment landscape, and account for differences in titration and onboarding versus maintenance dosing, as well as to account for treatment-free intervals. One separate commenter suggested that instead of using an approach based on 30-day equivalent supply, that CMS should adopt a lowest unit of measure-based approach (that is the same or common across all prices, volumes, dosage forms and strengths) for selected drugs. The commenter suggested that this approach reduces burden and facilitates easy conversion to package size or billing unit type (e.g., mg for Part B or mL for Part D) and that once a common billing unit conversion is established (e.g., mL), the prices can be appropriately weighted to derive at a combined single MFP ceiling for both Part B and Part D (e.g., both ceilings converted to price per mL). A few commenters requested that CMS consult with Primary Manufacturers on the methodology to be used for a selected drug, and if feasible, prior to the initial offer so any limitations are appropriately addressed and accounted for in the initial offer. A couple of the commenters supported the calculation of one MFP that would apply to all dosage forms and strengths and appreciated the clarity and transparency provided by CMS in section 60.1 of the draft guidance for initial price applicability year 2028. A couple of the other commenters suggested that CMS should divide all amounts of days between service by 30, not just those where days between service is greater than 34 because Part B products have dosing schedules that can have much more variability than in Part D.

Response: CMS thanks these commenters for their thorough and extensive feedback and suggestions to CMS' request for comments. CMS will continue to use the 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, as well as across drugs, and CMS appreciates the support from the commenters stating there is more clarity and transparency provided in this final guidance. As stated in section 60.2.1.1 of this final guidance, to calculate the 30-day equivalent supply for each PDE record associated with a selected drug that is a drug covered under Part D, CMS will use the methodology as described at 42 C.F.R. § 423.104(d)(2)(iv)(A)(2). This methodology relies on the "days' supply" field in PDE records. The methodology for a selected drug covered under Part D will remain the same because there is a "day supply" field in the PDE to calculate total 30-day equivalent supply for a selected drug, or therapeutic alternative(s), making it easier to apply this methodology.

To calculate the 30-day equivalent supply for Part B data associated with selected drugs that are payable under Part B, CMS must use an alternative methodology because Part B data does not contain a "days' supply" field. CMS appreciates the suggestions from commenters and has taken into consideration the commenters' input and updated the methodology for the calculation of 30-day equivalent supply methodology in section 60.2.1.1 of this final guidance for selected drugs payable under Part B. For selected drugs payable under Part B, CMS will use the "days between service" amount calculated for each Part B claim to calculate the 30-day equivalent supply. For each Part B claim, the number of 30-day equivalent supplies is equal to the 'days between service' divided by 30. This updated methodology will also prevent overvaluing drugs with less

than 30 days between administration because under this methodology, they will have a 30-day supply equivalent less than 1. CMS understands that drugs payable under Part B often have recurrent administrations and variable dosing depending on body weight, indication, treatment phase, or response to treatment, and the "days between services" methodology addresses these concerns by using observed data from individual patients, which can be captured if providers are following patient-specific dosing regimens. CMS appreciates the commenters' suggestion of working with the Primary Manufacturers on the methodology to be used for a selected drug, but this would be time and resource intensive and potentially not lead to a standardized approach and methodology that could be used for selected drugs and their therapeutic alternative(s). For these reasons listed above (e.g., the suggested approach is time and resource intensive and may not lead to a standardized approach and methodology that could be used for selected drugs and their therapeutic alternative(s)), CMS does not believe that a price per course of treatment approach is feasible. CMS does not believe that a per unit price for Part B drugs would work as well as the 30-day equivalent supply methodology because unit type may differ both across HCPCS within a Part B selected drug and also across therapeutic alternative(s) for a selected drug, especially if it includes drugs payable under Part B and covered under Part D. The 30-day equivalent supply methodology provides a standardized methodology for CMS to calculate a price for a standardized treatment duration for all dosage forms and strengths of selected drugs and therapeutic alternatives and also allows for easier comparison across the selected drug and the respective therapeutic alternative(s).

Determination of the Ceiling for the MFP (Section 60.2.1)

Comment: A few commenters expressed concern for CMS' approach when determining a ceiling when a selected drug is payable under Part B and covered under Part D. One of the commenters stated that the combination of Part B and Part D prices in a qualified single source drug can lead to a ceiling for a drug payable under Part B calculated based on the price of a drug covered under Part D (or vice versa) and that it would lead to incongruous results. One of the commenters requested that CMS state whether the ceiling calculation methodology will differ between Part B and Part D products, and if so, how those differences will be reflected in the negotiation process. One of the commenters requested that CMS establish the MFP at the statutory ceiling for multi-indication drugs which could help ensure that the negotiation process rewards manufacturers' innovation. One of the commenters suggested that, with respect to a selected drug that is payable as a DCAPS drug under Part B and covered as a Part D drug, CMS should not include the Part B DCAPS utilization when calculating the ceiling.

Response: CMS appreciates the feedback and suggestions from the commenters. As described in section 60.2.1 of this final guidance, in accordance with section 1194(c) of the Act, for initial price applicability year 2028, when CMS is determining the ceiling for the MFP for selected drugs, it shall not exceed:

- As described in section 60.2.2 of this final guidance and section 1194(c)(1)(B) of the Act, an amount equal to one of the following, as applicable to the selected drug:
    - 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 described in section 60.2.2.1 of this final guidance; or

    - For a selected drug that is payable under Part B and paid according to section 1847A(b)(4), 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, as described in section 60.2.2.2 of this final guidance; or
    - 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 weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount (hereinafter the "combined Part B and Part D amount"), as described in section 60.2.2.3 of this final guidance. CMS interprets the language in section 1194(c)(1)(B) of the Act to mean that it should calculate a single ceiling incorporating both of these amounts for selected drugs payable under Part B and covered under Part D.
    - For a selected drug that is payable under Part B but not paid according to section 1847A(b)(4) of the Act (for example, selected drugs which are paid on the basis of 95 percent of Average Wholesale Price (AWP)), but is not covered under Part D, an amount based on the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance; or
    - For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and covered under Part D, an amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance or the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.
- As described in section 60.2.3 of this final guidance and section 1194(c)(1)(C) of the Act, an amount equal to the applicable percent, as applicable to the selected drug, of the lower of:
    - The average non-FAMP as defined in section 1194(c)(6) of the Act for such 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 Consumer Price Index for All Urban Consumers (CPI-U) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2025;[38] or
    - The average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for the calendar year prior to the selected drug publication date, February 1, 2026, which for initial price applicability year 2028 is 2025.

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean that it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan-specific enrollment weighted amounts under Part D, the payment amount under section 1847A(b)(4) of the Act under Part B, the combined Part B and Part D amount, and the applicable percent of the average non-FAMP in order to determine which one is lower and will serve as the ceiling for the MFP. To determine which of these will be used to calculate the ceiling for the MFP, CMS will aggregate the amounts determined for each NDC-11 for the selected drug to calculate a single amount—separately for each methodology—across dosage forms, strengths, and package sizes of the selected drug. These amounts can then be directly compared, and the

[38] Data retrieved from https://www.bls.gov/cpi/data.htm.

ceiling for the single MFP of the selected drug (including all dosage forms and strengths) will be the lower amount.

In response to the commenter that suggested CMS exclude DCAPS utilization when calculating a ceiling for a selected drug that is payable as a DCAPS drug under Part B and covered under Part D, CMS states in section 60.2.2.3 of this final guidance that for single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source dugs and biological products which are paid on the basis of 95 percent of AWP), and that are also covered under Part D, CMS will calculate the ceiling amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.2.2 of this final guidance and the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.

Determination of the 30-Day Equivalent Supply for a Selected Drug (Section 60.2.1.1)
Comment: Some commenters provided feedback on CMS' determination and calculation method of the 30-day equivalent supply for a selected drug. A couple of the commenters stated that they appreciate the complexity of the issues CMS is seeking to address with the 30-day equivalent supply calculation. One of these commenters stated practical limitations of standardizing pricing around a 30-day equivalent supply, particularly for topically applied drugs as the quantity used can vary significantly from patient-to-patient, and prescribers do not typically determine usage based on a fixed monthly amount, making the 30-day pricing model ill-suited for this route of administration and dosage regimen. They recommended that CMS describe how they would calculate the 30-day equivalent supply for these types of drugs and ensure that the methodology accounts for variable dosing patterns and real-world clinical use. The other commenter expressed concern that CMS' current approach may create calculated prices that are inconsistent with clinical use. This commenter also expressed concern with the use of claims data to determine the dose intervals for negotiated drugs, especially for Part B therapies, to include oncology products, and recommended that treatment intervals be based on FDA label, rather than claims data. One commenter suggested that CMS should also consider methods to exclude any outlier Part B claims in which the days between service exceeds the maximum days between service contemplated in the dosing schedules in the product's FDA-approved label. One commenter suggested for CMS to use accurate and consistent 30-day equivalent supply price calculations to calculate price of selected drugs and therapeutic alternative(s).

Response: CMS thanks these commenters for their feedback and suggestions. As stated in section 60.2.1.1 of this final guidance, CMS will calculate a single ceiling per 30-day equivalent supply across all dosage forms and strengths of the selected drug. 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 (e.g., mg versus mL) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ. In response to the commenter regarding topically applied drugs, CMS will use the methodologies described in section 60.2.1.1 of this final guidance depending on whether it is a drug covered under Part D or a drug that is payable under Part B. By using a 30-day equivalent supply methodology for both selected drugs covered under Part D and selected drugs payable under Part B, CMS is using a consistent approach but understands that there may be some outliers to this methodology. CMS

considered using treatment intervals based on FDA label but decided against doing so because the "days between services" methodology uses observed data from individual patients, which would capture patient-specific dosing regimens. CMS believes that the finalized methodology for 30-day equivalent supply for selected drugs payable under Part B and covered under Part D provides accurate and consistent calculations that can be used for most selected drugs and therapeutic alternative(s). CMS is considering a different methodology for future rulemaking to calculate the 30-day equivalent supply for drugs that have only one administration (e.g., CAR T-Cell, vaccines, gene therapies and cancer therapies), as well as an outlier policy.

Comment: A few commenters recommended for CMS to take this opportunity to re-assess the 30-day supply approach and substantially simplify and increase transparency in its approach to including drugs payable under Part B for initial price applicability year 2028 and subsequent years by adopting a unit-based approach rather than relying on calculation of a 30-day equivalent supply of the selected drug.

Response: CMS thanks this commenter for their suggestions and information. As stated in section 60.1 of this final guidance, once the MFP has been agreed upon, section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply the MFP across different dosage forms and strengths of a selected drug and a 30-day equivalent supply creates a more direct comparison for drugs that have different dosage form, strength, and treatment regimens than a unit-based approach. CMS believes that a 30-day equivalent supply methodology also gives a more complete picture of beneficiary utilization. A unit-based approach may have unit types that differ across HCPCS within a Part B selected drug and across therapeutic alternative(s) for a selected drug, especially if the selected drug and/or a therapeutic alternative has both Part B and Part D utilization. CMS will continue to use the 30-day equivalent supply methodology and for drugs payable under Part B, CMS has updated the methodology for calculation of 30-day equivalent supply in section 60.2.1.1 of this final guidance. For drugs payable under Part B, CMS plans to divide "days between services" by 30 instead of using the methodology described at 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for PDE records. This updated methodology should lessen the possibility of undervaluing the costs of Part B drugs when attempting to determine their cost per 30-day equivalent supply.

The Sum of the Plan-Specific Enrollment Weighted Amounts (Section 60.2.2.1)
Comment: One commenter recommended CMS incorporate all price concessions from manufacturers to Part D plans, including those required under the Manufacturer Discount Program and discounts provided to Part D plans under the redesign, 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.

Response: CMS thanks this commenter for their suggestion. CMS disagrees with this commenter's suggestion of including the Manufacturer Discount Program discounts as they are not a price concession based on current regulation at 42 C.F.R. § 423.100; CMS will continue to use the C.F.R. definition of direct and indirect remuneration (DIR) and incorporate the CGDP/MDP discounts in the ceiling calculation.

Payment Amount Under Section 1847A(b)(4) of the Act (Section 60.2.2.2)
Comment: A couple of commenters responded to CMS' request for comments on the approach, described in section 60.2.2.2 of the draft guidance for initial price applicability year 2028, and on other options to calculate the ceiling for MFP for selected drugs payable under Part B that are not paid based on section 1847A(b)(4) of the Act. One of these commenters supported CMS' proposal to default the ceiling amount calculated via the average non-FAMP methodology for the Part B drugs not paid under 1847A(b)(4) of the Act (e.g., those paid at 95 percent of the average wholesale price) but cautioned to ensure that the ceiling amount does not disrupt patient access due to misalignment with provider acquisition costs. The other commenter stated that CMS should not substitute an alternative payment amount to calculate the ceiling stating that CMS has no authority to substitute an alternative payment amount for purposes of calculating the single ceiling and setting the MFP. A few commenters recommended that CMS exclude Part B preventive vaccines from the Negotiation Program, as vaccines are paid under section 1842(o)(1)(A)(iv) of the Act, whereas statute refers to section 1847A(b) of the Act as the basis for determining key implementation provisions of the Negotiation Program in Part B.

Response: CMS thanks the commenters that gave feedback and suggestions to CMS' request for comments. For single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP but are not covered under Part D, CMS will use the amount determined under section 1194(c)(1)(C)(ii) of the Act as the ceiling. That is, for selected drugs payable under Part B but not paid based on section 1847A(b)(4) of the Act, CMS will calculate the ceiling based on the applicable percent of average non-FAMP. CMS is not substituting an alternative payment amount to calculate the ceiling for these drugs because drugs that are not paid under section 1847A of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP) do not have a "payment amount under 1847A," and so CMS is interpreting the statute as directing it to use the applicable percentage of the average non-FAMP amount to calculate ceiling and thus not having a comparison to the "lesser of" as is done for single-source drugs and biological products payable under Part B for which the payment amount is under section 1847A(b)(4) of the Act. As stated in section 60.2.2.3 of this final guidance, for single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP), and covered under Part D, CMS will calculate the ceiling amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance and the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.

In response to recommendations that CMS exclude Part B preventive vaccines from the Negotiation Program because they are paid under section 1842(o)(1)(A)(iv) of the Act, as CMS notes in section 30.1 of this final guidance comment and response section, nothing in the statute indicates that CMS should exclude vaccines or products with complex and time intensive production processes from being potential qualifying single source drugs nor from the Negotiation Program more broadly. In fact, section 1194(c)(3)(A) of the Act makes clear that vaccines are not categorically excluded from the Negotiation Program. Section 1194(c)(3)(A) of the Act specifies the same applicable percent, for purposes of calculating the ceiling under

section 1194(c)(1)(C) of the Act, for vaccines as it does short-monopoly drugs. By expressly specifying an applicable percent for establishing a ceiling for the MFP of vaccines as it does for short-monopoly drugs, the statute contemplates the selection of vaccines under the Negotiation Program.

Determination of Payment Amount for Selected Drugs Payable Under Part B and Covered Under Part D (Section 60.2.2.3)

Comment: One commenter recommended for CMS to negotiate and effectuate an MFP under either Part B or Part D separately rather than calculate a single MFP across Part B and Part D formulations of the selected drug. This commenter had significant concerns with the proposed methods discussed in this section such as using Part B claims data to calculate "days between service" as a proxy for days' supply as being inappropriate.

Response: CMS thanks this commenter for their input but disagrees with the recommendation. As stated in section 60.2.2.3 of this final guidance, CMS interprets the language in section 1194(c)(1)(B) of the Act to mean it should calculate a single amount across the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amounts for all dosage forms and strengths of a selected drug that is payable under Part B and covered under Part D. Section 1194(c)(1)(B) of the Act provides for the calculation of "an amount," in the singular, for each selected drug. It then specifies the payment amount under section 1847A(b)(4) of the Act as the amount to be used for selected drugs for which payment may be made under Part B and the sum of the plan-specific enrollment weighted amounts as the amount to be used for selected drugs covered under Part D. It does not specify that CMS should select only one when calculating the amount for a drug that fits into both categories. For such selected drugs, section 1194(c)(1)(B) of the Act's direction to calculate a single amount for each selected drug therefore means that CMS should calculate a single 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. CMS clarifies that for single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP) which do not have a payment amount under section 1847A(b)(4) of the Act, and covered under Part D, CMS will calculate the ceiling amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance or the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance. As described in section 60.2.4 of this final guidance, CMS will compare the lower amount of the applicable percent of the average non-FAMP as determined in section 60.2.3 of this final guidance to the amount calculated in section 60.2.2 of this final guidance (sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable) to determine the lower amount, which will be the ceiling for the selected drug. If an agreement on the MFP for a selected drug is reached, once CMS has determined the ceiling for the selected drug, CMS will ensure that the MFP per 30-day equivalent supply, as negotiated through the process described in sections 60.3 and 60.4 of this final guidance, is not greater than the ceiling.

Methodology for Developing an Initial Offer (Section 60.3)

Comment: A couple of commenters supported consideration of off-label use when determining the indications for a selected drug and the therapeutic alternatives, particularly in oncology, while a few commenters opposed the consideration of off-label use. One commenter asked CMS to clarify how manufacturers can provide evidence related to off-label use that may not be included in evidence-based guidelines.

Response: CMS appreciates commenters' feedback on the consideration of off-label use when reviewing the indications for a selected drug and determining its therapeutic alternatives, if any. In response to the request for clarification on evidence related to off-label use, consistent with the response provided on page 90 of the final guidance for initial price applicability year 2027, CMS encourages members of the public, including manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties to provide information about off-label use(s) through the Drug Price Negotiation ICR. CMS will consider information submitted through the Drug Price Negotiation ICR when developing the initial offer and throughout the negotiation process. CMS' policy includes the criteria that must be met for CMS to consider an off-label use of a selected drug. Per section 60.3.1 of this final guidance, CMS 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, and/or accepted standards of medical practice.

In section 60.4 of this final guidance, CMS sets forth negotiation process policies including an opportunity for the Primary Manufacturer to meet with CMS regarding the 1194(e) data submission 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) with CMS.

Comment: A few commenters stated that selection of a therapeutic alternative(s) should be based on only clinical factors and that CMS should not consider the cost of the therapeutic alternative(s). A couple of commenters urged CMS to limit the selection of therapeutic alternatives to the same pharmacologic class and a few commenters asked CMS to limit the selection of therapeutic alternatives to drugs with the same mechanism of action. One commenter stated that therapeutic alternatives should be chosen if they represent the standard of care for treatment of a given indication. One 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. Another commenter recommended that 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-word data studies of comparative effectiveness; and National Health Council (NHC) resources on patient-centeredness in value assessment. One commenter suggested that CMS consider the use of comparative effectiveness studies and real-world evidence to support the selection of therapeutic alternatives.

Response: CMS appreciates commenters' feedback regarding the identification of a therapeutic alternative(s) for the selected drug. Consistent with the response provided on pages 91-92 of the final guidance for initial price applicability year 2027 and as described in section 60.3.1 of this final guidance, CMS 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. CMS believes the framework described in section 60.3.1 of this final guidance allows CMS to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. CMS may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same indication. CMS may also consult with clinicians, patients or patient organizations, and/or researchers, to ensure that appropriate therapeutic alternatives are identified. CMS appreciates the suggested resources for best practices in observational comparative effectiveness research, real-world data studies of comparative effectiveness, and patient-centeredness in value assessments and intends to consider how these resources may be used in the Negotiation Program, consistent with section 1194(e) of the Act, for initial price applicability year 2028.

Comment: In the draft guidance for initial price applicability year 2028, CMS requested input on the possibility and feasibility of considering health care services payable under Medicare Part A or Part B as potential therapeutic alternatives to the selected drug for future rulemaking. One commenter supported the possibility of considering nonpharmacologic therapeutic alternatives that are included in clinical guidelines and another commenter supported the approach but advised CMS to consider ways to ensure that a comparison between a health service and a drug is fair and appropriate. Some commenters opposed the use of health services as a potential therapeutic alternative. Among these commenters, one cautioned that expanding comparisons to including health services is not appropriate because such services do not reflect the risk, development cost, or patient impact of biopharmaceutical innovation; another commenter noted that comparing a drug to a health service is difficult because they are reimbursed using different methodologies; and a couple of commenters indicated that distinguishing between the impact of drugs and services would be difficult because health services may act as a complementary therapy to drugs or are part of a sequential order of treatments, such as in oncology (e.g., a health care service is considered a first or second line treatment, followed by a drug as a third line treatment). A few commenters indicated that CMS should provide a more detailed policy approach that includes which Part A and Part B services would be considered as therapeutic alternatives.

Response: CMS appreciates the feedback provided on this comment solicitation and may consider commenter feedback on using health care services as therapeutic alternatives for future rulemaking. CMS reiterates that for initial price applicability year 2028, only drugs or biological products payable under Part B and/or covered under Part D will be considered therapeutic alternatives to a selected drug. As stated in section 60.3.1 of this final guidance, at this time, CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials.

Comment: A few commenters requested that CMS prioritize clinical appropriateness when determining the therapeutic alternative(s) to a selected drug. A few commenters requested greater transparency into the methodology for identifying a therapeutic alternative and the evidence used for such identification. One commenter asked that CMS adopt a specific definition for "clinically comparable" and one commenter asked CMS to define "clinical benefit" to specifically prioritize evaluations around endpoints, patient reported outcomes, patient experience data, and patient preferences. One commenter suggested that therapeutic alternatives should have comparable real-world patient use to the selected drug. One commenter urged CMS to limit therapeutic alternatives to selected drugs that treat HIV to antiretrovirals, account for dosing requirements, and account for last-line antiretrovirals with no therapeutic alternative. One commenter cautioned that the use of claims to identify utilization and spend for oncology drugs lacks specificity and may introduce a large margin of error but did not suggest an alternate data source. One commenter asked that CMS revert to using the "most" clinically comparable therapeutic alternative(s) as was described in the revised guidance for initial price applicability year 2026. One commenter stated that therapeutic alternatives should be considered at the time of approval rather than the time of negotiation to credit innovation, particularly first-in-class drugs.

Response: CMS appreciates commenters' feedback regarding the selection of a therapeutic alternative(s) for a selected drug. As indicated in CMS' response on page 91 of the final guidance for initial price applicability year 2027, CMS believes the framework described in this final guidance will allow CMS to identify appropriate therapeutic alternative(s) for the indications of current and future selected drugs, if such alternatives exist, including those used in cancer and HIV treatment. Consistent with the response provided on page 94 of the final guidance for initial price applicability year 2027 and as described in section 60.3.1 of this final guidance, CMS will identify the therapeutic alternative(s) for the indication of the 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. CMS believes that the current framework provides sufficient detail on how CMS will determine therapeutic alternatives to a selected drug and notes that both the Primary Manufacturer and other interested parties are able to provide input on therapeutic alternatives through the Drug Price Negotiation ICR. CMS also provides the option for a Primary Manufacturer to meet with CMS after the Drug Price Negotiation ICR information is submitted but before CMS provides the initial offer, which serves an opportunity for the Primary Manufacturer to provide additional context or information on possible therapeutic alternatives. Additionally, CMS will evaluate therapeutic alternative(s) for the indications of a selected drug, as described in this final guidance section 60.3.1, as of the time the section 1194(e)(2) data is submitted, which CMS believes is consistent with section 1194(e) of the Act. This also aligns with CMS' approach to reviewing the extent to which a selected drug addresses an unmet medical need, the extent to which a selected drug represents a therapeutic advance, manufacturer-submitted data, and other considerations related to the section 1194(e) negotiation factors. As such, CMS does not think it is necessary to adopt definitions for "clinically comparable" and "clinical benefit".

Comment: One commenter stated that defining an indication as condition or disease state for the purpose of determining a therapeutic alternative is inconsistent with statute, noting that the IRA uses the word "indication" twice, first in reference to orphan drug indications in section 1192(e)(3)(A) and then in reference to renegotiation in section 1194(f)(2)(A) of the Act. This commenter also stated that defining an indication as a condition or disease state for the purpose of determining a therapeutic alternative is inconsistent with other portions of guidance, including identifying FDA-approved indications of the selected drug and in the context of what factors CMS will consider when identifying therapeutic alternatives.

Response: CMS appreciates this commenters' feedback. CMS notes that title XI of Act specifically references section 526 of the FD&C Act when directing CMS to provide an exclusion for certain orphan drugs with an "approved indication" in section 1192(e)(3)(A) of the Act but does not do so in section 1194(f)(2)(A) of the Act when discussing renegotiation. CMS similarly differentiates the use of the term "FDA-approved indication" and "indication" to clarify when CMS is specifically referring to information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulations and when CMS is referring to the more common use of the word "indication" as the condition or disease state for which the selected drug is used. Further, the term "indication" as defined in section 60.3.1 and section 130.1.3 of this final guidance provides CMS with the ability to consider relevant clinical evidence for the selected drug, for example, related to off-label use.

Comment: Some commenters requested that clinicians, manufacturers, and patients be involved in the selection of the therapeutic alternative(s), and the initial offer more broadly, for a selected drug to ensure patient preferences and experiences are included and to leverage the expertise of practicing clinicians and manufacturers. A few commenters requested that CMS publish the potential therapeutic alternatives for a selected drug when the selected drugs are announced.

Response: CMS thanks these commenters for their input. CMS notes that statute does not require publication of potential therapeutic alternatives. However, as in past cycles of negotiation, CMS is committed to gathering and incorporating input from patients, clinicians, and other interested parties to inform negotiation. Consistent with CMS' response on page 92 of the final guidance for initial price applicability year 2027, CMS encourages all interested parties, including but not limited to clinicians, patients, caregivers, manufacturers, and researchers, to provide information on the selection of a therapeutic alternative(s) through the Drug Price Negotiation ICR for selected drugs for negotiation and renegotiation. CMS also encourages members of the public, including manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties to provide input through the public engagement events described in section 60.4 of this final guidance. Additionally, CMS sets forth negotiation process policies in section 60.4 of this final guidance, including the opportunity for the Primary Manufacturer to meet with CMS prior to sending the initial offer. This initial meeting, as well as the negotiation process including offer and counteroffer exchanges and negotiation meetings, provide Primary Manufacturers with additional opportunities to discuss the therapeutic alternative(s) with CMS.

Comment: CMS solicited comments on alternative approaches to establishing a starting point for developing the initial offer. Many commenters recommended that CMS use the ceiling as the

starting point for all or a subset of selected drugs; for example, drugs that provide a therapeutic advance, fill an unmet medical need, or otherwise demonstrated significant patient benefit; small molecule drugs; and HIV drugs. Many commenters opposed using the unit cost of production and distribution or other section 1194(e)(1) factors to establish the starting point; among these commenters, some stated doing so would stifle innovation and does not reflect value to patients. A few commenters opposed the use of a range of therapeutic alternative prices to establish a starting point and some commenters opposed the use of a domestic reference price to establish a starting point; one commenter also opposed the use of an international reference price. One commenter suggested that CMS weigh indications relative to patient utilization data. A few commenters suggested alternative approaches, including using a "Fair Market Price calculation," using a cost-effectiveness approach, or weighing biosimilars more when determining the starting point than Medicare utilization reflects to account for delays in formulary uptake. A few commenters supported continuing CMS' existing approach to determining a starting point. One commenter opposed using the price of a therapeutic alternative to determine the starting point.

Response: CMS thanks commenters for their feedback on this comment solicitation. Consistent with CMS' response on page 54 of the revised guidance for initial price applicability year 2026, CMS notes that some of the proposed alternatives for determining a starting point would limit CMS' ability to consider the benefit provided by the selected drug relative to its therapeutic alternative(s). Suggestions to use a starting point based on specific section 1194(e)(2) factors could also limit CMS' ability to adjust the starting point when developing the initial offer to incorporate these factors. Upon consideration of these comments, CMS declines 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.

CMS will maintain the overall approach in this final guidance to determining a starting point consistent with initial price applicability year 2027 and has added that CMS will consider the WAC of a therapeutic alternative for both drugs covered under Part D and drugs payable under Part B. This allows CMS to account for certain circumstances where other prices are misaligned with the WAC set by the manufacturer.

Comment: Some commenters opposed the removal of MDP and/or CGDP payments from Total Gross Covered Drug Cost (TGCDC) when determining the Net Part D Plan Payment and Beneficiary Liability during the process of determining a starting point for developing the initial offer. A couple of commenters also opposed using the MFP as the starting point for initial offer development in cases where the therapeutic alternative(s) is itself a selected drug where it is lower than the Net Part D Plan Payment and Beneficiary Liability or ASP, with one of these commenters stating that there is no statutory basis for doing so.

Response: CMS thanks commenters for their feedback. Consistent with CMS' response on page 97 of the final guidance for initial price applicability year 2027 and as discussed in section 60.3.2 of this final guidance, removing MDP and/or CGDP payments and DIR from TGCDC to determine the Net Part D Plan Payment and Beneficiary Liability of the therapeutic alternative(s) appropriately accounts for the price paid by the plan and the beneficiary for therapeutic alternative(s) to determine a starting point, which can then be adjusted based on the negotiation factors described in section 1194(e) of the Act. Further, removing MDP and/or CGDP payments

is appropriate because under the Manufacturer Discount Program, a selected drug during its price applicability period is not an applicable drug for which manufacturer discounts are required.

Similarly, the policy to use the MFP as the starting point in cases where the therapeutic alternative was itself a selected drug from initial price applicability year 2026 or 2027 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. The negotiation process outlined in sections 60.3 and 60.4 of this final guidance results in an MFP for a selected drug that reflects each selected drug's circumstances and is based on the negotiation factors that CMS is required to consider under section 1194(e) of the Act, regardless of whether 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 were selected drugs).

Comment: One commenter urged CMS to establish an MFP at the ceiling for selected drugs that provide a therapeutic advance and/or treat an unmet medical need. The commenter suggested that if a selected drug does not meet at least one of these criteria, CMS should consider comparative effectiveness evidence to determine whether the selected drug provides benefit compared to therapeutic alternatives.

Response: Consistent with CMS' response on page 53 of the revised guidance for initial price applicability year 2026, CMS notes that section 1194(b)(1) of the Act instructs CMS to develop and use a consistent methodology and process for negotiations that aims to achieve agreement on the lowest MFP for each selected drug and in doing so, to consider the nine factors described in sections 1194(e)(1) and 1194(e)(2) of the Act. Offering the ceiling without a more thorough review of those statutory factors, including manufacturer-submitted data, may not achieve that objective and is inconsistent with the statutory directive.

Comment: One commenter asked CMS to clarify how, whether quantitatively or qualitatively, the cost of a therapeutic alternative will impact the assessment of the extent to which a selected drug provides a therapeutic advance.

Response: CMS appreciates this commenters' request for clarification. As described in section 60.3.3 of this final guidance, CMS uses a qualitative approach to develop the initial offer, including for the consideration of the extent to which a selected drug represents a therapeutic advance.

Comment: CMS requested input on whether certain section 1194(e) factors should be emphasized over others when adjusting the starting point to determine the preliminary price. Many commenters supported emphasizing section 1194(e)(2) factors when developing the initial offer, stating that CMS should prioritize factors that are important to patient health and outcomes, as well as societal impact and other non-clinical benefits of a selected drug. A couple of commenters recommended that CMS apply an upward adjustment to the starting point for pending and approved patent applications, exclusivities, and pending or approved marketing applications as these indicate clinical benefit, innovation, manufacturer investment, and a lack of

therapeutic alternatives. A couple of commenters cautioned against applying a downward adjustment based on prior Federal financial support as this may discourage future innovation. One commenter asked that section 1194(e)(1) factors only be considered when a selected drug provides fewer benefits than its therapeutic alternative(s). One commenter supported the existing methodology and cautioned against using a formulaic approach; one commenter suggested applying an upward adjustment for a selected drug that advances the standard of care. One commenter opposed weighting section 1194(e) factors, stating that doing so is not in statute. One commenter stated that giving greater weight to some section 1194(e) factors over others without providing specific information on which factors would be given greater weight undermines transparency and due process.

Response: CMS appreciates commenters' feedback. After consideration of the comments received regarding whether CMS should place greater emphasis on certain section 1194(e) factors, CMS declines to change its methodology and process for negotiation in initial price applicability year 2028. 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 initial offer and counteroffers (section 1194(e) of the Act) but does not dictate the manner in which those factors must be considered. As such, CMS believes that flexibility in determining which section 1194(e) factors to emphasize over others will depend on the unique considerations related to each selected drug.

Comment: Some commenters requested more information on how section 1194(e) factors are weighted or otherwise used to adjust the starting point to determine the initial offer. Among these commenters, one requested more information on how health economic outcomes research is considered, one requested that CMS confirm that section 1194(e)(1) data will not be used to reduce prices, and a few specifically requested more clarity on how patents and exclusivities will be considered. Similarly, a few commenters asked CMS to provide more information on the methodology used to develop the initial offer and the process of negotiating the MFP. One commenter stated that the methodology described in draft guidance for initial price applicability year 2028 could not be standardized. One commenter suggested that CMS use a cost-effectiveness threshold to develop the initial offer. A few commenters suggested that CMS implement a framework or rubric to provide transparency and ensure consistency in the methodology used to review selected drugs.

Some commenters urged CMS to provide more detailed information to Primary Manufacturers and other interested parties on the framework, data, calculations, and other information so that a manufacturer can provide an informed counteroffer and patients and other stakeholders have more transparency into how the information they provide is used in the development of the initial offer. Suggestions of what CMS should share publicly included how patient input is used in the negotiation process, what types of evidence inform the assessment of unmet medical need and therapeutic advance, any decision-making framework CMS uses, and details of calculations related to the initial offer. A few commenters asked that CMS detail similar information in the MFP explanations. Some commenters urged CMS to provide more transparency on the types of evidence that would be prioritized during initial offer development, including during the

determination of therapeutic alternatives, adjusting the starting point, and determining the extent to which a selected drug fulfills an unmet medical need or represents a therapeutic advance. A few commenters supported CMS' consideration of real-world evidence in the development of the initial offer.

Response: CMS appreciates commenters' feedback and recognizes the importance of balancing transparency and confidentiality in the negotiation process. Consistent with CMS' response on page 99 of the final guidance for initial price applicability year 2027, CMS believes 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.

Considerations for how evidence will be prioritized are described in section 50.2 of this final guidance. This final guidance also describes the approach CMS will use to identify indications for a selected drug, identify a therapeutic alternative(s) for such indications, determine a starting point for the initial offer, and the factors CMS will consider when adjusting the starting point in section 60.3 of this final guidance. All applicable negotiation factors will be considered in totality for each selected drug. CMS directs interested parties to the comment summaries and responses for section 60.6 of this final guidance for a response to the comments received on the MFP explanations.

Comment: Some commenters requested that CMS consider factors not mentioned in the draft guidance for initial price applicability year 2028, including equity, the impact of a selected drug on the health system, the societal and public health value of a selected drug, the value of prevention, cost of care outcomes, the future value of a selected drug, adherence, and a manufacturer's global pricing strategy. 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. One commenter supported CMS' inclusion of patient and caregiver input.

Response: CMS thanks commenters for their suggestions. Consistent with the response provided on pages 87 and 102 of the final guidance for initial price applicability year 2027, CMS agrees that considerations related to the patient and caregiver experience are important and relevant for CMS' consideration of the section 1194(e)(2) factors. Outcomes such as changes to productivity, independence, and quality of life will be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug and are permitted in accordance with section 1194(e)(2) of the Act. In addition to patient and caregiver experience, CMS outlines in section 60.3.3.1 of this final guidance a variety of outcomes that CMS may consider when developing the initial offer. CMS encourages patients and other interested parties to submit their perspective on outcomes that CMS should consider for each selected drug through the Drug Price Negotiation ICR submission and in the public engagement events, per section 60.4 of this final guidance.

Comment: Some commenters suggested changes to the definition of unmet medical need, including expanding the definition to include non-clinical benefits such as patient and caregiver

mental and social wellbeing, patient and caregiver quality of life, improvement in health outcomes, sustainable costs for patients, value to society, and meeting public health needs; expanding the definition to account for subpopulations with disparate access or outcomes; expanding the definition to account for adherence and preventing resistance; accounting for characteristics, such as alternative dosing regimens, route of administration, reduction of side effects, shorter treatment periods, and diagnostic strategies.

One commenter recommended that CMS consider unmet medical need from initial approval of the selected drug through the time of assessment. One commenter requested that CMS align FDA's definition of unmet medical need with orphan and pediatric exclusivities codified in other federal statutes (the commenter did not suggest specific statutes). One commenter stated that CMS should review unmet medical needs specifically within the scope of FDA prescribing information.

Response: CMS appreciates commenters' feedback. Consistent with CMS' response on pages 100-101 of the final guidance for initial price applicability year 2027, CMS will consider any updates concerning unmet medical need that may be issued by FDA. The definition of unmet medical need included in section 60.3.3.1 of this final guidance was developed after consideration of public comments submitted for the initial price applicability year 2026 revised guidance 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. CMS will evaluate the extent to which a selected drug addresses an unmet medical need as of the time the section 1194(e)(2) data is submitted, 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: One commenter stated that the definition of "therapeutic advance" should include additional detail such as whether the definition includes both safety and efficacy of a drug. A couple of commenters recommended that the definition of therapeutic advance include factors such as how the drug impacts patient experience, mode of administration, adherence, and quality of life; whether the drug significantly impacts a socially or economically vulnerable population; whether the drug provides improvements in the symptoms or health outcomes associated with a disease (e.g., reduction of symptoms, ability to perform daily functions); and whether the drug offers improvement on a validated clinical outcome or a validated clinical measure.

Response: CMS thanks commenters for their input on the definition of therapeutic advance. CMS 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) as described in section 60.3.3.1 of this final guidance. Many of the other factors mentioned by commenters are considered during the development of the initial offer as outlined in sections 50.2 and 60.3.3 of this final guidance.

Negotiation Process (Section 60.4)

Comment: One commenter stated that CMS' decisions on the format and content of meetings, including meeting materials, meeting length, and meeting attendance, impose arbitrary limitations on manufacturers in the negotiation process. A couple of commenters stated that limiting negotiation meetings to a maximum of three meetings is restrictive, and one commenter recommended that CMS allow for more exchanges throughout the negotiation period. One commenter recommended CMS continue to hold at least three negotiation meetings. Another commenter indicated their support for an open and transparent dialogue with CMS earlier in the negotiation process that includes discussion of therapeutic alternatives.

Response: CMS recognizes commenters' interest in having meetings throughout the negotiation period. Consistent with CMS' response on pages 122-123 of the final guidance for initial price applicability year 2027, CMS will continue to hold one optional meeting with the Primary Manufacturer of each selected drug prior to CMS' initial offer to allow the Primary Manufacturer to provide context for and any new information about the section 1194(e) data submission as CMS reviews the submitted data and develops its initial offer for initial price applicability year 2028. Additionally, as described in section 60.4.2 of this final guidance, the first negotiation meeting may occur after CMS issues the initial offer and prior to the deadline for the Primary Manufacturer's response to CMS' initial offer, and up to two additional negotiation meetings, if applicable, may occur after the deadline for the Primary Manufacturer's response. This will enable CMS and Primary Manufacturers to engage in negotiation discussions at different intervals throughout the negotiation period and totals up to four optional meetings per selected drug. CMS believes that the duration, format, and number of the negotiation meetings continue to be sufficient for engagement and that additional meetings during the negotiation period are not feasible due to time constraints.

Additionally, consistent with CMS' response on page 123 of the final guidance for initial price applicability year 2027 and as described in section 60.4.5 of this final guidance, CMS is offering an additional price exchange functionality in 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 MFP, or by September 18, 2026, whichever is earlier. CMS believes this functionality will provide additional opportunities for exchanges between CMS and Primary Manufacturers throughout the negotiation period.

Comment: A couple of commenters asked that CMS' concise justification of its initial offer be meaningful and explain how CMS arrived at the offer. A couple of commenters recommended CMS provide manufacturers with the opportunity to comment on CMS' justification. One commenter suggested manufacturers should be able to submit additional data or other information to support their response to an offer. 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 justification should detail specific information, such as the sources CMS referenced, section 1194(e) data considered and how they were weighted, therapeutic alternatives considered, interested parties consulted, and benefits and impacts of the drugs considered.

Response: CMS thanks these commenters for their feedback. Consistent with CMS' response on page 107 of 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 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, CMS believes 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 section 60.4.3 of this final guidance, a Primary Manufacturer making a statutory written counteroffer should provide a justification for such counteroffer based on the data described in section 50 of this final guidance.

As described in section 60.4.2 of this final guidance, CMS will offer to schedule an optional negotiation meeting after CMS provides the initial offer to the Primary Manufacturer and before the Primary Manufacturer's statutory written counteroffer is due. The purpose of this meeting is to allow both parties to begin discussion related to negotiating an MFP for the selected drug, including with respect to CMS' initial offer for the MFP. CMS anticipates that such discussion might focus on CMS' initial offer and the evidence CMS used to develop the initial offer; nevertheless, as applicable, both CMS and the Primary Manufacturer could discuss other potential offers or counteroffers during this meeting, including discussion of the Primary Manufacturer's forthcoming statutory written counteroffer, as applicable. CMS will not revise the initial offer in this negotiation meeting. Consistent with the statutory framework, CMS anticipates that any oral potential counteroffers discussed during this meeting might be provided later in writing consistent with section 1194(b)(2)(C) of the Act. Accordingly, while CMS may engage in discussion about an oral potential counteroffer, CMS does not intend to accept or reject any such oral potential counteroffer in this first meeting and intends to respond to any later statutory written counteroffer consistent with the agency's obligations to respond in writing under section 1194(b)(2)(D) of the Act. Additional details around this first optional negotiation meeting can be found in section 60.4.2 of this final guidance.

Comment: One commenter stated that CMS should provide a confidential report to manufacturers alongside the initial offer and concise justification. This confidential report would include information on how CMS evaluated a selected drug based on section 1194(e)(2) data submitted by other interested parties and allow manufacturers to use this information in developing a statutory written counteroffer.

Response: Consistent with CMS' response on page 106 of the final guidance for initial price applicability year 2027, CMS understands that Primary Manufacturers may benefit from awareness of section 1194(e)(2) data submitted by other interested parties during the negotiation period. CMS maintains in this final guidance that CMS will aim to share with the Primary Manufacturer of a selected drug the section 1194(e)(2) data received from other interested parties

during the negotiation period when feasible. These data will be appropriately redacted and will not include proprietary information, PHI / PII, or information that is protected from disclosure under other applicable law. CMS does not plan on issuing a confidential report or other summary document in addition to the agency's provision of these redacted section 1194(e)(2) submissions. If agreement on an MFP is reached during the negotiation period, CMS will issue the MFP explanation no later than March 1, 2027. As part of this MFP explanation, CMS will share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. This redacted information will not contain any proprietary data, as described in section 40.2.1 of this final guidance, PHI / PII, or other information that is protected from disclosure under other applicable law. However, as described in section 40.2.1 of this final guidance, 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 will no longer consider that material proprietary and will not redact it in the MFP explanation.

Comment: A couple of commenters suggested that CMS provide justifications for all offer and counteroffer responses and not just initial offers. One commenter recommended CMS update its latest offer after each negotiation meeting.

Response: CMS thanks these commenters for their feedback. Section 1194(b)(2)(D) of the Act requires that CMS provide the Primary Manufacturer with a written response to the Primary Manufacturer's statutory written counteroffer. Consistent with our response on page 122 of final guidance for initial price applicability year 2027, CMS believes that if CMS declines the Primary Manufacturer's statutory written counteroffer and conducts a subsequent negotiation meeting with the Primary Manufacturer, this meeting will provide an opportunity for CMS to explain its rationale for not accepting the manufacturer's statutory written counteroffer, and this meeting or any subsequent meeting would provide further opportunities for both parties to discuss their rationales for making and responding to offers and counteroffers. Additionally, as described in section 60.4.5 of this final guidance, CMS is offering additional price exchange opportunities in 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 MFP, or by September 18, 2026, whichever is earlier. CMS believes that if a Primary Manufacturer or CMS makes an offer or counteroffer via the additional price exchange functionality, the negotiation meetings will provide an opportunity for both parties to discuss their justifications for the offer or counteroffer and rationale for determinations with respect to the offer or counteroffer. The additional price exchange functionality in the CMS HPMS will include an optional text field to enable either party to include additional contextual information for the offer or counteroffer. Only one offer or counteroffer per selected drug may be active at a time in the CMS HPMS as part of the additional price exchange functionality. An offering/counteroffering party may revise its offer/counteroffer in the period before the other party accepts or rejects it, but not afterwards, which has the effect of nullifying the previously submitted offer or counteroffer before it has been accepted or rejected. Parties do not need to alternate making offers and counteroffers.

Comment: One commenter suggested CMS broadly allow a manufacturer to supplement a timely submission of 1194(e) data if new information of relevance to the negotiation process

becomes available after the submission deadline or otherwise for good cause shown. Another commenter suggested CMS should allow manufacturers to submit comparative effectiveness data after the submission deadline, such as when CMS has identified therapeutic alternatives.

Response: CMS thanks the commenters for their input. Pursuant to sections 1194(b)(2)(A) and 1193(a)(4)(B) of the Act, Primary Manufacturers must submit the manufacturer-specific data described in sections 1193(a)(4)(A) and 1194(e) of the Act to CMS by March 1, 2026 for initial price applicability year 2028. Consistent with CMS' response on page 104 of the final guidance for initial price applicability year 2027, CMS will use data submitted by the Primary Manufacturer and other interested parties when developing the initial offer for a selected drug along with CMS analyses and assessments of evidence as described in section 60.3 of this final guidance. 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, 2026, it is not feasible to extend the timeframe for the submission of information under section 1194(e)(2) of the Act. CMS is abiding by the statutory deadlines in this final guidance.

As described in section 60.4.1 of this final guidance, interested parties will have several opportunities to provide additional section 1194(e)(2) information after the March 1, 2026 deadline.

First, CMS will invite the Primary Manufacturer of each selected drug to a meeting after the March 1, 2026 deadline and before CMS makes an initial offer to allow the manufacturer an opportunity to present its section 1194(e) data submission and share its perspective. These meetings will occur in Spring 2026. Primary Manufacturers may bring materials to facilitate discussion, and CMS may request any materials presented in the meeting afterwards. Primary Manufacturers are limited to sharing 50 pages (or a combination of pages, slides, and/or charts totaling 50 pages) of material to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. This material is meant to provide context on the Primary Manufacturer's 1194(e) submission and may also be used to share any new information regarding the section 1194(e)(2) data that has been identified following the March 1, 2026 data submission.

Second, CMS will host public engagement events to gather patient-focused feedback on the selected drugs as well as feedback from the larger community of interested stakeholders. CMS will host patient-focused roundtable events for patients, patient advocacy organizations, and caregivers. Selected participants for the roundtables will be invited to share feedback on patient experiences with the conditions or diseases treated by the selected drugs, as well as with the selected drugs and therapeutic alternatives to the selected drugs, and other information. CMS will also host a town hall meeting for clinicians and other interested parties, such as researchers, manufacturers, and members of the public. Selected speakers for the town hall meeting will be invited to share additional input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs. Interested parties may also use these events to share new information regarding the section 1194(e)(2) factors that has been identified since the March 1, 2026 deadline. These events will occur in Spring 2026 after the section 1194(e) data submission

deadline, which will give patients and other interested parties additional time to prepare their input. Additional information about these events will be shared in the future.

Primary Manufacturers are required to provide information on the non-FAMP and information required to carry out negotiations (including manufacturer-specific data described in section 1194(e)(1) of the Act) by March 1, 2026 for initial price applicability year 2028. CMS expects Primary Manufacturers to submit information that is complete and accurate by this deadline. As noted above, while Primary Manufacturers may share new information on section 1194(e)(2) data during meetings before the initial offer, new manufacturer-specific data (described in section 1194(e)(1) of the Act) will not be considered; rather, any information shared during these meetings and materials shared afterwards should only contextualize the Primary Manufacturer's March 1, 2026 submission of manufacturer-specific data.

As described in section 50.1 of this final guidance, the Primary Manufacturer has an ongoing obligation to timely report certain updates to data submissions required of Primary Manufacturers under sections 1193(a)(4)(A) and 1194(e)(1) of the Act and previously submitted to CMS through the initial response to the Negotiation Data Elements ICR Form.[39] Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under sections 1193(a)(4)(A) and 1194(e)(1) to CMS if the data was restated due to requirements of the government entity that initially receives and oversees processing of such data.

In addition to gathering section 1194(e)(2) data from interested parties and conducting public engagement events, CMS will review existing literature and real-world evidence, conduct internal analytics, and consult with clinicians, patients or patient organizations, and/or academic experts (described in section 60.3.1 of this final guidance) when considering available evidence about the selected drug and alternative treatments.

Comment: Some commenters suggested the negotiation process lacks transparency. One commenter stated that CMS restricts manufacturers from publicly disclosing information about their participation in the negotiation process and emphasized the importance of transparency.

Response: CMS thanks commenters for their feedback regarding providing transparency in the negotiation process. CMS believes the information provided about the negotiation process in section 60.4 of this final guidance provides sufficient insight. CMS refers interested parties to the MFP explanations published on the CMS website for more information about the negotiation process for specific selected drugs.[40] As described in section 40.2.2 of this final guidance, CMS will 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 its discretion. If a Primary Manufacturer discloses information regarding any aspects of the negotiation process prior to the explanation for the MFP

[39] As discussed in section 50 of this final guidance, CMS published the Drug Price Negotiation ICR in the Federal Register for a 60-day public comment period that ended on August 29, 2025. CMS intends to publish a revised version of the ICR for a 30-day comment period in late Fall 2025.

[40] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices.

being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

Engagement with Primary Manufacturers and Interested Parties Prior to Initial Offers (Section 60.4.1)

Comment: Many commenters expressed appreciation for CMS' efforts to improve the public engagement events for initial price applicability year 2027. In particular, a couple of commenters noted improvements included CMS' efforts to directly solicit patient-focused input via a discussion-based format and to make the roundtable events private allowed for greater participation and positive interactions. A couple of commenters recommended CMS continue to refine public engagement events. One commenter recommended CMS make the roundtable events public for provider advocacy organizations. Another commenter suggested CMS prioritize opportunities to hear a greater amount of patient-centered evidence directly from patients and their advocates, caregivers, and providers throughout the negotiation process.

Response: CMS thanks commenters for this feedback. Similar to the public engagement events held for initial price applicability year 2027, CMS will host up to 15 patient-focused roundtable events, which will be open to patients, patient advocacy organizations, and caregivers and will allow for discussion among speakers for initial price applicability year 2028. These events will include discussion of selected drugs for initial price applicability year 2028 and discussion of drugs selected for renegotiation, if applicable. CMS believes the private, discussion-based roundtable events—facilitated by a moderator—elicited valuable patient-focused input from patients and caregivers for initial price applicability year 2027, and CMS believes maintaining this approach will continue to foster meaningful engagement and input. Additionally, CMS declines the suggestion to make the roundtable events public for provider advocacy organizations because of the sensitive nature of information discussed during these roundtable events. Finally, CMS broadly welcomes input from interested parties and the public at all times by email at: IRARebateandNegotiation@cms.hhs.gov.

Comment: A few commenters acknowledged that CMS made changes to the public engagement events for initial price applicability year 2027; however, they were disappointed by those changes and wrote that CMS did not provide opportunities for meaningful engagement. A couple of these commenters added that neither the patient-focused roundtable events nor the clinically focused town hall meeting enabled dialogue between participants. One of these commenters recommended that CMS undertake a patient engagement campaign before implementing final guidance for initial price applicability year 2028 to ensure that Medicare beneficiaries understand how the Negotiation Program will impact them and to allow patients to provide meaningful feedback. Another of these commenters noted that while it was clear that CMS staff were present during the public engagement events, they were merely observers. This commenter recommended that CMS refine the engagement process to facilitate meaningful dialogue between patients, clinicians, researchers, and CMS staff. Additionally, one of these commenters noted that CMS released redacted transcripts one month after the public engagement events, which they contended is too late in the negotiation process for Primary Manufacturers because they were published after Primary Manufacturers received initial offers from CMS for initial price applicability year 2027. Another commenter noted that stakeholders do not have insight

into how public engagement event are selected. Finally, one commenter expressed concern that there has been limited input from health care providers to date, adding that they should be expressly included in the public engagement events because they are uniquely positioned to contribute information about relevant medical conditions, selected drugs, and therapeutic alternatives.

Response: CMS appreciates these commenters sharing their concerns but disagrees with commenters that the roundtable events did not provide opportunities for meaningful engagement. For initial price applicability year 2027, CMS established a discussion-based format for patient-focused roundtable events. CMS also engaged a moderator to facilitate discussion among participants during roundtable events and to facilitate follow-up questions from CMS during the town hall meeting. CMS engaged a moderator rather than having CMS staff facilitate discussions during public engagement events to mitigate the risk of bias. CMS implemented these changes based on commenter feedback received on draft guidance for initial price applicability year 2027. Additionally, CMS published redacted transcripts of all public engagement events, which demonstrate the extent of engagement that occurred during these events. As discussed in section 60.4.1 of this final guidance, CMS will host up to 15 patient-focused roundtable events, which will be open to patients, patient advocacy organizations, and caregivers and will allow for discussion among speakers. These events will include discussion of selected drugs for initial price applicability year 2028 and discussion of drugs selected for renegotiation, if applicable. CMS also will continue to engage a moderator to facilitate discussions for the roundtable events and CMS will have the opportunity to ask follow-up questions of participants during the town hall meeting. Additionally, CMS appreciates that commenters want CMS to post redacted transcripts more quickly. However, the process CMS uses to ensure that event transcripts are complete and accurate and that they de-identify all health information as required by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule[41] is thorough and takes time. Therefore, CMS will post redacted transcripts as soon as practicable after all public engagement events have concluded. Further, as with public engagement events held for initial price applicability year 2027, CMS will select speakers through an intentional process—rather than random selection—to help ensure diverse representation of viewpoints. Finally, with regards to participation among health care providers, CMS expressly included practicing clinicians in the town hall meeting for initial price applicability year 2027 and will continue to encourage their participation in the town hall meeting for initial price applicability year 2028.

Comment: Some commenters recommended that CMS expand the methods for patients and other interested parties to provide information to CMS—in addition to participating in public engagement events. For example, they suggested CMS provide opportunities for asynchronous input, such as written comments, audio submissions, recorded video statements, or structured telephone interviews. One of these commenters noted that such formats are important for patients living with fatigue, speech limitations, or limited Internet access. A couple of these commenters added that they were encouraged by the private nature of the patient-focused roundtable event, but not all patients feel comfortable sharing personal information about their condition or other aspects of daily life in a public setting. Another commenter recommended that CMS prioritize creating an environment that is supportive of feedback. For example, CMS should build in more

[41] See: 45 C.F.R. 164.514(b)(2); https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/deidentification/index.html#safeharborguidance.

flexibility for length of statements from participants and give extra time as needed. Similarly, some commenters noted that the patients and caregivers need more advance notice (i.e., a minimum of 30 days), more flexible participation options, and that event timing and length should be informed by the fact that caregivers may be participating in public engagement events while managing ongoing care responsibilities.

Response: CMS appreciates these suggestions about increasing the ways for individuals to share information with CMS. CMS recognizes the importance of patients having access to multiple methods for sharing information about their experiences. As described in section 60.4.1 of this final guidance, patients, patient advocacy organizations, and caregivers will have the opportunity to provide input during non-livestreamed, patient-focused roundtable events. CMS hosted such events in a non-livestreamed venue that included only patients, patient advocacy organizations, and caregivers for initial price applicability year 2027, and CMS believes this approach helped encourage engagement and mitigate barriers, such as the concern about speaking in a public setting, that may have prevented some individuals from participating in events for initial price applicability year 2026. Additionally, for initial price applicability year 2027, CMS strived to vary the times of day it scheduled patient-focused roundtable events, holding some events in the morning and others in the afternoon. If feasible, CMS intends to further vary the times of day roundtables events are held.

In addition, 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. This ICR will be available for patients and others to submit their information in early 2026. CMS streamlined this ICR for initial price applicability year 2028 to improve the content and structure of questions, including tailoring questions to patient populations. In addition, as noted in this final guidance in section 60.3.1, CMS may also consult with clinicians, patients or patient organizations, and/or researchers to ensure that appropriate therapeutic alternatives are identified. Finally, at this time, CMS is unable to accept recorded comments or conduct phone or online surveys for this program. However, CMS broadly welcomes input from interested parties and the public at all times by email at: IRARebateandNegotiation@cms.hhs.gov.

Comment: A couple of commenters noted that one town hall meeting for all selected drugs may not allow all interested parties to fully participate and does not provide for interactive discussion among participants. Additionally, one of these commenters wrote that two 3-hour sessions was a significant time commitment for individuals to participate. A couple of commenters supported CMS adding the clinically focused town hall meeting for all selected drugs. These commenters made suggestions for improvement, including expanding the town hall based on the various types of interested parties (e.g., holding a town hall meeting specifically for provider groups), breaking the town hall meeting into shorter sessions, or hosting more than one town hall event each year.

Response: CMS appreciates this feedback. For initial price applicability year 2027, CMS held one town hall meeting focused on the clinical considerations related to the selected drugs. The town hall meeting was divided into two sessions, which were scheduled for 2 hours and 2½ hours long, respectively. As stated in section 60.4.1 of this final guidance, for initial price

applicability year 2028, CMS intends to hold the town hall meeting in a similar format. That is, CMS will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. CMS continues to encourage practicing clinicians and researchers, as well as other interested parties, to register to participate. Additionally, CMS will have the opportunity to ask follow-up questions of participants at the town hall meeting. This town hall meeting may be divided into multiple sessions and may be held across multiple days. More information about the town hall meeting will be forthcoming.

Comment: A few commenters recommended CMS provide participants of public engagement events with a list of discussion topics and/or questions in advance of the events.

Response: CMS thanks these commenters for their recommendation. For initial price applicability years 2026 and 2027, CMS provided all public engagement event participants and the public with a list of possible discussion topics for the roundtable events and the town hall meeting. CMS provided this information on CMS' IRA website and in direct communications with selected participants. For initial price applicability year 2028, CMS will again provide such information to all public engagement event participants and the public.

Comment: A couple of commenters agreed with CMS' organization of patient-focused roundtable events by selected drug for initial price applicability year 2027 and recommended CMS continue to organize events specific to selected drugs. They noted that such organization would highlight different lived experiences and variation in treatment effects that may be lost in broader discussions.

Response: CMS thanks commenters for providing input on the organization of public engagement events. As described in section 60.4.1 of this final guidance, CMS will host up to 15 patient-focused roundtable events for initial price applicability year 2028. These events will include discussion of selected drugs for initial price applicability year 2028 and discussion of drugs selected for renegotiation, if applicable.

Comment: One commenter wrote that facilitators appeared responsible for the roundtable discussions but did not have sufficient scientific of clinical understanding of the treatments and disease states and did not use participant responses to inform follow-up questions. The commenter added that discussions seemed to have been driven by a predetermined set of questions drafted for all roundtable events; the result of which was that the events held for initial price applicability year 2027 were as static as the year before and did not allow CMS to ask or answer questions. Finally, this commenter recommended that CMS allow itself and other groups, including researchers and clinicians, to pose questions to the roundtable event participants and to CMS.

Response: CMS appreciates this input. As stated in section 60.4.1 of this final guidance, CMS will engage a moderator to facilitate discussions for both the patient-focused roundtable events and the town hall meeting. More specifically, CMS will engage a moderator who is experienced in hosting patient-focused and clinically focused discussions, knowledgeable about selected drugs and their clinical usage, and knowledgeable about alternate treatments to the selected drugs. CMS may consider the suggestion to engage with others, such as subject matter experts, to

develop follow-up questions. However, CMS declines to have other groups pose questions to event participants and to CMS.

Comment: A couple of commenters expressed concern that a few patient-focused roundtable events were not well attended. These commenters and a few others suggested CMS conduct additional outreach to include more diverse perspectives. For example, they recommended CMS prioritize outreach to patients, people with disabilities, and people living in underserved and rural communities to ensure that the Negotiation Program supports all patient populations. Another commenter recommended that CMS develop or leverage relationships with patient advocacy organizations to enable more meaningful participation.

Response: CMS thanks commenters for this feedback and these recommendations about patient-focused event outreach and recruitment. CMS agrees with commenters that increased participation generally and among underrepresented populations would help ensure diverse perspectives are communicated and heard during public engagement events, particularly the patient-focused roundtable events. Similar to initial price applicability year 2027, CMS intends to announce the dates for public engagements events when it publishes the selected drug list for initial price applicability year 2028 (i.e., by February 1, 2026). CMS conducted outreach to patient advocacy organizations, disease groups, and other consumer associations regarding patient-focused listening sessions for initial price applicability year 2027 and will continue to publicize and promote the patient-focused roundtable events for initial price applicability year 2028. Additionally, CMS worked with the CMS Office of Minority Health to redesign the patient-focused roundtable events for initial price applicability year 2027 and to help conduct outreach to underrepresented populations. CMS intends to continue to communicate and work with patient advocacy organizations, disease groups, other consumer associations, and federal agency partners and to help increase participation generally and among underrepresented populations. Additionally, CMS will consider using regional offices to increase awareness of patient-focused roundtable events among regional community organizations.

Comment: A couple of commenters expressed concern with CMS' registration process to participate in the public engagement events for initial price applicability year 2027, noting that the public did not have sufficient notice and faced technological barriers in the registration form. Specifically, one of these commenters wrote that offering only an online registration process and requiring an email address to register may have reduced participation among older patients and/or members of underrepresented communities. A couple of commenters recommended CMS announce the public engagement event dates and open registration at least 30 days before the scheduled events.

Response: CMS thanks commenters for this feedback on the registration process. For initial price applicability year 2027, CMS simplified the registration process for all interested parties to sign up to participate in the public engagement events compared to initial price applicability year 2026. This included minimizing the amount of individually identifiable health information required to be submitted. For initial price applicability year 2028, CMS will explore further simplifications to the registration process, including reconsidering the format in which participants must submit their registration and any related forms, and extending the duration of the registration period. More information on the registration process will be forthcoming.

Comment: Some commenters recommended CMS offer accessibility and language services by default for all public engagement events and not contingent upon requests. Additionally, a few commenters wrote that CMS' current process for participation and comment submissions should be more accessible for the average patient who may not be familiar with regulatory and advocacy processes and recommended CMS simplify the processes for providing both verbal and written comments. Suggestions from these commenters included: using plain language and health literacy principles; providing closed captioning during events; offering multilingual translation; providing accommodations for individuals with cognitive or sensory impairments. A couple of these commenters noted that CMS' lack of accommodations for patients with disabilities may have reduced participation among older patients and/or members of underrepresented communities. One of these commenters suggested CMS create an ombudsman or identify a point of contact designated to engage with patients and disability communities.

Response: CMS appreciates this input. CMS is committed to providing educational materials to patients, including informational materials about public engagement events using plain language. CMS will explore enhancing the language services it offers for the public engagement events and expanding the translation of materials for initial price applicability year 2028 to make the events more accessible. For example, CMS will explore providing enhanced Spanish language interpretation for initial price applicability year 2028. As done for initial price applicability years 2026 and 2027, CMS will ask potential speakers if they require language interpretation services, such as Spanish language interpretation or American Sign Language interpretation services, during the registration process for initial price applicability year 2028. CMS acknowledges that it has an independent obligation, under the rule governing HHS-conducted activities under Section 504 of the Rehabilitation Act, to ensure effective communication with individuals with disabilities.[42] This includes, among other things, an obligation to provide appropriate auxiliary aids and services where necessary to afford an individual with a disability an equal opportunity to participate in, and enjoy the benefits of, program or activity conducted by the agency.[43] CMS is dedicated to making its electronic information technologies accessible to people with disabilities. CMS is subject to, and strives to exceed, the requirements of Section 508 of the Rehabilitation Act (29 U.S.C. 794d), which requires agencies to provide people with disabilities equal access to electronic information and data comparable to those who do not have disabilities, unless doing so would impose an undue burden on the agency.[44]

Comment: One commenter suggested CMS compensate patients and caregivers to acknowledge their time and expertise when they participate in public engagement events, noting that many patients and caregivers had to take time off of work and caregiving duties to participate.

Response: CMS is committed to collaborating with and engaging the public in the policymaking process and values the feedback and input interested parties provide. Interested parties, including patients and caregivers, have a long history of providing meaningful information to CMS without being compensated. As such, CMS declines to compensate patients, patient advocacy organizations, and caregivers participating in public engagement events.

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[42] See 45 C.F.R. § 85.51.
[43] Id. at § 85.51(a)(1).
[44] See: https://www.cms.gov/about-cms/web-policies-important-links/accessibility-compliance.

Comment: A couple of commenters recommend that CMS have long-term engagements and continuing dialogues with patients, rather than yearly or ad-hoc engagements. One of these commenters recommended CMS establish a structured process for continuous review, assessment, and refinement of its interested party engagement strategy in collaboration with patients and people with disabilities.

Response: CMS recognizes these commenters' desire for long-term engagements, a continuous cycle of review, and refinement of the public engagement process. CMS conducts regular and informal reviews of its public engagement processes and outcomes, including engaging with patient advocacy organizations regarding events for initial price applicability years 2026 and 2027, and will continue to do so for initial price applicability year 2028. CMS does not believe it is feasible at this time to establish an additional structured review in the manner suggested by commenters.

Comment: One commenter expressed concern that the draft guidance for initial price applicability year 2028 does not include information about conflict-of-interest disclosure for the roundtable events, noting that CMS revised the conflict-of-interest disclosure request for initial price applicability year 2027 to require potential speakers to disclose potential conflicts of interest. This commenter recommended that all speakers at roundtable events should be required to disclose potential conflicts of interest for initial price applicability year 2028 and beyond so CMS may discern which participants have specific ties to drug manufacturers and to understand the influences behind what is presented in public engagement events.

Response: CMS thanks the commenter for this feedback. For initial price applicability year 2027, CMS revised the conflict-of-interest disclosure request and required potential speakers in the roundtable events and the town hall meeting to include information about the existence and nature of conflicts of interest. That approach aimed to promote transparency during the public engagement events. CMS also revised the conflict-of-interest disclosure request to more clearly and plainly describe the type of conflict information speakers need to submit to participate in roundtable events and the town hall meeting. CMS will take the same approach for initial price applicability year 2028 as it did for initial price applicability year 2027. CMS does not intend to implement additional conflict-of-interest requirements for initial price applicability year 2028.

Comment: A few commenters recommended CMS develop a centralized, publicly accessible archive of all materials related to public engagement events, including agendas, prompts, summaries, transcripts, and recordings (where participant consent is granted). They noted that this would allow interested parties, such as academic researchers, patient organizations, and clinicians, to review patterns in patient-reported data and to understand how those perspectives inform Medicare drug pricing decisions. Additionally, a few commenters suggested CMS publish post-event summaries that highlight patient and caregiver input, including key insights shared during events, a description of how CMS incorporated these insights into the negotiation process, and a discussion of any themes that were considered but not acted upon and why.

Response: CMS appreciates this input. For the past two negotiation cycles, CMS has posted redacted transcripts for all public engagement events and will post such transcripts for events

held for initial price applicability year 2028. CMS also provided all public engagement event participants and the public with a list of possible discussion topics for the roundtable events and the town hall meeting for initial price applicability year 2027. CMS again will provide this information to event participants and the public for initial price applicability year 2028. CMS will provide this information on CMS' IRA website and in direct communications with selected participants. At this time, CMS declines to publish a post-event summary in the manner suggested and declines to publicly post recordings of public engagement events.

Application of the MFP Across Dosage Forms and Strengths (Section 60.5)

Comment: A few commenters expressed concerns or opposition regarding the application of the MFP across dosage forms and strengths. One commenter stated that section 60 of the draft guidance for initial price applicability year 2028 purports to require Primary Manufacturers to offer the MFP for every package size or type of a product dosage form and strength and that such a requirement is not consistent with statute as the statute requires only that the manufacturer offer the MFP across different dosage forms and strengths of a selected drug and not across every formulation, package size, or configuration ever derived from the original active ingredient. A couple of the commenters stated that CMS' application of a single MFP across all formulations with the same active ingredient, regardless of regulatory pathway, instead of applying a single MFP only across the dosage forms and strengths within the selected product's NDA / BLA conflicts with FDA standards which could create disincentives for label expansion, lifecycle development, investment in therapies serving underserved populations, or even force market exit of products by manufacturers. The commenter suggested that CMS only apply the MFP across dosage forms and strengths within the selected product's NDA / BLA. One commenter suggested for CMS to negotiate and apply an MFP for a selected drug payable under Part B only with respect to Part B, and that CMS should negotiate and apply an MFP for a selected drug covered under Part D only with respect to Part D, following the IRA's statutory language and removing a significant amount of confusion and complexity that would be created by attempting to develop and apply a single MFP to both Part B and Part D. One of the commenters suggested that if pricing varies by indication, CMS should clarify how those prices will be applied at the point of sale, especially when utilization management tools cannot verify diagnosis, to ensure accurate MFP application. This commenter also requested that CMS clarify how the MFP will apply to MA enrollees for a Part B drug, particularly for drugs with multiple indications or indication-specific pricing.

Response: Consistent with CMS' response on page 124 of the final guidance for initial price applicability year 2027, 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. In addition, section 1194(e)(1)(D) of the Act instructs CMS, for purposes of the negotiation process, 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. 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." The aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act require a Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug included on the list of NDC-9s and NDC-11s for the selected drug maintained on the CMS HPMS and published in accordance with sections 30.4 and 60.6 of this final guidance. A Primary Manufacturer may not selectively apply the MFP to certain dosage forms and strengths or package sizes of the selected drug, nor may the MFP vary based on indication of the selected drug. As stated in section 60.5 of this final guidance, an MFP that is agreed upon, as described in section 60.4 of this final guidance, establishes one price for the selected drug. In accordance with section 1196(a)(2) of the Act, 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 or package size or package type of such drug. Regardless of whether a selected drug is payable under Part B only, covered under Part D only, or is payable under Part B and covered under Part D, the MFP will apply to all dosage forms and strengths of that selected drug. For the commenter requesting information on how the MFP will apply to MA enrollees for a selected drug payable under Part B, CMS intends to address Part B MFP effectuation in the future.

Publication of the MFP (Section 60.6)

Comment: A few commenters asked that CMS detail specific information in the explanations of MFP. These elements include information on how therapeutic alternatives were selected, specific data and evidence used, benefits and impacts considered, stakeholders consulted and how their input was used, sources for information used in negotiation, and details on how information influenced the MFP. Another commenter suggested CMS publish justifications for how MFPs are determined. One commenter stated that a lack of transparency regarding how the public engagement events and data submitted by the public are used in negotiations may deter the public from participating in the events or from submitting data. The same commenter said the explanations of the MFP for initial price applicability year 2026 largely restated information in prior guidance rather than providing more detail on the negotiation process or how CMS used submitted data. Some commenters requested CMS discuss in the MFP explanations how stakeholder input was used in negotiations.

Response: CMS thanks these commenters for their suggestions to include specific information in the MFP explanations. Consistent with our response on page 126 of the final guidance for initial price applicability year 2027, as required under section 1195(a)(1) of the Act, CMS will publish the explanation of the MFP for all selected drugs where there is an agreed-upon MFP for initial price applicability year 2028 no later than March 1, 2027. The MFP explanation, as described in section 60.6.1 of this final guidance, will include a narrative explanation of the negotiation process that occurred with that manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable, in alignment with the confidentiality policy described in section 40.2 of this final guidance. CMS 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 as per the confidentiality standards described in section 40.2 of this final guidance and

will not include proprietary information, PHI / PII, or other information that is protected from disclosure under other applicable law.

CMS also thanks commenters for their recommendation to include more detail in the MFP explanations, including regarding how stakeholder input was used in negotiations. CMS refers interested parties to the MFP explanations published on the CMS website for more information about the negotiation process for initial price applicability year 2026 through which CMS and Primary Manufacturers reached agreement on an MFP.[45] Additionally, as discussed in section 60.4.1 of this final guidance, CMS will use the information gathered during the public engagement events to better understand patients' experiences with the condition(s) treated by a selected drug as well as the drug itself, to inform identification of therapeutic alternatives for each indication of the selected drug, if applicable, and to identify key outcomes considered during negotiations.

Comment: One commenter emphasized the importance of CMS publishing MFPs by November 30, 2026, for initial price applicability year 2028 so that Part D plans have time to operationalize provisions around formulary inclusion and inform dispensing entity negotiations and bid development. Another commenter noted that publishing the explanations of the MFP after an MFP is agreed upon prevents the public from providing effective input and recommended CMS provide timely and detailed information to all stakeholders.

Response: As stated in section 60.6 of this final guidance, in accordance with section 1195(a)(1) of the Act, CMS will publish by November 30, 2026, the MFP for each drug selected for initial price applicability year 2028 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Additionally, according to the statute, the MFP explanation must be published no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2027, for initial price applicability year 2028. CMS will strive to publish these MFP explanations earlier than March 1, 2027, if feasible.

Comment: One 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 lean toward disclosure to the maximum extent possible when the statute is silent. Another commenter recommended CMS provide the public with the opportunity to review and comment on the explanation of the MFP.

Response: Consistent with CMS' response on page 127 of the final guidance for initial price applicability year 2027, the MFP explanation, as described in section 60.6.1 of this final guidance, will include a narrative explanation of the negotiation process that occurred with that manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable, in alignment with the confidentiality policy described in section 40.2 of this final guidance.

Consistent with CMS' response on page 126 of the final guidance for initial price applicability year 2027, CMS does not intend to provide a public comment period after MFP explanations are

[45] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices.

released. However, interested parties are welcome to provide feedback on the Negotiation Program via email at IRARebateandNegotiation@cms.hhs.gov.

Comment: A couple of commenters suggested CMS share a draft of the MFP explanation with Primary Manufacturers prior to publication for the manufacturers to dispute any concerns with the confidentiality of information included in the explanation.

Response: Consistent with our responses on page 127 of the final guidance for initial price applicability year 2027 and page 69 of the revised guidance for initial price applicability year 2026, CMS recognizes the interests of the manufacturers in making sure that certain data they provided to CMS for the negotiation process remain confidential. The MFP explanation, as described in section 60.6.1 of this final guidance, will include a narrative explanation of the negotiation process that occurred with that manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable, in alignment with the confidentiality policy described in section 40.2.1 of this final guidance. The statute does not require disclosure of the explanations of the MFP provided to manufacturers before the explanations are made public, and CMS does not intend to share the explanations of the MFP with Primary Manufacturers before releasing the explanations to the public.

MFP-Eligible Individuals in 2026, 2027, and 2028 (Section 80)

Comment: One commenter recommended CMS require MA plans to ensure access to the MFP. Another commenter stated that CMS should not broaden the scope of MFP-eligible individuals to include individuals enrolled in MA plans.

Response: CMS thanks these commenters for their input. As CMS stated in section 80 of this final guidance, for 2026, 2027, and 2028, in accordance with section 1191(c)(2)(A) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" means, with respect to a selected drug, the following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispensing entity, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan), if Part D coverage is provided under such plan for such selected drug. For 2028, in accordance with section 1191(c)(2)(B) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" also means, with respect to a selected drug, the following: 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 Medicare Part B or in an MA plan under Medicare Part C, if payment may be made under Part B for such selected drug. For 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, CMS expects Primary Manufacturers to provide access to the MFP of a selected drug to hospitals, physicians and other providers of services and suppliers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in a Medicare Advantage plan under Part C.

Comment Solicitation on Monitoring MA Plans' Step Therapy Practices
Comment: Many commenters raised concerns about step therapy practices and recommended CMS take action to ensure that there is appropriate oversight over MA plans so that enrollees do not face undue barriers to selected drugs payable under Part B in initial price applicability year 2028. Some commenters stated opposition to MA plans' use of step therapy for drugs payable under Part B and recommended CMS prohibit MA plans from applying step therapy requirements for selected drugs or all drugs payable under Part B. One commenter stated that MA plans' use of step therapy violates section 1852(a) of the Act because they permit MA plans to impose restrictions that do not exist in Original Medicare. Some commenters cited studies to support that MA plans' use of step therapy for drugs payable under Part B has been linked to significant burdens for physicians attempting to prescribe, and patients attempting to access, clinically appropriate treatments. A couple of commenters recommended that if CMS continues to allow MA plans to use step therapy, that CMS should develop policies to protect access to drugs payable under Part B, including by implementing strong coverage determination and appeals processes with short adjudication timelines. One of these commenters also recommended CMS implement policies to maintain lengthy lookback periods to reflect complex therapy intervals and protect stability in patient treatments, require that plan documents identify which drugs are subject to step therapy, and prohibit mid-year step therapy additions.

Many commenters recommended that CMS monitor MA plans' (and their contractors') implementation of the MFP effectuation process for selected drugs payable under Part B to ensure enrollees can access medically necessary care. One commenter recommended CMS leverage any lessons learned from selected drugs covered under Part D in initial price applicability years 2026 and 2027 and issue policy to conduct rigorous formulary and coverage policy review to assess instances in which MA plans impose more restrictive step therapy and other utilization management practices for certain drugs payable under Part B compared to another drug in the same class.

A few commenters stated that CMS can monitor MA plans' use of step therapy practices under existing program rules and stated that no additional requirements or clarifications are needed at this time. A couple of commenters stated that step therapy is used to ensure appropriate use of drug therapies and to prevent fraud, waste, and abuse. A couple of other commenters cited the regulations at 42 C.F.R. § 422.136 to support their assertion that additional policy is not needed related to MA plan's step therapy practices and noted that CMS can monitor issues and conduct audits related to step therapy. A few commenters stated that given the President's directive to reduce regulatory burdens, CMS should rely on existing processes unless and until there is an indication that process changes may be needed. One of these commenters stated that increased regulatory burdens acutely impact regional and not-for-profit organizations compared to for-profit national organizations and smaller health plans are less able to absorb administrative costs. Another commenter stated that CMS should not place higher standards of review for selected drugs.

Response: CMS thanks these commenters for their input related to the comment solicitation on monitoring MA plans' use of step therapy practices. As CMS stated in section 80 of this final guidance, for 2028, in accordance with section 1191(c)(2)(B) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" also means, with respect to a selected

drug, the following: 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 Medicare Part B or in a Medicare Advantage plan under Medicare Part C, if payment may be made under Part B for such selected drug.

CMS anticipates that Medicare Advantage plan requirements under 42 C.F.R. Part 422 will apply to selected drugs. CMS notes that 42 C.F.R. § 422.136 requires MA plans that implement a step therapy program for Part B-covered drugs to: apply step therapy only to new administrations of drugs payable under Part B, using at least a 365 day lookback period; establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies; and ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee. CMS conducts audits that target pre-service organization determination and appeal cases related to requests for drugs payable under Part B, monitors the Complaints Tracking Module (CTM) for access concerns, and monitors MA plans' use of Part B step therapy practices through MA reporting requirements that cover organization determinations and reconsiderations. Requests for drugs payable under Part B, including drugs payable under Part B subject to step therapy, are processed under the same adjudication timeframes as used in the Part D drug program. Under the standard timeframe, an MA plan must provide notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, while notice of an expedited decision must be provided as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.

Direct Member Reimbursements and Access to the MFP for Selected Drugs in 2026, 2027, and 2028 (Section 80.1)

Comment: A few commenters recommended that CMS create a process for manufacturers to reimburse Part D plans for any difference between the cash price paid by beneficiaries and MFP for direct member reimbursement (DMR) claims for selected drugs paid by the Part D plan. One commenter asserted that if there is not one standardized process for manufacturers to reimburse plans, it would result in inefficiencies and make oversight challenging for CMS. A couple of commenters recommended CMS leverage the MTF or develop a new process like the MDP and work to develop guidance on a PDE submission field to indicate the amount the manufacturer owes to the plan. A couple of commenters recommended CMS align the DMR process for selected drugs with the existing framework for other Part D drugs to avoid additional complexity for plan sponsors. A few commenters stated that manufacturers are unlikely to reimburse Part D plans if they are not required to do so.

A few commenters requested additional clarifications in the guidance, including more detailed examples on how to facilitate implementation of the DMR process for situations involving in-network and out-of-network claims and for the different phases of plan benefits. A few commenters requested more information on how a plan should process DMR requests if it does not know the associated dispensing fees. One commenter requested that CMS define a standard dispensing fee in this process. One commenter requested that CMS provide more detailed information no later than the end of July 2025 to provide time for plans and their PBMs to make any changes to adjudication and PDE systems. This commenter stated that DMR requests are

more common in the first quarter of the year due to enrollment and eligibility issues that individuals encounter at the point of sale. Another commenter requested that CMS provide more information on how the DMR process interacts with the Executive Order on Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients.

Response: CMS thanks these commenters for their input and recommendations. At this time, CMS declines to leverage the MTF or detail a standardized process for manufacturers to reimburse plan sponsors in a specific method. CMS does not believe that creating a standard process for this purpose is critical to the efficient administration or oversight of the Negotiation Program. Plans and manufacturers negotiate prices and contracts directly. Therefore, plans and manufacturers can negotiate for resolution of DMR requests for MFP-eligible claims as they are best positioned to determine payment of owed amounts, frequency of reimbursement, and other elements related to reimbursement. As CMS stated in section 80.1 of this final guidance, Primary Manufacturers and Part D plan sponsors may establish a reimbursement process related to DMR requests for MFP-eligible claims as necessary to ensure MFP effectuation for these MFP-eligible individuals.

In response to the comments requesting more information on how a plan should process DMR requests if it does not know the associated dispensing fees, CMS notes that in instances where the plan does not know the dispensing fee charged by the pharmacy and paid by the enrollee for the out-of-network claim, it may reimburse the enrollee based on the MFP and the plan's customary dispensing fee, if any, paid on an out-of-network point-of-sale electronic claim. CMS recommends that plans populate PDE records for these claims with the MFP and the dispensing fee paid, if any.

Lastly, CMS notes that comments related to the Executive Order on Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients are outside the scope of this guidance.

Comment: A couple of commenters thanked CMS and expressed support for the process CMS outlined for DMR requests. One commenter agreed that in the process for DMR requests, dispensing entities have already received the cash payment at the point of sale and are not involved in the submission of the claim to the Part D plan or the transaction to reimburse the MFP-eligible individual.

A couple of commenters objected to plan sponsors being held responsible for reimbursement to members and stated that manufacturers should be required to provide access to the MFP to MFP-eligible individuals through MTF-enrolled dispensing entities. One commenter stated that the actual number of DMR requests for selected drugs is not insignificant and noted that these must be handled manually by the plan sponsor within a specified timeframe.

A couple of commenters requested that CMS consider potential incentives for increased out-of-network pharmacy use under the DMR process outlined in the draft guidance for initial price applicability year 2028 and requested that CMS ensure that the new process not disrupt existing plan utilization management practices. One of these commenters also noted that this policy would incentivize pharmacies not to submit claims through beneficiaries' Part D plans, even

though pharmacy contracts include language requiring in-network pharmacies to process claims through the Part D benefit when they have the beneficiary's Part D insurance information.

Response: CMS thanks these commenters for their support and input. CMS does not believe that pharmacies would change procedures to avoid submitting claims to enrollees' Part D plans because, as one commenter noted, under 42 C.F.R. § 423.120(c)(3), a Part D sponsor must require its network pharmacies to submit claims to the Part D plan or its intermediary whenever the beneficiary's Part D insurance card is presented or on file at the pharmacy, unless the enrollee expressly requests the claim not be submitted.

As CMS details in section 80.1 of this final guidance, sections 1196(a)(1) and (a)(3)(A) of the Act direct the Secretary to establish procedures to ensure that the MFP for a selected drug is applied before any coverage or financial assistance under other health benefit plans or programs or other discounts, as well as to establish procedures to carry out the provisions of the IRA with respect to MFP-eligible individuals who are enrolled in a Part D plan. DMR requests are unique from typical claims for selected drugs and, therefore, warrant procedures to facilitate access to the MFP for MFP-eligible individuals that differ from how the MFP is normally effectuated for selected drugs. For example, when an eligible individual submits a DMR request, the Part D benefit is not used at the point of sale, the dispensing entity does not bill the individual's Part D plan but rather charges the individual the cash price established by the dispensing entity, and the individual's status as an MFP-eligible individual is not determined until after the point of sale when the individual submits the DMR request to their Part D plan. While a Primary Manufacturer of a selected drug that is participating in the Negotiation Program and reaches agreement upon an MFP remains responsible for providing access to the MFP to MFP-eligible individuals who are dispensed that selected drug during a price applicability period, CMS believes that, in light of these unique aspects of DMRs, it is necessary to establish a procedure that leverages existing Part D plan sponsor procedures for DMRs to help ensure that the MFP is available to an MFP-eligible individual that submits a covered DMR request. For 2026, 2027, and 2028, access to the MFP for an MFP-eligible individual that submits a covered DMR request for a selected drug will be facilitated by the Part D plan sponsor. Primary Manufacturers and Part D plan sponsors may establish a reimbursement process related to DMR requests for MFP-eligible claims as necessary to ensure MFP effectuation for these MFP-eligible individuals.

Monitoring of Manufacturer Compliance (90.1)

Comment: One commenter asked that CMS explicitly permit manufacturers, dispensing entities and other stakeholders to enter into agreements to audit data submitted in the MTF.

Response: CMS appreciates this commenters' request. CMS is not in a position to dictate terms or take a position on the establishment of any such agreement between private parties, and parties could choose to establish these types of agreements at their own discretion and with no involvement from CMS.

Manufacturer Plans for Effectuating MFP (Section 90.2.1)

Comment: A few commenters responded to a comment solicitation on the types of information that should be included in MFP Effectuation Plans for drugs payable under Part B, and how requirements for MFP Effectuation Plans for drugs payable under Part B should differ from what is outlined in section 90.2.1 for drugs covered under Part D. One commenter only recommended changes where they were reflective of differences between the two programs. Commenter recommendations for considerations specifically related to Part B included payment timing adjustments, including advance payment options, differing methodologies for determining and effectuating the MFP, and the possibility of manufacturers submitting Part B specific "refund plans" to account for the differences between the programs.

Response: CMS thanks these commenters for their responses to the comment solicitation. CMS will consider these suggestions in CMS' policy development for MFP Effectuation Plans for drugs payable under Part B.

Comment: A few commenters provided feedback on CMS' plan to bifurcate the due date for the MFP Effectuation Plan starting with initial price applicability year 2027, such that the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they anticipate having material cashflow concerns at the start of the initial price applicability year, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM will be required to be submitted via the MTF DM by June 1 of the calendar year before the MFP goes into effect, and the remainder of the information in the MFP Effectuation Plan will be due September 1 of the calendar year before the MFP goes into effect. A few commenters opposed CMS' proposed bifurcation and urged CMS to maintain a single September 1 deadline for all information, with one commenter expressing that it would be incredibly challenging for manufacturers to submit any aspect of their plans by June 1st given the many operational complexities. A couple of commenters supported the earlier date and requested that CMS move the deadline for the entire MFP Effectuation Plan to June 1, to provide pharmacies and CMS more time to review the MFP Effectuation Plans.

Response: CMS thanks these commenters for their feedback. In this final guidance, CMS confirms that, starting with initial price applicability year 2027, the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they anticipate having material cashflow concerns at the start of the initial price applicability year, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM must be submitted via the MTF DM by June 1 of the calendar year before the MFP goes into effect, and the remainder of the information in the MFP Effectuation Plan is due September 1 of the calendar year before the MFP goes into effect. CMS believes this is the best way to balance the interests of dispensing entities, who need information about how MFP access will be effectuated and the interests of Primary Manufacturers, who need time to develop appropriate processes and procedures. This will also allow CMS earlier insight into the MFP Effectuation Plans for the purpose of undertaking a risk assessment of the plans. CMS notes that the MTF functionality will allow Primary Manufacturers to submit required information by the June 1 deadline, with the rest of the information submitted by September 1.

Comment: A few commenters requested, if the due date for the entire MFP Effectuation Plan was not moved up to June 1, then CMS should require manufacturers to submit information about whether they will use the SDRA, or another mechanism to determine a pharmacy's cost when providing retrospective reimbursements by the earlier June 1 deadline. One commenter reinforced their concern that the manufacturers use of SDRA must be mandatory, unless a different amount is agreed upon by both the dispensing entity and the Primary Manufacturer.

Response: CMS thanks these comments for their input. At this time, CMS declines to require additional sections of the MFP Effectuation Plan be due by June 1. The sections due by June 1 include the entirety of the sections of the MFP Effectuation Plan that contain information that is directed towards dispensing entities: specifically, the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they anticipate having material cashflow concerns at the start of the initial price applicability year, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM.

CMS interpreted the concern about Primary Manufacturer use of the SDRA as a concern that Section 3, Question 8, where the Primary Manufacturer indicates the Primary Manufacturer's general plan for calculating the MFP refund amount if using a retrospective reimbursement model, will not be due by June 1 and will not be shared with dispensing entities or other stakeholders. As described in section 40.4.3.1 of this final guidance, the obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP rests with the Primary Manufacturer. A Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines some other amount is appropriate and sufficient to make the MFP available. That is, regardless of the response that a Primary Manufacturer provides in the MFP Effectuation Plan, it is the Primary Manufacturer's responsibility to make the MFP available for every claim, and the Primary Manufacturer may elect to use the SDRA or may refund a different amount if the Primary Manufacturer determines some other amount is appropriate to make MFP available on that claim. For this reason, on the Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form[46] CMS indicated that any responses to Section 4, MFP Effectuation are for CMS use only and will not be made public. CMS is collecting this information for oversight purposes only and believes receiving it by September 1 allows CMS enough time to review and complete a risk assessment.

Comment: One commenter urged CMS to require information on a Primary Manufacturer's general plan and procedures for contacting and receiving communications from pharmacies due on June 1.

Response: CMS thanks this commenter for their suggestion. This information is included as part of the Primary Manufacturer's communication plan, which will be due by June 1 starting with initial price applicability year 2027.

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[46] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that Primary Manufacturers will be required to provide as part of the MFP Effectuation Plan. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

Comment: A couple of commenters suggested that CMS should provide manufacturers with an opportunity to review the redacted versions of their effectuation plans to ensure that confidential information is not being released.

Response: CMS thanks these commenters for their feedback. CMS refers these commenters to the Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form,[47] where CMS discusses which components of the information collected will be shared, "CMS understands that some information provided by a Primary Manufacturer may be proprietary, CMS reiterates that the MFP Effectuation Plans will not be shared publicly by the agency and a limited subset of the information will be provided to MTF DM participants, and possibly interested stakeholders via request, in the form of a redacted MFP Effectuation Plan. Specifically, CMS plans to make Section 1, Question 1; Section 2, in its entirety; and Section 3, in its entirety, available within the MTF DM, while Section 1, Question 2; and Sections 4 – 6, in their entirety, will be redacted and collected solely for CMS' use to ensure effectuation of the MFP. CMS notes that Primary Manufacturers will respond to Section 1 in the MTF DM user interface during their enrollment process; thus, the response to Question 1 will be attached to sections 2 and 3 and made available to dispensing entities within the MTF DM when they enroll in the system." CMS adopted this approach to balance the needs of dispensing entities to have access to information related to MFP effectuation before January 1, and the need to ensure that Primary Manufacturer proprietary information is protected.

Comment: One commenter noted that a manufacturer's process for deduplicating 340B claims is proprietary information and should be redacted from the written MFP effectuation plans.

Response: Information about the Primary Manufacturer's process regarding nonduplication of 340B claims is provided in Section 4, Question 6, of the Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form. This section and question will be collected solely for use by CMS for program monitoring and oversight and will not be made public. The Primary Manufacturer's response to this question will not be shared with dispensing entities or other stakeholders.

Comment: One commenter recommended that CMS limit the stakeholder types to whom CMS would disclose the Primary Manufacturer's MFP Effectuation Plan to those in the drug supply chain.

Response: CMS thanks this commenter for their input. As stated in section 90.2.1 of this final guidance, CMS may, but is not required to, release redacted plans to other applicable stakeholders. If information is shared, the information that will be shared is the same content that would be shared with dispensing entities via the MTF; no additional sections of the MFP Effectuation Plan may be made public. CMS will review stakeholder requests for redacted MFP

[47] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that Primary Manufacturers will be required to provide as part of the MFP Effectuation Plan. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

Effectuation Plans with careful consideration and ensure that the Primary Manufacturer's proprietary information is not disclosed if a redacted version of the plan is shared.

Comment: Many commenters provided feedback related to CMS' decision to allow dispensing entities to identify themselves as anticipating material cashflow concerns at the start of an initial price applicability year with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and requiring that a Primary Manufacturer include a process for mitigating material cashflow concerns for dispensing entities in its MFP Effectuation Plan. One commenter expressed appreciation for this effort. A couple of commenters worried about the effectiveness of this effort and whether this policy may actually create additional burden for pharmacies, for example, in the types of information Primary Manufacturers might request related to material cashflow concerns. One commenter expressed appreciation for CMS' commitment to evaluate the degree to which pharmacy self-identification provides useful data for Primary Manufacturers. One commenter suggested recommended criteria for when a pharmacy would qualify for having material cashflow concerns, and requested a mechanism where pharmacies can easily inform manufacturers and change their status as having material cashflow concerns throughout subsequent time periods.

A few commenters emphasized that manufacturers have limited capacity and no statutory obligation to address these cash flow concerns, and one stated that attempts to mitigate will cause large financial and operational strain on manufacturers. Another commenter expressed appreciation for CMS' clarification in the Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form that MFP Effectuation Plans may vary across a manufacturer's different selected drugs, but wanted confirmation that the approach to mitigating material cashflow concerns identified by dispensing entities may also vary across different selected drugs. One commenter requested CMS provide additional clarification as to the types of dispensing entities that may self-identify as anticipating material cashflow concerns.

Response: CMS thanks these commenters for their feedback. As CMS stated in comment responses to comments received on the Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form,[48] the questions related to material cashflow concerns in the MFP Effectuation Plan are designed to implement a collaborative process between Primary Manufacturers and dispensing entities when a dispensing entity indicates that they may have material cashflow concerns at the start of the price applicability period with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. Regardless of whether or not a dispensing entity has self-identified as potentially having material cashflow concerns, Primary Manufacturers have a statutory obligation to make the MFP available to dispensing entities and this final guidance establishes a 14-day prompt MFP payment window by which payment must be available. Sections 100.1 and 100.2 of this final guidance describe possible enforcement mechanisms where a Primary Manufacturer fails to make the MFP available or fails to transmit

[48] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that Primary Manufacturers will be required to provide as part of the MFP Effectuation Plan. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

the claim-level payment elements within the 14-day prompt MFP payment window. CMS appreciates concerns about the effectiveness of this approach and reiterates a commitment to evaluating the degree to which pharmacy self-identification provides useful data for Primary Manufacturers, and as part of the effort will monitor the effectiveness of mitigation strategies described in MFP Effectuation Plans and the impact on dispensing entities. CMS appreciates the suggestion of criteria for when a dispensing entity may qualify as having material cashflow concerns, but maintains that a Primary Manufacturer, in the MFP Effectuation Plan, is responsible for describing their approach to mitigating material cashflow concerns, including establishing qualifying criteria for dispensing entities to participate in their approach. Dispensing entities may update whether or not they anticipate experiencing potential material cashflow concerns at any time via the MTF DM.

CMS acknowledges that Primary Manufacturers have limited ability to address potential cash flow concerns, but as stated above, hopes that the questions related to material cashflow concerns are the start of a collaborative process between the Primary Manufacturer and the dispensing entity. CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP Effectuation Plan. CMS affirms that a Primary Manufacturer's mitigation approaches may vary across different selected drugs, and that a Primary Manufacturer's plans for addressing such concerns will have flexibility to evolve over time. A Primary Manufacturer may update its mitigation approach by submitting an updated MFP Effectuation Plan, as soon as practicable, and in any event, within 90 days of the change.

Comment: CMS also received a couple of comments about the burden placed on dispensing entities regarding MFP effectuation. One commenter urged CMS to consider the operational realities faced by providers in implementing MFP-related processes. Another commenter encouraged CMS to consider alternatives to reduce the burden on pharmacies in future years, including looking at ways that that pharmacies could be made whole at the point of sale.

Response: CMS appreciates these comments. By creating clear timelines and expectations for MFP effectuation and options like the ability of dispensing entities to identify themselves as anticipating material cashflow concerns at the start of a price applicability period with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, CMS has adopted policy positions to address dispensing entity burden. CMS will continue to consider dispensing entity burden for future years of the Negotiation Program but otherwise retains the approach described in draft guidance for initial price applicability year 2028.

Comment: A couple of commenters requested that dispensing entities be required to use the MTF PM.

Response: CMS seeks to clarify dispensing entity interaction with the MTF DM and the MTF PM. Consistent with CMS' previous response on page 134 of the final guidance for initial price applicability year 2027, during a dispensing entity's enrollment process into the MTF DM, a dispensing entity will have the option to select whether it prefers to receive MFP refund payments through electronic transfer of funds, which will be the default election for dispensing

entities at the time of enrollment, or paper check. If the Primary Manufacturer participates in the MTF PM and elects to send an MFP refund payment to the dispensing entity through the MTF PM, then the MTF PM will pass through the payment to the dispensing entity in accordance with the dispensing entity's preferred payment method (i.e., electronic transfer of funds or paper check). As discussed in section 40.4.3.3 of this final guidance, the MTF PM will not require an affirmative election of participation by dispensing entities for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer. During dispensing entity enrollment in the MTF DM, they will provide information that will allow for payment through Primary Manufacturer utilization of the MTF PM, as well as for payment outside of the MTF PM, for Primary Manufacturers who decline to participate in the MTF PM.

Comment: One commenter supported CMS' approach to the MFP Effectuation Plan, namely requiring manufacturers to describe details of their approach for MFP effectuation outside of the MTF PM, and for an approach that requires dispensing entities and Primary Manufacturers to come to an agreement on MFP effectuation outside of the MTF PM.

Response: CMS thanks this commenter for the support of CMS' approach to the MFP Effectuation Plan.

Centralized Intake System for Complaints and Disputes Related to MFP Availability and MTF Functionality (Section 90.2.2)

Comment: CMS received a few comments in response to its comment solicitation on how the complaints and disputes process for drugs payable under Part B should differ from what is outlined in section 90.2.2 of this final guidance, in particular the types of documentation CMS should consider when a complaint or dispute is filed regarding a selected drug payable under Part B. A couple of commenters emphasized that CMS would need to provide more resources and support to hospitals and other Part B providers as they access the complaints and disputes process. Other commenters raised concerns about the timeliness of complaints and disputes related to Part B. Finally, commenters supported that the complaints and disputes process for Part B should be as similar to the Part D process as possible.

Response: CMS thanks these commenters for their input. CMS will consider these suggestions in CMS' policy development for the complaints and disputes process for drugs payable under Part B.

Comment: A few commenters requested more information about the process for assessment of complaints and disputes, including procedural steps, complaint management methodology and evaluation criteria.

Response: CMS appreciates this input. To reflect further policy and process development regarding CMS' process for assessing complaints and disputes, this final guidance provides more information about the operational steps CMS will take once an issue is submitted. Upon receipt of a reported issue, a threshold review will be completed, including a review to ensure, among other factors, that the issue is timely, contains supporting documentation or an explanation as to why supporting documentation is not available, and contains enough information on the face of

the submission for CMS to move forward with the triage process, and to identify the appropriate track, either as a complaint or dispute. Once the issue has been identified as either a complaint or dispute, it will be triaged and prioritized, taking into account market factors, including but not limited to the monetary value and/or the number of claims at issue; and the extent to which the price made available to the dispensing entity appears to differ from the MFP, among other factors. This prioritization is to ensure CMS is reviewing all submissions systematically and in appropriate order with the potential impact on the dispensing entity, Primary Manufacturer, or other stakeholder submitting the issue. For example, a complaint that includes substantial financial ramifications to either the dispensing entity or a Primary Manufacturer will be prioritized for review, investigation, and resolution compared to complaints with lesser financial impact. CMS is committed to reviewing all submitted issues in a timely and efficient manner; prioritization will allow CMS to identify and address the most urgent concerns. After a complaint or dispute is triaged, as part of the investigation, CMS may reach out to impacted parties, as appropriate, to request additional information or documentation as needed. CMS intends to include more information about the operationalization of the complaint and dispute processes in future technical instruction.

Comment: CMS received a few comments relating to timelines for complaints and disputes, with one commenter urging CMS to establish timelines for resolving complaints and disputes. Another commenter suggested 30 days for a response. A couple of commenters suggested that CMS use the same resolution deadlines as CGDP. One commenter recommended that the deadline to file a complaint or dispute 120 days from the date of the subject of the complaint or dispute be shortened to 60 days.

Response: CMS thanks these commenters for their input. CMS declines to make updates to this final guidance. Consistent with CMS responses on page 142 of the final guidance for initial price applicability year 2027, CMS intends to respond as quickly and efficiently as practicable to address concern(s) raised in a dispute or a complaint (and expects the same from the MTF Contractor), however, at this time CMS wants to gain more practical experience implementing the disputes and complaints process before establishing further timelines. CMS has not updated this approach at this time. CMS has not yet gained the operational experience necessary to set timelines for the resolution of complaints and disputes, so declines to do so in this final guidance.

Comment: CMS received a few comments regarding an appeal process or dispute arbitration process for complaints and disputes, including whether there will be an opportunity for an appeal or further engagement, as well as a couple of suggestions for the creation of an independent review process. This included recommendations for neutral decisionmakers who are a dedicated resource with the appropriate training to be able to handle all issues expeditiously.

Response: CMS thanks commenters for their input. Consistent with our responses on pages 137-138 of the final guidance for initial price applicability year 2027, CMS reiterates that anytime CMS seeks to impose a CMP on a manufacturer for noncompliance relating to MFP availability, manufacturers will be able to appeal the CMP through an administrative appeals process. CMS intends for the dispute process to be a fact-finding exercise with the goal of resolving a potential error in the MTF process identified by a Primary Manufacturer or a dispensing entity (e.g., two claims that were identified as MFP-eligible appear to be duplicates). CMS will perform a fact-

based analysis to determine if there is indeed an error, and either correct the issue or provide information to the dispensing entity or Primary Manufacturer affirming that the information in the MTF DM is correct. If a stakeholder submits a complaint, CMS will assess the complaint to determine if further investigation is appropriate to determine whether there is noncompliance. If, after providing an opportunity for corrective action, CMS determines that it is appropriate to move forward with the imposition of a CMP, as established in section 100.4 of this final guidance, CMS is adopting the existing procedures as codified in 42 C.F.R. § 423 Subpart T: Appeal Procedures for Civil Money Penalties (see § 423.1000 through § 423.1094) which provide an opportunity for an administrative appeal, if requested by the manufacturer. CMS has not changed its position on an appeals process for complaints and disputes. CMS will consider the recommendations made as the operational approach to disputes is developed.

CMS also highlights, as described in section 90.2.2 of this final guidance, that for both complaints and disputes, as part of the investigation, CMS will reach out to impacted parties, as appropriate, to request additional information or documentation as needed.

Comment: One commenter recommended that CMS establish an online portal for submitting and tracking complaints.

Response: CMS thanks this commenter for this suggestion. As described in section 90.2.2 of this final guidance, Primary Manufacturers, dispensing entities, and other stakeholders will have access to a web-based portal for submitting complaints and disputes.

Comment: CMS received a few comments regarding beneficiary complaints, urging CMS to provide clear direction to beneficiaries on the system and what types of complaints to send. One commenter also urged CMS to establish a maximum allotted time for resolution of complaints brought by beneficiaries, and to publish an annual report with information on beneficiary complaints. Two commenters also recommended a patient-facing error and correction appeals process.

Response: CMS thanks these commenters for their input. As described in section 90.2.2 of this final guidance, beneficiaries are able to submit a complaint to CMS that the MFP was not made available. Complaints will be captured through a public-facing online portal and phone number, supported by the MTF platform, which are already live. CMS is also providing scripts to 1-800 MEDICARE to direct beneficiaries to these pathways if they call with complaints related to the MFP. When a beneficiary submits a complaint, the complaint will be triaged and if the issue is more appropriately handled by the beneficiary contacting their plan or following up with their pharmacy, information on how to pursue those options will be provided. If it is an appropriate complaint about MFP availability, CMS will review the complaint and any supporting documentation to determine if the Primary Manufacturer failed to make the MFP available and is therefore potentially subject to a CMP. As stated in the previous comment response, CMS intends to respond as quickly and efficiently as practicable to address concern(s) raised in a dispute or a complaint (and expects the same from the MTF Contractor), including a beneficiary complaint, however, is declining to set specific timeframes for resolution in this final guidance, as CMS wants to gain more practical experience implementing the disputes and complaints process before establishing further timelines. Finally, as stated in a previous comment response, if a

stakeholder, including a beneficiary, submits a complaint, CMS will assess the complaint to determine if further investigation is appropriate to determine whether there is noncompliance. If, after providing an opportunity for corrective action, CMS determines that it is appropriate to move forward with the imposition of a CMP, as established in section 100.4 of this final guidance, CMS is adopting the existing procedures as codified in 42 C.F.R. § 423 Subpart T: Appeal Procedures for Civil Money Penalties (see § 423.1000 through § 423.1094) which provide an opportunity for an administrative appeal, if requested by the manufacturer. This is why an appeals process is not contemplated directly as part of the complaints process; anytime CMS seeks to impose a CMP on a manufacturer for noncompliance relating to MFP availability, manufacturers will be able to appeal the CMP through an already-established administrative appeals process.

Comment: CMS received a few comments about how the MFP will be provided at the point of sale. One commenter stated that CMS should "clearly articulate how beneficiaries will be notified if they are charged more than the MFP," and that CMS should require that "point-of-sale systems generate standardized alerts for overcharges." Another commenter also questioned how the MFP will be operationalized at the point of sale.

Response: CMS thanks these commenters for this input and points commenters to section 40.4 of this final guidance, "[I]n accordance with 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 such drug.[49] In Part D, the negotiated price of a drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point-of-sale. That is, in the case of a selected drug for which an MFP is in effect, the MFP-eligible individual's Part D cost-sharing is based on a negotiated price that cannot exceed the MFP plus any dispensing fees for such drug. Therefore, the requirement that the price used for MFP-eligible individual cost-sharing and benefit administration cannot exceed the applicable MFP (plus dispensing fees) helps to ensure that MFP-eligible individuals will have access to the MFP at the point-of-sale for selected drugs covered under Part D."

Comment: One commenter asked for more information regarding the refund and reconciliation process, specifically, "how such refunds are initiated, how patients will receive them (e.g., direct deposit, mailed check, or copay credit), or how long processing will take."

Response: CMS wishes to clarify that the "retrospective refunds" discussed throughout this final guidance reference refund payments that a Primary Manufacturer may use to provide access to the MFP for the selected drug to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drugs. The MFP refunds discussed in this guidance are not intended to be directed to, or received by, beneficiaries. As discussed in the prior comment response, the requirement that the price used for MFP-eligible

[49] CMS notes that Part D plan sponsors have flexibility to negotiate additional price concessions, similar to any other Part D covered drug. A Primary Manufacturer that negotiates additional price concessions with a Part D plan sponsor will still be responsible for providing access to the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed that selected drug.

individual cost-sharing and benefit administration cannot exceed the applicable MFP (plus dispensing fees) helps to ensure that MFP-eligible individuals will have access to the MFP at the point-of-sale for selected drugs covered under Part D. CMS is still considering how MFP-eligible individuals will have access to the MFP at the point-of-sale for selected drugs payable under Part B and will say more on this topic in the future.

Comment: CMS received a few comments regarding the intersection between the 14-day prompt payment window and disputed claims. One commenter asked CMS to clarify if it will "pause" the 14-day prompt MFP payment window while disputes are reviewed and addressed. One commenter recommended that manufacturers not pause payments to dispensing entities during disputes, as the credit/debit ledger system exists as a mechanism to address MFP refund payments that are later adjusted.

Response: CMS thanks these commenters for their input. Consistent with CMS' response on page 140 of the final guidance for initial price applicability year 2027, CMS disagrees with the recommendation to suspend or toll the 14-day prompt MFP payment window for disputed amounts. It is essential that Primary Manufacturers make timely payments to make the MFP available to pharmacies, mail order services, and other dispensing entities that dispense the selected drug with respect to MFP-eligible individuals pursuant to the requirements of section 1193(a)(3)(A) of the Act. If the resolution of a dispute results in a claim adjustment or reversal that entitles a Primary Manufacturer to a credit towards a future MFP refund payment, the MTF PM system will provide this credit to the Primary Manufacturer (if that Primary Manufacturer participates in the MTF PM and payment was passed through the MTF PM). CMS has not changed this position in this final guidance. The initiation of a dispute on a claim does not negate the Primary Manufacturer's statutory responsibility to make the MFP available to the dispensing entity for an MFP-eligible claim subject to a dispute. Nor does initiating a dispute affect the Primary Manufacturer's obligation to transmit the claim-level payment elements for such claim within the 14-day prompt MFP payment window, including the manufacturer-determined MFP refund amount (if any) and the appropriate transaction code. As is the case for any claim, whether it is under dispute or not, Primary Manufacturers may make individual determinations about whether an MFP refund is appropriate, and, if so, the amount of the MFP refund, to effectuate the MFP. If the Primary Manufacturer provides an MFP refund on a claim for which there is a dispute and the dispute results in an updated amount required to make the MFP available, the Primary Manufacturer utilizing the MTF PM can use the adjustment processes described in sections 40.4.3.2 of this final guidance. Primary Manufacturers who elect not to use the MTF PM can utilize the method they have established for handling changes to payment amounts, as discussed in section 40.4.4.4 of this final guidance.

Comment: One commenter requested that CMS confirm that manufacturers have an unspecified amount of time to resolve, submit evidence, and adjust payments where required.

Response: CMS assumes that this commenter is referring to responses from manufacturers once a complaint has been received by CMS. CMS confirms that manufacturers, and all interested parties, will have the ability to submit evidence, and are free to resolve issues and adjust payments while CMS is investigating a complaint, which would likely have an impact on CMS' decision to move forward with any enforcement action. When requesting evidence, CMS plans to

set reasonable timelines within which evidence must be produced to be considered while CMS is investigating the complaint. CMS plans to provide more information about the complaint process in future technical instruction and other outreach and education efforts.

Comment: CMS received a few comments about public reporting of compliance data, including complaints and disputes, including recommendations about reporting related to complaint and dispute volumes, types of complaints and disputes, outcomes, and the timeframes for resolution.

Response: CMS thanks these commenters for their input. As stated in section 90.2.2 of this final guidance, CMS intends to track complaints and disputes over time to monitor overall trends and emerging compliance issues, and to make process improvements in the implementation of the complaint and dispute process, as applicable. CMS will consider the extent to which CMS will share these findings publicly and in what format.

Comment: CMS also received a couple of comments regarding the publication of MFP effectuation data including data related to complaints and disputes, specifically regarding beneficiaries. One commenter recommended that CMS should publish annually a report detailing the number of beneficiary complaints and outcomes. Another commenter urged CMS to "carefully monitor whether beneficiary cost-sharing does indeed reflect the negotiated price, and that savings actually accrue to beneficiaries."

Response: CMS appreciates these suggestions. As stated in this final guidance, CMS intends to track complaints and disputes over time to monitor overall trends, which will include beneficiary complaints. As part of CMS' oversight responsibilities, CMS intends to monitor MFP effectuation and market impact, including metrics related to drug access and costs during MFP effectuation from a beneficiary perspective. CMS will consider to the extent to which CMS will share these findings publicly and in what format.

Comment: One commenter requested that CMS clarify that Part D plans may avail themselves of the "first track" of the complaint and dispute process described in the draft guidance for initial price applicability year 2028.

Response: CMS understood this comment as a request to clarify in guidance that Part D plans may avail themselves of the dispute process outlined in section 90.2.2 of this final guidance. CMS thanks this commenter for their comment. Consistent with CMS' response on page 140 of the final guidance for initial price applicability year 2027, the dispute process is intended to allow manufacturers and dispensing entities to raise a specific, identifiable challenge with a technical aspect of the MTF. As Part D plans are not directly interacting with the MTF, the dispute process is not an appropriate mechanism for Part D plans to raise concerns. Part D plans will have access to the complaint process established in section 90.2.2 of this final guidance, as will all interested stakeholders.

Comment: One commenter recommended that disputes be submitted using the specific X12 835 claim number, and that parties to a dispute identify a singular point of contact for all disputes.

Response: CMS refers the commenter to the Drug Price Negotiation Complaint and Dispute Intake Form[50] for information that is included (both required and optional) when a dispensing entity or Primary Manufacturer is filing a dispute.

Comment: One commenter requested that CMS further clarify who can be an appropriate party to a dispute or a complaint and requested further information on how a scenario where a Part D plan sponsor submitted the wrong claims level data would be handled.

Response: CMS thanks this commenter for this input. CMS declines to make any policy changes at this time. As described in section 90.2.2 of this final guidance, "This system is intended to address complaints and disputes related to MFP availability and MTF functionality and is not intended to receive general comments or feedback related to the implementation of the Negotiation Program as a whole. Any issues unrelated to MFP availability and MTF functionality will be directed to the appropriate review mechanism." Complaints or disputes that are outside the above scope will be referred to the appropriate channels for assistance. Additionally, CMS describes the verification of data that will take place prior to the claim making its way to the MTF in section 40.4.2.1 of this final guidance, "[T]he claim-level data elements will be derived from claims that have been verified…by both the Part D plan and DDPS[.]"

Comment: CMS received a couple of comments regarding a good faith effort on the part of Primary Manufacturers and dispensing entities to resolve issues before utilizing the CMS complaint and dispute process. One commenter recommended that CMS should expand upon the definition of "good faith" in compliance efforts. Another commenter stated that CMS must ensure that dispensing entities and manufacturers engage in good faith efforts to resolve issues before using CMS' complaints process.

Response: CMS thanks these commenters for their input. CMS declines to make further updates to final guidance at this time. As described in section 90.2.2 of this final guidance, CMS encourages dispensing entities and Primary Manufacturers to work together in good faith to resolve any issues regarding MFP availability. Proof of any efforts to resolve the issue should be submitted once the complaint is filed and will be considered by CMS as part of the investigation into the complaint.

Civil Monetary Penalties (Section 100)

Comment: One commenter noted that CMS added an additional example to Table 10, titled "Violations of the Agreement," specifically the "[f]ailure to submit data requested by CMS in accordance with its oversight responsibilities under section 1196(b) of the Act." The commenter requested this example be struck or specified further.

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[50] OMB approved the ICR titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" (0938-1483), which includes details on information that dispensing entities, Primary Manufacturers and other stakeholders will be required to provide when submitting a complaint or dispute. See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

Response: CMS thanks this commenter for their feedback. The example added to Table 10 is consistent with the requirements outlined in the revised guidance for initial price applicability year 2026 and the final guidance for initial price applicability year 2027. This example refers to the Primary Manufacturer's responsibility to submit information requested by CMS to support CMS' compliance monitoring responsibilities described in section 1196(b) of the Act. CMS revised the language in this example in Table 10 to clarify that a manufacturer must provide any information requested by the agency in the course of executing its compliance monitoring responsibility including data and failure to do so may be a violation of the Negotiation Program agreement. CMS declines to adopt the commenter's suggestion to strike or narrow this language which is consistent with the compliance monitoring authority provided to CMS through statute and CMS' corresponding need to collect a variety of materials related to such authority.

Comment: Some commenters requested that CMS create a safe harbor for "good faith efforts" to effectuate the MFP. In particular, commenters expressed concerns about Primary Manufacturers being subject to CMPs for technical issues with the MTF PM or MTF DM that were beyond the control of the manufacturer.

Response: CMS thanks these commenters for their feedback. Consistent with our response on page 135 of the final guidance for initial price applicability year 2027, CMS declines to designate a safe harbor in this final guidance. Section 1193(a) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to dispensing entities that dispense the selected drug to MFP-eligible individuals. CMS stresses that a Primary Manufacturer's decision to participate in the voluntary MTF PM alone is not sufficient to negate its responsibilities set forth in section 40.4.3 of this final guidance (e.g., returning their claim-level payment elements to the MTF DM to effectuate payment), nor does it absolve a Primary Manufacturer of its statutory responsibility to provide access to the MFP to dispensing entities. Additionally, if the Primary Manufacturer uses the MTF PM to pass through an MFP refund payment, the receipt of such payment by the dispensing entity (either electronically or via paper check issued by the MTF PM) does not constitute the dispensing entity's agreement that access to the MFP has been provided by the Primary Manufacturer. CMS will take into consideration a Primary Manufacturer's choice to participate in the MTF PM, a system that CMS has designed with safeguards and procedures it has deemed sufficient to facilitate manufacturer effectuation of the MFP, when conducting the risk assessment procedures set forth in section 90.2.1 of this final guidance. CMS has not updated this approach and will not explicitly create a safe harbor from CMPs in this final guidance. As stated in section 100 of this final guidance, 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. CMS is 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. Further, section 100.1 of this final guidance, related to potential imposition of CMPs for failure to make the MFP available, states that, upon discovery and confirmation of a Primary Manufacturer's failure to make MFP available, CMS intends to send the Primary Manufacturer a Notification of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS intends to establish a process in which the Primary Manufacturer will have 10 business days to respond to the Notice of Potential Noncompliance to provide additional context, evidence refuting the violation, proof of mitigation of

noncompliance, and/or other factors for CMS' consideration. CMS intends to consider the materials provided by the Primary Manufacturer when determining the Primary Manufacturer's CMP liability, including any technical failures outside the control of the Primary Manufacturer related to the transmission of payment.

Comment: One commenter urged CMS to establish an escalation and remediation pathway for enforcement actions to include informal correction opportunities, formal notices, and CMPs with well-defined criteria. The commenter suggested the compliance program within the Medicare Shared Savings Program as a model. A couple of commenters requested that CMS provide a dispute resolution or appeals process for manufacturers facing an enforcement action. One commenter requested that manufacturers have 30 days to cure a compliance issue.

Response: CMS appreciates commenters' feedback. CMS provides opportunities, described in sections 100.1 and 100.2 of this final guidance, for the Primary Manufacturer to engage in corrective action in applicable circumstances, including examples of substantive violations in section 100 that would warrant the issuance of a CMP based on agency discretion. Consistent with CMS' response on page 143-144 of the final guidance for initial price applicability year 2027, CMS believes the timeframes outlined in sections 100.1 and 40.2.3 of this final guidance provide sufficient time for the Primary Manufacturer to address correction of any compliance issue while also ensuring program operations are not impacted by manufacturer non-compliance.

Comment: CMS received a comment stating that the commenter was concerned that the 10 business days does not provide enough time for manufacturers to investigate, gather required information and provide it to the MTF, particularly in light of the broad scale of the program, and high volume of claims, including for Secondary Manufacturers. This commenter recommended that the 10 days be extended to 60 days.

Response: CMS assumes the 10-business-day time period mentioned in the comment is a reference to the 10 business days for response triggered by the Notification of Potential Noncompliance, discussed in section 100.1 of this final guidance. CMS appreciates this feedback but declines to change the 10 business days for response triggered by the Notification of Potential Noncompliance. In circumstances where the Notification of Potential Noncompliance is the result of an investigation related to a complaint, CMS will likely have engaged the Primary Manufacturer to provide evidence and information during the complaint investigation. Even where the Notification of Potential Noncompliance is the result of an audit or other investigation, CMS envisions engaging with the Primary Manufacturer during the audit or investigation. The Notification of Potential Noncompliance merely represents the final opportunity a Primary Manufacturer has to provide evidence or take corrective action before CMS makes a decision regarding potential enforcement action.

Comment: CMS received a comment requesting that manufacturers be given the opportunity to correct potentially incorrect refund amounts without fear of incurring CMPs.

Response: CMS thanks this commenter for this comment. CMS refers the commenter to the Medicare Transaction Facilitator Data Module User Agreement for Manufacturers which includes a responsibility for Primary Manufacturers to submit revised claim-level payment

elements if the Primary Manufacturer knows or has reason to know that previously returned claim-level payment elements do not accurately reflect the amount needed to make the MFP available to dispensing entities. Primary Manufacturers can do so following the process described in sections 40.4.3.2 and 40.4.4.4 of this final guidance. Primary Manufacturers can follow this process if they determine that a refund amount is "incorrect." Additionally, once CMS has sent a Primary Manufacturer the Notice of Potential Noncompliance described in section 100.1 of this final guidance, Primary Manufacturers can follow the above process to update the rebate amount paid to the dispensing entity, and CMS will take that action into account when deciding whether to move forward with a decision to assess CMPs.

Part D Formulary Inclusion of Selected Drugs (Section 110)

Comment: A few commenters stated that research is showing that Part D plan sponsors are already making changes to steer beneficiaries away from selected drugs. A couple of commenters cited an analysis evaluating changes in formulary coverage for the 25 medicines selected for negotiation in initial price applicability years 2026 and 2027, which found that fewer medicines are available on formulary in 2025 relative to 2024, and that Part D plan sponsors are combining utilization management and tiering strategies to restrict access to selected drugs. Another commenter acknowledged CMS' statement in the draft guidance for initial price applicability year 2028 that it is aware of concerns that Part D plan sponsors could broadly shift access with respect to a selected drug after the drug has been announced as a selected drug. This commenter expressed support for CMS' statement that it will continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year.

Response: CMS thanks these commenters for their feedback. CMS is aware of 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, i.e., in the contract year prior to the selected drug's MFP taking effect. While CMS did not see this occur in contract year 2025 with respect to selected drugs for initial price applicability year 2026, CMS will continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year (e.g., contract years 2026, 2027, 2028, and each additional year in the selected drug's price applicability period, if an MFP is in place with respect to that year).

CMS expects Part D sponsors to provide their enrollees with meaningful access to selected drugs and will use its comprehensive formulary review process to assess any practices that may undermine beneficiary access to selected drugs, as discussed in section 110 of this final guidance. To help ensure that beneficiaries have meaningful access to selected drugs and consistent with the agency's statutory obligation to monitor plan compliance with all applicable formulary requirements, CMS will use its formulary review process to assess any instances where Part D sponsors place selected drugs on non-preferred tiers or where a selected drug is placed on a higher tier than non-selected drugs in the same class. As discussed in section 110 of this final guidance, as part of the annual bid review process, CMS will expect Part D sponsors to provide CMS with a reasonable justification to support the submitted plan design that includes any such practices. 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 (e.g., 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). As CMS reviews Part D plan formularies to ensure they comply with statutory and regulatory requirements, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, CMS will only approve a Part D plan bid submitted by a Part D plan sponsor if CMS 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. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs through tier placement in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected drugs and inform new requirements for future contract years.

Comment: A couple of commenters expressed support for CMS maintaining the existing Part D formulary review standards and not implementing explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies for initial price applicability year 2028. Some commenters disagreed that CMS does not have sufficient information to determine whether to change its formulary inclusion policies and expressed concerns with what they referred to as CMS' "wait and see" or "passive" approach to monitoring Part D plans' compliance with existing formulary requirements. Many commenters expressed concern that plans may hinder beneficiary access to selected drugs or non-selected drugs (e.g., 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). These commenters recommended CMS take additional steps to ensure broad beneficiary access under Part D by, for example, providing additional specificity around the requirements for coverage of both selected and non-selected drugs and establishing a mechanism for patients to provide feedback directly to CMS on any access issues they experience and publicizing such feedback. A few commenters recommended changes to CMS' formulary review processes, including that CMS strengthen its current formulary review standards, collect additional information, and increase transparency by making public the results of its formulary reviews. A couple of commenters opposed the oversight of formularies described in section 110 of the draft guidance for initial price applicability year 2028 and stated that the steps CMS is taking lack statutory basis and restrict Part D plan sponsors.

Response: CMS thanks these commenters for both their support and feedback. CMS agrees with commenters about 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.

As stated in CMS' response on pages 146 and 147 of the final guidance for initial price applicability year 2027, CMS shares concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. CMS understands that sponsors could also be incentivized in certain circumstances to steer Part D beneficiaries away from non-selected drugs in favor of selected drugs. CMS reiterates that CMS expects Part D sponsors to provide their enrollees with meaningful access to selected drugs and will use its comprehensive formulary review process to

assess any practices that may undermine beneficiary access to selected drugs, as discussed in section 110 of this final guidance.

Consistent with CMS' response on page 147 of the final guidance for initial price applicability year 2027, CMS appreciates commenters' suggestions for changes to CMS' formulary review processes. Plan sponsors must submit their drug formularies to CMS for approval each contract year, and CMS maintains, and will continue to maintain, a robust, clinical formulary review process to ensure that all Part D plan formularies comply with statutory and regulatory requirements. This includes the requirement under section 1860D-11(e)(2)(D)(i) of the Act that CMS may only approve a Part D plan if it "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." Further, if CMS identifies that Part D sponsors are not providing beneficiaries with meaningful access to selected drugs, CMS may consider implementing new requirements for future contract years. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs when clinically appropriate while allowing CMS to monitor practices that may undermine enrollee access to selected drugs and inform further action, as necessary. 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. Coverage information is available when beneficiaries search for plans by inputting their drugs into the Medicare Plan Finder and is also required to be available on the plan's printed formulary, on the formulary on the plan's website, and by calling the plan.

As explained in section 110 of this final guidance, CMS does not have sufficient information at this time to determine whether changes to formulary inclusion policies are warranted. The formulary inclusion requirement in section 1860D-4(b)(3)(I) of the Act has not taken effect yet, and plan sponsors did not submit their formularies for the first contract year in which MFPs are in effect (i.e., contract year 2026) until June 2, 2025. In light of the substantial time required for CMS to complete the formulary review process and analyze the impacts of the formulary inclusion requirement, information is not yet available to inform whether changes to formulary inclusion policies are warranted. For these reasons, CMS will continue monitoring Part D plans' compliance with all applicable formulary requirements and treatment of drugs and may further address formulary inclusion policies in the future.

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 for the Negotiation Program, supported by the MTF platform, or by contacting 1-800-MEDICARE, which has scripts to direct beneficiaries to one of the above pathways if they call with a complaint related to the MFP. In addition, as described in section 90.2.2 of this final guidance, CMS will establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals, including complaints from the public related to MFP availability.

Comment: A commenter recommended CMS only require the formulary inclusion of dosage forms and strengths of selected drugs that are necessary to meet the needs of the Part D plan's patient population.

Response: Consistent with CMS' response on page 148 of the final guidance for initial price applicability year 2027, section 1860D-4(b)(3)(I) of the Act requires Part D plan formularies to include 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. Accordingly, all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect must be included on formulary.

Comment: A few commenters asked that CMS consider a selected drug's protected class status during the formulary review process to ensure that protected class drugs are not disadvantaged. One commenter requested that CMS explicitly state that it will not approve a formulary that violated protected class policy.

Response: CMS thanks commenters for their feedback. CMS' robust, clinical formulary review process ensures that all Part D plan formularies comply with statutory and regulatory requirements. CMS' formulary policies relating to protected class drugs, as outlined in 42 C.F.R. § 423.120(b), apply regardless of whether a drug is a selected drug or not. Protected class requirements are longstanding CMS policy, and we do not believe additional clarification is necessary at this time.

Comment: Some commenters suggested that CMS engage with stakeholders to collect feedback related to formulary coverage. A few commenters proposed additional stakeholder engagement events to obtain feedback and real-world input from patients, caregivers and clinicians on access of selected drugs or leverage existing surveys to include questions about beneficiary experience with utilization management and their formulary design to ensure patients have access.

Response: CMS appreciates the input and will take this feedback into consideration for future initial price applicability years.

Formulary Inclusion Exception Successor Regulation for 2027 and 2028 (Section 110.1)

Comment: One commenter opposed CMS' identification in the Final CY 2026 Part D Redesign Program Instructions of a successor regulation that permits immediate substitution of selected drugs for interchangeable biological products. This commenter remarked broadly on policies beyond those finalized in the Final CY 2026 Part D Redesign Program Instructions, asserting that allowing substitutions of biological products, whether an interchangeable biological product or a biosimilar biological product other than an interchangeable biological product, and whether via immediate substitution or maintenance changes, undercuts the IRA's explicit requirement that Part D sponsors include selected drugs on their formularies, and that allowing biosimilar biological product substitution (including interchangeable biological product substitution) exceeds CMS' authority because the plain language of the statute applies only to generic drugs. In contradiction to these statements, this same commenter also requested that CMS maintain its formulary inclusion exception for 2027 and 2028 as described in section 110.1 of the draft guidance for initial price applicability year 2028 for selected drugs covered under Part D and extend the exception for all future initial price applicability years. One commenter supported the policy to allow Part D sponsors to replace selected drugs on formulary through immediate

substitution when a generic or interchangeable biological product comes to market, stating that this proposal provides appropriate flexibility for plan sponsors to develop formularies that drive the lowest net costs to the plan, the Medicare program, and Medicare beneficiaries.

Response: CMS thanks these commenters for their perspectives and support. Comments on the Final CY 2026 Part D Redesign Program Instructions are outside the scope of this guidance. With regard to the incorporation of section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extension of the policies therein to 2027 and 2028, CMS reiterates its response on pages 11 through 14 of the Final CY 2026 Part D Redesign Program Instructions. The statutory exception to the selected drug formulary inclusion requirement in section 1860D-4(b)(3)(I)(ii) of the Act allows for a Part D plan sponsor to remove a selected drug from its formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation). Because 42 C.F.R. § 423.120(b)(5)(iv) no longer exists in the Part D regulations, CMS was required to name a successor regulation.

The statute does not explicitly limit the exception to 42 C.F.R. § 423.120(b)(5)(iv) at the time of enactment. We believe it is significant that the statute did not establish a static exception (e.g., by indicating that the exception was limited to 42 C.F.R. § 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 42 C.F.R. § 423.120(b)(5)(iv) at the time of enactment (i.e., 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 C.F.R. 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 C.F.R. § 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 42 C.F.R. § 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.

Consistent with the text of section 1860D-4(b)(3)(I)(ii) of the Act, in this final guidance CMS is maintaining the policy described in the draft guidance for initial price applicability year 2028 to incorporate section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extension of the policies therein to 2027 and 2028.

Comment: A few commenters took the view that the successor regulation identified for 2027 and 2028 takes an overly narrow interpretation of the underlying statute and regulations and will limit generic and biosimilar biological product uptake. These commenters stated that the proposed implementation is confusing and raised concerns that plans will be restricted in their formulary decisions based solely on when during a year a generic or interchangeable biological product comes to market. To address this concern, a couple of commenters recommended that CMS interpret the successor regulation to include maintenance changes, which would give Part D plans flexibility to remove a selected drug when there is a generic or interchangeable biological product being marketed, but because of the timing of formulary submissions, the immediate substitution conditions for removal could not be met. A couple of commenters recommended that CMS revise the immediate substitution requirements as applied to selected drugs to allow their removal as soon as a generic or interchangeable biological product becomes available, and irrespective of whether this is before or after the initial formulary submission. One of these commenters stated that the immediate substitution rationale (namely, that plans should not have the option to replace a brand with a generic after the formulary is submitted if they could have done so before) does not apply with respect to a selected drug, since plans must include the selected drug as part of their initial formulary submission, even if a generic or interchangeable biological product has become available by then, and even if that generic or interchangeable biological product is included on the formulary as part of the initial formulary submission. One commenter expressed concern with the policy in the draft guidance for initial price applicability year 2028 to not allow plans to continue similar formulary treatment from year-to-year after a selected drug has been removed via immediate substitution, stating that this policy is not aligned with Congressional intent, and urged CMS to expand the successor regulation to include maintenance changes.

Response: In response to the requests that CMS expand the successor regulation to include maintenance changes, CMS reiterates its response on pages 12 and 13 of the Final CY 2026 Part D Redesign Program Instructions. CMS understands that permitting the removal of a selected drug via maintenance changes (which allow for substitution with a generic drug, interchangeable biological product, or a biosimilar biological product other than an interchangeable biological product) would provide Part D sponsors with greater flexibility to design their benefits and further promote access to potentially lower cost alternatives to the selected drugs. While we maintain that section 1860D4(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 declines to do so at this time. In the future, however, CMS may identify new regulations that constitute the successor regulation (e.g., as the biosimilar market matures or as additional changes are made to the underlying regulations). CMS also reminds Part D plan sponsors that they can add new generic drugs and biosimilar products to their formularies at any time during the plan year. Part D plan sponsors may also make maintenance changes with respect to selected drugs other than removing them from the formulary, in accordance with 42 C.F.R. § 423.120(e) and the notice requirements of 42 C.F.R. § 423.120(f). Comments with requests for revisions to the immediate substitution requirements in the Part D regulations, including with respect to timing, are outside the scope of this guidance.

CMS thanks the commenter for their feedback on the policy in the draft guidance to not allow plans to carry over similar formulary treatment from year-to-year within the price applicability period after a selected drug has been removed in a preceding year via immediate substitution. This policy is consistent with CMS' longstanding policy to consider each plan year's formulary to be separate and distinct from the prior year. CMS maintains in this final guidance 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: One commenter requested clarity on the formulary inclusion requirements for a selected drug for which multiple generics or interchangeable biological products come to market. Specifically, the commenter presented a scenario where one interchangeable biological product for a drug selected for initial price applicability year 2026 came to market prior to the CY 2026 formulary submission deadline and another interchangeable biological product for that selected drug came to market after the CY 2026 formulary submission deadline. The commenter stated that they expect, but ask CMS to confirm, that Part D sponsors would be permitted to, in accordance with the successor regulation, substitute the selected drug with the interchangeable biological product that came to market after the CY 2026 formulary submission deadline.

Response: For questions about the successor regulation exception to the formulary inclusion requirement for selected drugs in 2026, CMS refers the commenter to section 90 of the Final CY 2026 Part D Redesign Program Instructions. If the scenario described by the commenter were to occur with respect to plan years 2027 or 2028, CMS affirms that Part D sponsors would be permitted to substitute the selected drug with the interchangeable biological product that came to market after the 2027 or 2028 formulary submission deadline, if such removal meets the requirements specified in 42 C.F.R. § 423.120(e)(2)(i) and the notice requirements specified in 42 C.F.R. § 423.120(f)(2), (3), and (4), and irrespective of whether a different interchangeable biological product came to market prior to the such formulary submission deadline.

Application of Medicare Part B and Part D Drug Inflation Rebate Programs to Selected Drugs (Section 120)

Comment: Two commenters opposed CMS' application of the Medicare Part B and Part D Drug Inflation Rebate Programs to selected drugs. These commenters contended that manufacturers should not be obligated to pay an inflation rebate on a selected drug in both Part B and Part D because Medicare expenditures on a selected drug are already constrained by the MFP. The commenter further expressed that Medicare does not need to be made whole on account of such a price increase, and, therefore, no inflation rebate should be due. These commenters pointed to the Part B inflation rebate calculation in statute to assert that Congress did not intend for rebates to apply to selected drugs. One of these commenters urged CMS to clarify that a selected drug is not subject to inflation rebates.

Response: CMS thanks these commenters for their feedback. Consistent with CMS' response on page 85 of the revised guidance for initial price applicability year 2026, the statute provides that the inflation rebates apply to selected drugs.[51] Specifically, the rebate calculation specified in section 1847A(i)(3)(A)(ii)(l) of the Act references section 1847A(b)(1)(B) of the Act, which

[51] See sections 1847A(i) and 1860D-14B of the Act.

includes payment for selected drugs. That is, there is no statutory exemption from inflation rebates for selected drugs.

For additional information about the application of inflation rebates to selected drugs, CMS refers commenters to section 120 of this final guidance, as well as the CY 2025 Physician Fee Schedule final rule, in which CMS codified with modification and additional clarification in parts 427 and 428 of title 42, Chapter IV of the Code of Federal Regulations[52] the policies set forth in the revised Medicare Part B Drug Inflation Rebate Guidance and the revised Medicare Part D Drug Inflation Rebate Guidance.[53]

Comment: One commenter recommended that CMS monitor the impact of inflation rebates on selected drugs and also recommended CMS clarify how inflation rebate benchmarks will be maintained or recalculated when a selected drug transitions in to or out of the Negotiation Program.

Response: CMS thanks this commenter for these recommendations. CMS intends to monitor trends in the application of Part B and Part D drug inflation rebates to selected drugs. Additionally, as described in section 120 of this final guidance, in the case where a Part B rebatable drug is no longer a selected drug, the payment amount benchmark quarter is reset as the calendar quarter beginning January 1 of the last year during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the July of the year preceding such last year beginning during such price applicability period in accordance with section 1847A(i)(4)(C) of the Act. Identification of the payment amount benchmark quarter and identification of the benchmark period CPI-U are codified at 42 C.F.R. § 427.302(c) and (e), respectively. As further described in section 120 of this final guidance, in the case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period will be reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U will be the January of the last year beginning during such price applicability period in accordance with section 1860D-14B(b)(5)(C) of the Act. Identification of the payment amount benchmark period and identification of the benchmark period CPI-U are codified at 42 C.F.R. § 428.202(c) and (e), respectively.

Renegotiation of a Maximum Fair Price for Initial Price Applicability Year 2028 (Section 130)

Comment: A few commenters requested additional clarity on the timeline for renegotiation. Among these commenters, a couple of commenters also requested clarification as to whether renegotiation would be assessed on a set schedule or an ad-hoc basis. One commenter asked that CMS restrict renegotiation to no more than once annually and provide 120-day advance notice to MA plans of any changes to the MFP of a selected drug.

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[52] CMS, Final Rule, "Medicare and Medicaid Programs: CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments," December 9, 2024 (89 Federal Register, 97710).

[53] See: https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf and https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.

Response: CMS thanks commenters for their inquiry. As described in section 130 of this final guidance and section 1194(f) of the Act, CMS will review selected drugs with an agreed-upon MFP from initial price applicability years 2026 and 2027 for renegotiation eligibility. If any of these selected drugs are renegotiation-eligible based on the criteria described in section 130.1 of this final guidance, CMS will then determine whether to select those renegotiation-eligible drugs based on the criteria described in section 130.2 of this final guidance. Any drugs that are renegotiation-eligible and selected for renegotiation will be renegotiated for initial price applicability year 2028. Per section 1194(f) of the Act this process will occur annually thereafter. CMS notes that this guidance applies only to initial price applicability year 2028.

Regarding the request for notice to MA plans of changes to the MFP of a selected drug, CMS notes that renegotiation will occur at the same cadence (per section 1194(f) of the Act, that is annually beginning for initial price applicability year 2028) and on the same timeline (i.e., adhering to the same statutory deadlines provided in section 1194(b) of the Act) as negotiation. As such, a renegotiated MFP will be publicly available no later than November 30 two years prior to the relevant initial price applicability year when the MFP becomes effective in accordance with section 1195(a)(1) of the Act and as described in section 60.6 of this final guidance. Additionally, per section 60.6 of this final guidance, CMS will publish an updated MFP no later than November 30 of the year that is two years prior to such subsequent year. Given this timeline, the renegotiated MFP will be publicly available (including for MA plans) more than 120 days before a renegotiated MFP takes effect.

Comment: One commenter said that CMS should only consider selected drugs to be renegotiation-eligible if the MFP is likely to be reduced during renegotiation. One commenter supported the notion that renegotiation would not always result in a lower negotiated price.

Response: Section 1194(f)(2) of the Act defines a "renegotiation-eligible" drug as a selected drug that has a new indication, a change of status to an extended-monopoly drug, a change in status to a long-monopoly drug, or a material change to a section 1194(e) factor. Section 130.1 of this final guidance aligns with this statutory definition and provides additional detail on how CMS will determine renegotiation eligibility. CMS declines to only consider selected drugs as renegotiation-eligible if the MFP is likely to be reduced during renegotiation as this is not part of the definition of a renegotiation-eligible drug per section 1194(f)(2) of the Act.

Section 1194(b)(1) of the Act directs CMS to develop a methodology and process for negotiations that "aims to achieve the lowest maximum fair price for each selected drug." CMS notes that the lowest MFP that may be achieved through renegotiation of a selected drug may increase or decrease based on the emergence of new information about the drug related to section 1194(e) factors. For example, new data could emerge after an MFP is negotiated for a selected drug indicating a significant improvement in outcomes not previously reported that may warrant an increase in the MFP should that selected drug be eligible and selected for renegotiation. As such, CMS will strive to negotiate the lowest MFP for each selected drug based on the evidence available at the time of negotiation and renegotiation, as applicable.

Comment: A couple of commenters suggested that CMS should issue a public notice of the agency's intent to renegotiate a selected drug followed by a public comment period for interested parties to submit updated information. Another commenter requested clarification on whether CMS would notify a Primary Manufacturer if its selected drug is eligible for renegotiation, and if so, when that notification would be provided.

Response: Section 1194(f)(4)(B) of the Act requires the methodology and process for renegotiation to be consistent with the methodology and process for negotiation established under 1194(b) of the Act to the extent practicable. As such, CMS intends to follow the same process and timeline for publishing the selected drug list for renegotiation as this is both practicable and follows a similar process and methodology to align with statute. As for notice to the manufacturer, CMS indicated in section 30.1 of the draft guidance for initial price applicability year 2028 and now in this final guidance that CMS will publish the list of selected drugs selected for renegotiation, if any, no later than February 1, 2026. CMS added this information to section 130.2 of this final guidance for additional clarity. CMS appreciates the commenter's request for public notice and comment, but CMS does not believe this is operationally feasible on this timeline.

Identification of Renegotiation-Eligible Drugs for Initial Price Applicability Year 2028 (Section 130.1)

Comment: One commenter requested that CMS delay eligibility for renegotiation for two years following a selected drug's initial price applicability year because CMS will not be able to understand if there has been a material change without seeing the financial impact of MFP. One commenter noted a drug could be subject to multiple rounds of renegotiation in a short period of time if a drug with an agreed-upon MFP had multiple new indications and a change in monopoly status. Some commenters suggested that CMS restrict renegotiation-eligible drugs to those with a change in monopoly status for initial price applicability year 2028. These commenters noted the short timeframe between MFP agreements signed for initial price applicability years 2026 and 2027 and potential renegotiation, the need for simplification and specificity, and the need to follow the statute more closely as concerns warranting this policy change. One commenter suggested restricting renegotiation eligibility to selected drugs with a new indication, a change in safety, or a patent expiration.

Response: CMS appreciates the perspective offered by these commenters and acknowledges that it is possible under the statute that a selected drug with an agreed-upon MFP could be renegotiated relatively shortly after the conclusion of a prior negotiation. However, as discussed in section 130.1 of the draft guidance for initial price applicability year 2028 and this final guidance, CMS interprets 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. Because calendar year 2028 will be a year within the price applicability period for drugs selected for initial price applicability years 2026 and 2027, such selected drugs may be eligible for renegotiation in calendar year 2026 (i.e., for initial price applicability year 2028) and may be selected for renegotiation if certain criteria are met (as discussed in sections 130.1 and 130.2 of this final guidance). Section 1194(f)(2) of the Act also establishes that the definition of a "renegotiation-eligible drug" includes not only drugs with certain changes in monopoly status

but also selected drugs for which a new indication is added or for which the Secretary determines there has been a material change to a section 1194(e) factor. Section 1194(f)(3) of the Act then 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.

Comment: One commenter urged CMS to work with Congress to remove new indications as a trigger for renegotiation eligibility. A couple of commenters expressed concern that using new indications as a trigger for renegotiation eligibility might disincentivize post-approval label expansion, particularly for rare and ultra-rare diseases.

Response: CMS will continue to implement the Negotiation Program, including renegotiation, in accordance with current law.

Comment: One commenter stated that the requirement for a new indication to be for a new disease or condition outlined in draft guidance for initial price applicability year 2028 departs from the statutory definition of new indication in section 1192(e)(3)(A) of the Act and from the FDA definition of new indication.

Response: As discussed in section 60.3.1 of this final guidance, for purposes of the Negotiation Program, CMS distinguishes between use of the word "indication" and "FDA-approved indication." As specified in sections 60.3.1 and 130.1.3 of this final guidance, CMS will consider an "indication" to be the condition or disease state that the selected drug treats. "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s). CMS also notes that the statutory text at section 1192(e)(3)(A) of the Act related to the Orphan Drug Exclusion does not define a "new indication." Additionally, the language at section 1192(f)(2)(A) of the Act, where the statute directs CMS to consider a selected drug "for which a new indication is added" to be renegotiation-eligible, does not use the same language of "approved indications" as is used in section 1192(e)(3)(A) of the Act nor does it reference section 526 of the FD&C Act.

Comment: A couple of commenters stated that the draft guidance for initial price applicability year 2028 did not sufficiently define what constitutes a material change to a section 1194(e) factor and expressed concern that this could lead to confusion and/or inconsistent application of CMS' approach. A few commenters requested additional clarity around the process that CMS will use to assess a material change to a section 1194(e) factor, including the suggestion to publish examples or specific circumstances to illustrate CMS' approach.

Response: CMS thanks these commenters for their feedback. CMS simplified the description of the criteria for what constitutes a material change(s) to a section 1194(e) factor in this final guidance to provide additional clarity. Table 11 of this final guidance provides examples to illustrate CMS' approach.

Comment: One commenter asked that assessments of caregiver burden and family financial impact be considered when assessing material change. One commenter recommended that the

entry of a new biosimilar or generic that could be considered a therapeutic alternative to a selected drug be considered as a potential material change.

Response: CMS thanks the commenter for their suggestion to assess caregiver and family financial burden when considering a material change. In alignment with section 60.3.3.1 of this final guidance, CMS may consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug for purposes of evaluating the factors under section 1194(e)(2). CMS also confirms that the entry of a new biosimilar or generic that could be considered a therapeutic alternative to a selected drug could be considered a material change as it would reflect a change in a section 1194(e)(2) factor. In both cases, the change would have to meet the criteria to be considered "material" as outlined in section 130.1.2 of this final guidance.

Comment: A couple of commenters stated that Part B utilization for a selected drug that has an agreed-upon MFP based upon Part D information (i.e., a selected drug negotiated for initial price applicability year 2026 or 2027) does not constitute a material change to a section 1194(e) factor and should not trigger renegotiation eligibility.

Response: CMS provided edits to language in section 130.1 of this final guidance to clarify that the existence of Part B utilization for a selected drug that was negotiated in initial price applicability year 2026 or 2027 does not automatically result in a selected drug becoming renegotiation eligible. Rather, for example, CMS notes that Part B utilization could impact the section 1194(e) factors (e.g., the factor under section 1194(e)(1)(E) of the Act ("market data and revenue and sales volume data from the drug in the United States")) and may be renegotiation-eligible as a material change to a section 1194(e) factor under section 1194(f)(2)(D) of the Act. To the extent that CMS determines that there has been a material change in a section 1194(e) factor after considering the Part B utilization, the drug would be deemed renegotiation-eligible.

Selection of Drugs for Renegotiation for Initial Price Applicability Year 2028 (Section 130.2)

Comment: A few commenters supported CMS' holistic approach to the selection of renegotiation-eligible drugs. One commenter expressed support for the general parameters outlined in draft guidance for initial price applicability year 2028 for the renegotiation process.

Response: CMS thanks these commenters for their support.

Comment: Many commenters asked that CMS provide additional clarity on the rationale for the 15 percent renegotiation selection criterion concerning 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 as well as more information on what factors CMS would consider during the holistic evaluation and additional detail on how CMS would consider various factors, including section 1194(e) factors, during its holistic evaluation. In addition to reviewing the impact on the Medicare program and beneficiaries, a few commenters recommended that CMS consider the impact on value to patients when assessing the potential for a significant change to the MFP. A couple of commenters alleged that the criterion concerning 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 is a "threshold", for which there is no statutory authority or basis, including one based on the change in the non-FAMP ceiling.

Response: CMS thanks commenters for their input. As described in section 130.2.1 of this final guidance, CMS 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, CMS 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. As described in section 130.2.1 of this final guidance, CMS' 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. The scope of information considered may include a CMS-led review of the information sources discussed in section 50 of this final guidance pertaining to section 1194(e)(1) and section 1194(e)(2) factors. CMS notes 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 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.

Comment: One commenter supported the criterion regarding assessing the likelihood of a 15 percent or greater change to the current MFP to define what constitutes a significant change in the MFP. One commenter suggested that CMS revise the approach such that a renegotiation-eligible drug must only fulfill one of the two criteria in section 130.2 of the draft guidance for initial price applicability year 2028 rather than requiring the renegotiation-eligible drug to meet both criteria in order to be selected for renegotiation. One commenter requested that CMS make clear that the criteria could reflect potential increases or decreases in the MFP. One commenter asked CMS to clarify how the agency would analyze a material change that would significantly impact the Medicare program but the anticipated percent change to the MFP is less than 15 percent.

Response: CMS appreciates these commenters' feedback. Regarding the suggestion to require a selected drug with an agreed-upon MFP to meet one of the two criteria describe in this final guidance for "likely to result in a significant change to the MFP" rather than both criteria, CMS believes these criteria are complementary and important to consider holistically. There may be circumstances for a selected drug that is likely to result in a 15 percent or greater change to the MFP if renegotiated, but that change would have minimal impact on the Medicare program or

Medicare beneficiaries (for example, if CMS expects robust generic competition may occur, as described in section 130.2.1 of this final guidance). In such a case, it may not be prudent to select such a drug for renegotiation given the resources invested in the negotiation process by both Primary Manufacturers and CMS. A holistic approach of both criteria is important to consider the circumstances for each selected drug.

Additionally, to clarify, and as described in section 130.2.1 of this final guidance, in assessing the likelihood of a 15 percent or greater change to the current MFP, CMS will consider either a potential increase or decrease to the MFP. The criterion reflects the magnitude of the change that CMS considers to be significant, not whether that change is an increase or a decrease to the MFP. Additionally, as discussed in section 130.2.1 of this final guidance, 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, CMS does not presume that the result of a renegotiation will reflect these approximations, for example, with respect to the impact of a renegotiated MFP on the Medicare program. These criteria only 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.

Comment: Some commenters asked that CMS change the renegotiation selection criterion concerning the likelihood that renegotiation of a renegotiation-eligible drug due to a new indication or material change could result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP by instead evaluating the likelihood that renegotiation could result in at least a 35 percent change to the current MFP. Among these commenters, some stated that a 35 percent change to the current MFP would be more appropriate because when a drug moves from short-monopoly to long-monopoly status, there is a 35 percent change applied to the non-FAMP ceiling.

Response: CMS appreciates commenters' feedback. CMS 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. The agency balanced considerations about the resources invested in renegotiation in determining what constitutes a significant change, and maintains that a 15 percent change is more appropriate than a 35 percent change. As discussed in section 130.2 of this final guidance, CMS also recognizes 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, CMS added the complementary criterion of evaluating whether renegotiation would likely have a significant impact to the Medicare program. As such, CMS declines to revise the criterion.

Data Collection to Inform Renegotiation Drug Eligibility, Selection, and Renegotiation of the MFP for Initial Price Applicability Year 2028 (Section 130.3)

Comment: Many commenters provided feedback on the manufacturer data submission processes. Some commenters requested CMS streamline the data submission requirements to reduce manufacturer burden and provide predictability in the requirements by permitting a

manufacturer to update its original ICR submission or to attest that no material or significant change(s) had occurred in the data of its original ICR submission. Other commenters requested CMS provide additional flexibility with data submissions, including making the post-selection data submission optional, accepting data during the renegotiation process, and accepting information on factors that were not available during the initial negotiation. A couple of other commenters expressed concerns that the pre-selection data submission is voluntary and suggested the data submission prior to selection be mandatory so that it would not be biased to the manufacturer. A few other commenters thanked CMS for making the pre-selection data submission optional to reduce manufacturer burden.

Response: CMS thanks commenters for their feedback. First, regarding the submission of information prior to identification of renegotiation-eligible drugs and selection, as specified in section 130.3.1 of this final guidance, section 1194(f) of the Act does not require CMS to collect data from Primary Manufacturers to determine if a new indication has been added to the selected drug or if there has been a material change in any of the section 1194(e) factors. However, CMS believes that it may be helpful to permit a voluntary submission of new information regarding the addition of a new indication to the selected drug or new information regarding the section 1194(e) factors, that was not included in the original submission of data from the Primary Manufacturer, prior to the CMS determination of renegotiation eligibility and selection from Primary Manufacturers of selected drugs that do not have a change to long-monopoly status. CMS is aware of the burden an information collection request poses to manufacturers and CMS has endeavored to provide limited questions to capture critical information a Primary Manufacturer may choose to share to inform eligibility and selection of a selected drug due to the addition of a new indication or material change in a section 1194(e) factor.

Additionally, in response to other commenters' concern that Primary Manufacturers may self-select the information to be shared in a voluntary submission, CMS directs interested parties to sections 130.1.3, 130.1.4, and 130.2.1 of this final guidance for the discussion of evidence CMS will review for identification of and selection of drugs due to a new indication or material change in a section 1194(e) factor, separate from the voluntary submission of manufacturers. Also, when submitting a response to the Drug Selection ICR, the Primary Manufacturer must follow the instructions provided by CMS and must certify that the information provided is accurate.

Second, regarding the mandatory submission of data from Primary Manufacturers of drugs selected for renegotiation, while post-selection submission of section 1194(e)(1) data is required of Primary Manufacturers, CMS has also endeavored to streamline the data required in this step. In keeping with section 1194(f)(4)(B) of the Act to establish a renegotiation process that is consistent with the negotiation process to "the extent practicable," as provided in the 60-day revisions to the Drug Price Negotiation ICR, Primary Manufacturers will use a system, process, and questions already familiar to them to submit limited, new information for renegotiation. The data requested covers time periods separate from the original submission of 1194(e) data. With respect to commenters' request to accept data during the renegotiation process, Primary Manufacturers have the flexibility to share additional section 1194(e) information with CMS during the negotiation meeting process by following the instructions described in section 60.4.4 of this final guidance.

Finally, for both submissions, neither a supplementation to the original 1194(e) submission from the Primary Manufacturer or an attestation of no additional information from the Primary Manufacturer is sufficient for CMS' determination of renegotiation eligibility or selection and to determine an initial offer or, if any, counteroffers. As stated above, CMS has provided a narrow set of questions to capture new information that is distinct from the original submission, however, to reduce burden.

Comment: Some commenters requested clarification of the data submission timeline. A couple of commenters requested additional time to submit manufacturer data.

Response: CMS thanks commenters for their questions. For the voluntary submission of data from the Primary Manufacturer, as specified in section 130.3.1 of this final guidance, CMS will provide the date and time by which the information must be submitted to CMS upon approval from the Office of Management and Budget of the Drug Selection ICR. For the mandatory submission of data from Primary Manufacturers and the voluntary submission of section 1194(e)(2) data from any interested party, submissions must be provided by March 1, 2026, as specified in sections 50, 50.2, and 130.3.2 of this final guidance.

The statutory deadline for the Negotiation Program to publish the selected drug list does not provide enough time to extend the submission window for the voluntary submission of manufacturer data beyond what is anticipated to be at least a 30-day window similar to the period of time that has been generally provided in past initial price applicability periods for the small biotech exception and a request for a biosimilar delay. The submission of data post-selection is specified in the statute for Primary Manufacturers (sections 1193(a)(4)(B) and 1194(b)(2)(A) of the Act) and CMS' intention to require public submission on the same date as manufacturer submission (i.e., March 1, 2026) serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer, pursuant to general program administration authority. For operational feasibility and for consistency, to the extent practicable, CMS is adopting for initial price applicability year 2028, the same deadlines for post-selection data submission to enable the timeline to be identical between renegotiation and negotiation.

Comment: A couple of commenters suggested CMS permit other interested parties to submit evidence prior to selection of renegotiation-eligible drugs.

Response: CMS thanks commenters for their feedback. As discussed in section 130.3.1 of this final guidance, CMS is not obligated to collect information from external parties prior to identification and selection of drugs for renegotiation due to the addition of a new indication or material change in a section 1194(e) factor. CMS believes that the information that the public may provide that is critical to identification and selection of such drugs will already be identified by CMS in the evidence CMS will review, through the reviews specified in sections 130.1.3, 130.1.4, and 130.2.1 of this final guidance. However, CMS recognizes the importance of ongoing feedback from other interested parties in the renegotiation process and is providing an opportunity for public feedback on the section 1194(e)(2) factors post-selection for renegotiation, which is consistent with section 1194(f)(4)(B) of the Act.

Comment: A couple of commenters expressed concern that it may be difficult to predict which drugs would be selected for negotiation. Specifically, one commenter asked how the public would be aware that renegotiation may be triggered for a selected drug and invited to submit information about selected drugs. Another commenter stated that this would make preparing for potential selection challenging for a manufacturer.

Response: CMS thanks commenters for their feedback. CMS has provided a few examples of scenarios and the potential result in determination of material change in section 130.1.4 of this final guidance to also aid Primary Manufacturers prior to submission of the voluntary collection of information prior to identification of renegotiation-eligible drugs and their selection. In addition, as specified in sections 30.4 and 130.2.2 of this final guidance, CMS will publish the list of drugs selected for renegotiation for initial price applicability year 2028 prior to the deadline for the submission of the section 1194(e)(2) information from interested parties (see additional details on the submission by interested parties for renegotiation in section 130.3.2 of this final guidance).

Comment: One commenter suggested that a notice and comment process should be used for consideration of new evidence and that CMS must use an evidence-based approach.

Response: Section 11001(c) and 11002(c) of the IRA direct CMS to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 through program instruction or another form of program guidance. When required by law, CMS will develop its policies for 2029 and all future years of the Negotiation Program through notice-and-comment rulemaking. CMS appreciates the input received from commenters on this methodology through the voluntary solicitation of comments in the guidance process.

CMS directs interested parties to sections 130.1.3, 130.1.4, and 130.2.1 of this final guidance for the discussion of evidence CMS will review for identification of and selection of renegotiation-eligible drugs due to a new indication or a material change in a section 1194(e) factor.

Renegotiation Process (Section 130.4)

Comment: A few commenters requested that CMS provide public input opportunities for renegotiations, such as through public data submissions, public comment periods before establishing a renegotiated MFP, and public engagement events. A couple of commenters requested CMS provide additional details regarding how public engagement will be implemented in the renegotiation process. Another commenter recommended CMS hold additional roundtable events for drugs selected for renegotiation.

Response: CMS recognizes the importance of ongoing feedback from other interested parties, including patients, in the renegotiation process. As stated above, CMS is providing an opportunity for public feedback on the section 1194(e)(2) factors for drugs selected for renegotiation, consistent with section 1194(f)(4)(B) of the statute. Additionally, CMS directs commenters to sections 60.4.1 and 130.4.3 of this final guidance, which provide specific steps for engagement with interested parties prior to the issuance of initial offers. CMS 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 section 130.4.3 of this final guidance.

Comment: One commenter encouraged CMS to publish an MFP explanation for drugs selected for renegotiation. One commenter recommended CMS provide the public with a summary of the outcomes of renegotiation. The same commenter recommended CMS provide advance notice and a justification for the renegotiated MFP. A few commenters asked that CMS detail specific information to be included in the MFP explanation, such as details on the reason a drug was selected for renegotiation and how patient-focused considerations were used in renegotiations.

Response: CMS thanks these commenters for their feedback. As described in section 130.4.5 of this final guidance, CMS will release an MFP explanation for each selected drug with a renegotiated MFP following the completion of the renegotiation process in accordance with section 60.6.1 of this final guidance and in accordance with the confidentiality policy described in sections 40.2.1 and 50.2 of this final guidance. As stated in response to comments above, CMS notes that renegotiation will occur at the same cadence (per section 1194(f) of the Act that is annually beginning for initial price applicability year 2028) and on the same timeline (i.e., adhering to the same statutory deadlines provided in section 1194(b) of the Act) as negotiation. As such, a renegotiated MFP will be publicly available no later than November 30 two years prior to the relevant initial price applicability year when the MFP becomes effective in accordance with section 1195(a)(1) of the Act and as described in section 60.6 of this final guidance.

CMS thanks commenters for their recommendation to include more detail regarding the reason for selection and how patient-focused considerations were used in renegotiations in the MFP explanations. CMS will further consider these suggestions as CMS develops the renegotiated MFP explanations.

Comment Solicitation on the Procedures, Structure, and Timing of the Renegotiation Process

Comment: A couple of commenters expressed support for the renegotiation process conforming to the procedures, structure, and timing of the negotiation process. One commenter asked CMS to provide flexibility in circumstances where a manufacturer has a drug selected for negotiation and renegotiation during the same initial price applicability year, such as by extending the negotiation and renegotiation timeframe. Another commenter suggested aligning the renegotiation process with the negotiation process is burdensome to manufacturers and other stakeholders interested in submitting input on the selected drugs and asked CMS to consider simplifying the renegotiation process where possible.

Response: CMS thanks commenters for their feedback. 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, 2026, and the requirement under section 1194(b)(2)(E) of the Act that negotiations must end prior to November 1, 2026, it is not feasible to extend the timeframe for the negotiation period. CMS is abiding by the statutory deadlines for the negotiation period in this final guidance. As described in section 130.4.3 of this final guidance, and in accordance with section 1194(f)(4)(B) of the Act, CMS intends, to the extent practicable, for the renegotiation

process to conform to the procedures, structure, and timing established under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act as set forth in section 60.4 of this final guidance. Additionally, CMS has endeavored to streamline the renegotiation process where possible. For example, as noted in response to comments above, for the data submission process for renegotiations, as provided in the 60-day revisions to the Drug Price Negotiation ICR, Primary Manufacturers will use a system, process, and questions already familiar to them to submit limited, new information for renegotiation.

Appendix A

Comment Solicitation on Streamlining the Definitions

Comment: CMS received many comments in response to CMS' solicitation for suggestions to streamline the definitions included in Appendix A. Some of these commenters suggested CMS refine the definitions by reducing the scope of the data collected to items critical to the Negotiation Program, improving alignment of the data with collection of such information in the pharmaceutical industry, and restructuring calculations to adhere to U.S. GAAP and SEC requirements. To do so, some of these commenters suggested removing distinct definitions for R&D costs (e.g., costs related to the selected drug, costs for failed and abandoned products related to the selected drug) and permitting the Primary Manufacturer to attest to recoupment of R&D costs and provide optional supplemental information. A few of these commenters suggested the delineated terms were difficult for manufacturers to identify in their data and questioned their relevance to the Negotiation Program. One commenter suggested streamlining by permitting manufacturers to use reasonable assumptions to determine and submit statutorily required information. Additionally, some of these commenters requested CMS revise and/or remove definitions related to data collection of pricing data in the ICRs beyond the collection of non-FAMP because, the commenters stated, the collection of such data is not required by the statute and the requested data metrics are not consistent with industry-practices. Specifically, one commenter disagreed with the aggregation of price concessions from supply chain entities across the pharmaceutical supply chain in "Manufacturer Net Part D Price." Another commenter suggested additional guidance is needed if CMS retains CMS-specific pricing metrics (e.g., manufacturer net Medicare Part D average unit price, manufacturer U.S. commercial average net unit price) because manufacturers needed to rely on assumptions to respond. Some commenters also included overall feedback on the data submission and information collection process, including the removal of character limitations on responses, the burden of submitting free response field explanations, and the requirement to provide certain information on behalf of a Secondary Manufacturer.

Response: CMS thanks commenters for their suggestions. CMS has included further revisions to the definitions for R&D costs to clarify which costs should be included for Questions 1 and 2 of the Drug Price Negotiation ICR. For example, CMS removed the word "indications" from the terms defined for consistency with the revisions to the definitions of these terms included in the draft guidance for initial price applicability year 2028, which expanded collection of R&D costs to include costs for indications that have not been approved by the FDA. CMS does not intend the language included in this final guidance to substantially change the definitions for the terms as compared to the language included in the draft guidance. CMS declines to revise the definitions for R&D costs beyond these changes because CMS believes the information included

in the definitions 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.

Consistent with CMS' response on page 83 of the final guidance for initial price applicability year 2027, CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions for manufacturer-specific data submissions or otherwise use reasonable assumptions, except where the use of assumptions is explicitly indicated in the Drug Selection ICR and Drug Price Negotiation ICR. For example, in the ICR forms, CMS instructs the Primary Manufacturer of the selected drug to explain the methodology used to calculate certain costs reported to CMS (e.g., Question 4 related to unit production and distribution cost in the Drug Selection ICR and Question 7 related to prior Federal financial support in the Drug Price Negotiation ICR). CMS continues to provide specific terms and instructions to make clear the information required for the Negotiation Program, and CMS believes Primary Manufacturers have experience providing similar data and information to other federal and state entities. CMS included technical corrections to the specific definitions that clarify the items that should or should not be deducted from the price for: manufacturer U.S. commercial average net unit price, manufacturer U.S. commercial average net unit price—net of patient assistance, manufacturer net Medicare Part D average unit price, and manufacturer net Medicare Part D average unit price—best. CMS declines to further revise the series of terms on manufacturer U.S. commercial average net price and manufacturer net Medicare Part D price because CMS believes that the Primary Manufacturer has access to the specific data required to calculate these data elements included in the related ICRs, CMS provides terms and instructions to clarify which specific data should be included in this set of metrics, and CMS believes this information is relevant to the section 1194(e)(1)(E) of the Act "market data" factor for adjusting the preliminary price (see section 60.3.4 of this final guidance).

Regarding the requirement to provide certain information on behalf of a Secondary Manufacturer, CMS directs commenters to section 40 of this final guidance regarding the definition of manufacturer and the requirements of manufacturers of selected drugs. 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." CMS believes this indicates that the information for section 1194(e)(1) factors must come from the manufacturer of the selected drug (which will be the Primary Manufacturer on behalf of the Secondary Manufacturer, as applicable).

Additionally, CMS directs interested parties to responses provided in response to comments received about data collection burden, instructions, and questions on the 60-day revisions to the Drug Selection ICR (as included with the 30-day revisions published concurrently with this final guidance) and the Drug Price Negotiation ICR (as included in the 30-day revisions, which CMS expects to publish in late Fall 2025).

Comments About Specific Terms

Comment: A few commenters disagreed with CMS' removal of acquisition costs from the definition for R&D costs. These commenters argued that while CMS appears to believe that an acquisition results in zero R&D costs, these commenters contend that the acquisition is part of

the actual costs for developing and marketing a product. One commenter supported the removal of acquisition costs as an R&D cost to help streamline the data required of manufacturers.

Response: CMS thanks commenters for their feedback. CMS, however, disagrees with the comments that opposed the removal of acquisition costs. CMS believes the information included in the definitions 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. As included in Appendix A of the draft guidance for initial price applicability year 2028, CMS has removed the separate question regarding acquisition costs because, among other impacts on the data, CMS understands that acquisition costs are generally driven by the estimated net of the present value that is assessed based on the future revenue expectations for a drug, and that acquisition costs are not driven by R&D.

Comment: A few commenters raised concerns about the definitions related to prior Federal financial support. Specifically, one commenter disagreed with including tax credits for orphan drugs because the commenters say the tax credit is intended for drug development related to treatment of rare diseases and reporting of this information may not be known to manufacturers or at the specificity required. These commenters suggested limiting funding related only to a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government entity. Additionally, one commenter raised concerns about the applicability of early-stage research federal funding because it may not indicate the purpose of the funding, and the commenter also noted the documentation may not be available to the manufacturer. Finally, another commenter stated that the definition was overly broad regarding discovery and development for a selected drug.

Response: CMS thanks the commenters for their feedback. CMS declines to further revise the series of terms on prior Federal financial support because the information collected is consistent with section 1194(e)(1)(C) of the Act (and in line with the revisions CMS has incorporated to the collection of R&D costs) and CMS provides terms and instructions to clarify which specific data should be included in this set of data elements in the appliable ICRs.

Comment: One commenter raised concerns about the feasibility of manufacturers reporting abandoned and failed products with the same mechanism of action because the commenter said drug development investment is not structured at this product level.

Response: CMS thanks the commenter for the feedback. CMS has continued to incorporate revisions to definitions and collection of information related to R&D costs in response to public comment. Based on the collection of information from Primary Manufacturers in two cycles of the Negotiation Program thus far, CMS believes the information included within the definition for R&D costs for failed and abandoned products related to the selected drug is feasible for Primary Manufacturers to submit to CMS. Further, CMS believes the term as defined in this final guidance is consistent with section 1194(e)(1)(A) of the Act and is necessary for the Negotiation Program, as discussed in further detail in sections 50.1 and 60.3 of this final guidance.

Comment: One commenter provided suggested revisions to the definitions for patents and exclusivities. Specifically, the commenter suggested removing expired and non-public patents

and expired regulatory exclusivities, unless the Primary Manufacturer chooses to share this information.

Response: CMS thanks the commenter for the feedback. CMS declines to further revise the series of terms on patents and exclusivities because the information collected is consistent with section 1194(e)(1)(D) of the Act and CMS provides terms and instructions to clarify which specific data should be included in this set of data elements in the applicable ICRs.

Comment: One commenter requested CMS clarify the replacement of "related" to "relevant" within the definitions for patents, exclusivities, and approvals.

Response: CMS included the revision in the draft guidance for initial price applicability year 2028 to align with the structure of questions about patents, exclusivities, and approvals in the Drug Selection ICR and the Drug Price Negotiation ICR. However, CMS clarifies that the revisions are not intended by CMS to substantively alter the definitions for patents, exclusivities, and approvals.

Comment: Some commenters provided suggestions to revise the terms related to the section 1194(e)(2) factors.

Response: CMS directs interested parties to responses to these and similar comments in comment summary and responses for section 60.3 of this final guidance.

Out of Scope Comments Submitted on Draft Guidance on the Medicare Drug Price Negotiation Program for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Comment: Many commenters submitted recommendations related to incorporating the MFP into ASP calculations. Many commenters stated that CMS should not incorporate units of selected drugs sold at the MFP into ASP calculations and expressed concerns about reducing provider payments.

Response: These comments are outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. CMS notes that this topic is addressed in the CY 2026 Physician Fee Schedule Proposed Rule.[54]

Comment: One commenter urged CMS to rescind the provision in the CY 2026 Parts C&D Final Rule requiring Part D plans to submit initial PDEs for selected drugs within seven days of receipt of a claim for a selected drug. Another commenter expressed concern that the shortened PDE submission window for selected drugs will increase claim reversals and adjustments. The commenter encouraged CMS to pursue alternatives to the use of PDE data, while limiting delays in MFP refunds and any undue burdens placed on pharmacies. One commenter expressed

[54] CMS Proposed Rule, "Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program," July 16, 2025 (90 Fed. Reg. 32352). See: https://www.federalregister.gov/d/2025-13271.

support for CMS shortening the PDE submission requirement timing. One commenter recommended that CMS monitor the impacts of this policy to determine whether a shorter period is needed.

Response: These comments are outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. This topic is addressed in the CY 2026 Parts C&D Final Rule.[55]

Comment: One commenter expressed disappointment that the IRA did not address PBM requirements that providers send prescriptions to PBM mail order or specialty pharmacies rather than allowing providers to fill prescriptions in the office.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028.

Comment: One commenter recommended reforms for the 340B Drug Pricing Program, including strengthening 340B participation requirements and requiring transparency and reporting in 340B.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028.

Comment: One commenter acknowledged that the commenter's feedback was outside the scope of the comment solicitation related to step therapy and was, rather, in relation to the President's directive to reduce regulatory burden; the commenter recommended that CMS consider revising limitations on MA plans' use of Part B step therapy and better align step therapy practices allowed in MA with those allowed under Medicare Part D, including by allowing step therapy practices for existing utilizers of a product in addition to members who are new to a product.

Response: As the commenter noted, this comment is related to MA step therapy practices and is in response to the President's Executive Order related to reducing regulatory burden.[56] Therefore, it is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028.

Comment: One commenter expressed concerns with the recently finalized MTF Agreements, and in particular two provisions included in the Medicare Transaction Facilitator Data Module User Agreement for Manufacturers; the provision in which CMS reserved the right to terminate MTF functionality with 180 days notice to manufacturers and the "as is" language in the liability disclaimers.

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[55] CMS Final Rule, "Medicare and Medicaid Programs: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," April 15, 2025 (90 Fed. Reg. 15834). See: https://www.federalregister.gov/d/2025-06008.

[56] See: https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. CMS previously solicited feedback on the MTF Agreements and refers to the previously released responses, available here.

Comment: One commenter urged CMS to propose and finalize ICRs related to initial price applicability year 2027 as soon as possible.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. All ICRs for initial price applicability year 2027 are final.

Comment: One commenter recommended that CMS require MA plans and Part D plan sponsors to distribute standardized educational materials on the MFP.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028.

Comment: One commenter raised questions about and recommended CMS provide transparency around penalty provisions related to the Medicare Prescription Drug Inflation Rebate Program.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. CMS addressed the enforcement of manufacturer payment of rebate amounts in the CY 2025 Physician Fee Schedule final rule (89 Fed. Reg. 98271 through 98275 and 89 Fed. Reg. 98311 through 98312) as well as in 42 C.F.R. § 427.600 and 42 C.F.R. § 428.500.

Comment: One commenter expressed concerns with the specific time periods in the current Part D formulary substitution regulations for immediate substitutions and maintenance changes.

Response: This comment is outside the scope of this final guidance.

Comment: A couple of commenters asked CMS to work with Congress to extend the SBE.

Response: This comment is outside of the scope of this final guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028.

D. Final Guidance on the Medicare Drug Price Negotiation Program

10. Introduction

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (P.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).[57] for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereinafter "the Act"), as added by sections 11001 and 11002 of the IRA.

The Centers for Medicare & Medicaid Services (CMS) is committed to actively engaging with interested parties to consider opportunities to bring greater transparency to the Negotiation Program. Through the final guidance, CMS gathered input from a broad range of interested parties regarding the implementation of the Negotiation Program for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. Public feedback on all aspects of the negotiation process and manufacturer effectuation of the MFP is critical to achieving the goals of greater value for beneficiaries and taxpayers and continuing to foster innovation. CMS is committed to learning from, collaborating with, and engaging the public, including patients, consumer advocates, health and data experts, and pharmaceutical supply chain entities in the policy-making process.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the Department of Health and Human Services (HHS) (hereinafter "the Secretary") to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this final guidance for implementation of the Negotiation Program for initial price applicability year 2028, including for renegotiation, and for manufacturer effectuation of the MFP in 2026, 2027, and 2028. To improve program transparency, CMS also voluntarily solicited comments on the topics in the draft guidance, except section 90.3.[58]

This final guidance is not subject to the notice-and-comment requirements of the Administrative Procedure Act (APA) or the Medicare statute due to the requirement in sections 11001(c) and 11002(c) of the IRA to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. The statutory directive in sections 11001(c) and 11002(c) thus specifies that CMS shall follow policymaking procedures

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[57] In accordance with section 1191(c)(3) of the Social Security 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.

[58] CMS did not solicit comments on section 90.3 of the draft guidance for initial price applicability year 2028 because the Department of the Treasury and the Internal Revenue Service (IRS) issued regulations that govern the administration of the excise tax (*see* Excise Tax on Designated Drugs; Procedural Requirements, 88 Fed. Reg. 67690, available at https://www.federalregister.gov/documents/2023/10/02/2023-21586/excise-tax-on-designated-drugs-procedural-requirements and Notice 2023-53; *see also*, Notice 2023-52, Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax, available at https://www.irs.gov/pub/irs-drop/n-23-52.pdf. Revenue Procedure 2025-9, available at https://www.irs.gov/pub/irs-drop/rp-25-09.pdf. Excise Tax on Designated Drugs; Notice of Proposed Rulemaking, available at https://www.federalregister.gov/documents/2025/01/02/2024-31462/excise-tax-on-designated-drugs).

that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute. Congress underscored this directive by placing the Negotiation Program in the newly enacted Part E of Title XI of the Act.

Moreover, although CMS has endeavored to solicit public comment and to respond to comments to the extent feasible consistent with the statutory deadlines for implementation of the Negotiation Program, to the extent this final guidance establishes or changes any substantive legal standard, CMS finds that notice and public procedure on this final guidance would be impracticable, unnecessary, and contrary to the public interest in light of the statutory requirement to implement sections 11001 and 11002 of the IRA for 2026, 2027, and 2028 by program instruction and in light of the complexity of the preparations that must be undertaken in advance of the publication by February 1, 2026 of the selected drug list for initial price applicability year 2028 and to establish the mechanisms necessary for manufacturers to provide access to any MFP agreed upon for drugs selected for initial price applicability year 2026 starting on January 1, 2026. In particular, manufacturers need to take a number of actions well in advance of February 1, 2026, to prepare for the possibility that a drug they manufacture might be included on the selected drug list for initial price applicability year 2028. For example, manufacturers may need to engage in internal discussions regarding whether the manufacturer would choose to participate in the Negotiation Program if its drug is included among the selected drug list published not later than February 1, 2026, review the template Medicare Drug Price Negotiation Program Agreement and guidance to understand Negotiation Program requirements for participating manufacturers in advance of the statutory deadline for entering agreements of February 28, 2026, and gather information for potential submission to CMS by the statutory deadline of March 1, 2026. In addition, for the reasons explained below, interested manufacturers will need to submit a request for a Small Biotech Exception under section 1192(d)(2) of the Act or a request for a Biosimilar Delay under section 1192(f) of the Act in advance of selection for initial price applicability year 2028 and by the date to be specified by CMS. Similarly, both CMS and manufacturers must prepare for and take various actions on an accelerated timeline to ensure manufacturers are able to effectuate any agreed-upon MFPs starting on January 1, 2026 for drugs selected for initial price applicability year 2026.

CMS could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far in advance of these statutory deadlines to allow them adequate time to complete these complex preparations. For the same reasons, CMS also concludes that there is good cause to issue this guidance as final without a delayed effective date, in order to meet the statutory deadlines of the Negotiation Program and consistent with the authority provided to CMS in sections 11001(c) and 11002(c) of the IRA. See 5 U.S.C. § 553(b)(B) & (d)(3); see also section 1871(b)(2)(C) of the Act.

This final guidance describes how CMS will implement the Negotiation Program for initial price applicability year 2028 (January 1, 2028 to December 31, 2028), including the renegotiation process for MFPs.[59] (whether negotiated or renegotiated) to take effect January 1, 2028. This final guidance also sets forth additional policies regarding manufacturer effectuation of the MFP in 2026, 2027, and 2028, and specifies the requirements that will be applicable to manufacturers of drugs that are selected for negotiation or renegotiation. Additionally, this final guidance

[59] To the extent applicable, any references in this final guidance to the "MFP" includes a renegotiated MFP.

includes information on the successor regulation exception to the IRA's formulary inclusion requirement for 2027 and 2028. Finally, this final guidance describes the procedures that may be applicable to drug manufacturers, Medicare Part D plan sponsors (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) Plans), pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D, in addition to hospitals, physicians, and other providers of services and suppliers that furnish or administer drugs to individuals enrolled under Medicare Part B (including individuals enrolled in Medicare Advantage plans under Part C). In this final guidance, CMS has made changes to certain policies in response to comments received, based on the agency's further consideration of the relevant issues, or if necessary to incorporate any enacted legislation impacting administration and operations of the Negotiation Program.

If any provision in this final guidance is held to be invalid or unenforceable, CMS intends that it shall be severable from the remainder of the final guidance, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances. CMS has determined that all relevant provisions of the final guidance could function independently from one another.

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20. Overview

This final guidance describes how CMS will implement the Negotiation Program for initial price applicability year 2028, building on policies established in final guidance for initial price applicability year 2027 and applying the experience of CMS from the first two cycles of negotiations. As required by law, this final guidance includes policy to incorporate drugs payable under Part B into the Negotiation Program and implements requirements for renegotiation. This final guidance also describes refinements to MFP effectuation policies for 2026 and 2027, including adjustments to Medicare Transaction Facilitator (MTF) operations, and the extension of such policies to 2028. Furthermore, this final guidance establishes the successor regulation exception to the IRA's formulary inclusion requirement for 2027 and 2028.

The MFP effectuation policies established for 2026 and 2027 in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 are final policies that remain in effect for 2026 and 2027. In this final guidance, CMS makes updates and includes supplemental information regarding these policies for 2026 and 2027, and is extending these same policies to 2028 for drugs covered under Part D. For ease of reference, CMS is restating the MFP effectuation sections from final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 in this final guidance so that the changes and updates to those policies can more easily be read in context with the policies in the prior final guidance that CMS is modifying or supplementing.

In accordance with sections 11001 and 11002 of the IRA, which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary is required to establish the Negotiation Program to negotiate MFPs for certain high expenditure, single source drugs covered by Medicare and to renegotiate the MFP for certain selected drugs. 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, including auditing 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, CMS shall also: (1) determine renegotiation-eligible drugs; (2) select drugs for renegotiation; and (3) renegotiate the MFP for any drug selected for renegotiation. To the extent applicable, any references in this final guidance to the "MFP" includes a renegotiated MFP. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

To allow for public input, CMS voluntarily solicited comments on all sections of the draft guidance, except for section 90.3 (which refers to the Department of the Treasury regulations that govern the administration of the excise tax[60]).

Topics that are not relevant to Negotiation Program implementation for initial price applicability year 2028 or for MFP effectuation in 2026, 2027, and 2028 are not addressed in this guidance. The IRA requires implementation of the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. CMS intends to engage in rulemaking to address program policies related to implementation for initial price applicability year 2029 and subsequent years.

[60] See: Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507, available at https://www.federalregister.gov/documents/2024/07/05/2024-14706/excise-tax-on-designated-drugs-procedural-requirementsand Notice 2023-53. See also, Notice 2023-52, Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax, available at https://www.irs.gov/pub/irs-drop/n-23-52.pdf. Revenue Procedure 2025-9, available at https://www.irs.gov/pub/irs-drop/rp-25-09.pdf. Excise Tax on Designated Drugs; Notice of Proposed Rulemaking, available at https://www.federalregister.gov/documents/2025/01/02/2024-31462/excise-tax-on-designated-drugs.

30. Identification of Selected Drugs for Initial Price Applicability Year 2028

Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs for an initial price applicability year. First, CMS will identify qualifying single source drugs in accordance with section 1192(e) of the Act, as described in section 30.1 of this final guidance. CMS will exclude certain drugs in accordance with section 1192(e)(3) of the Act.

Next, in accordance with section 1192(d)(1)(A) of the Act, CMS will use Total Expenditures[61] under Part D of Title XVIII of the Act for these qualifying single source drugs, calculated using Part D prescription drug event (PDE) data for dates of service between November 1, 2024 and October 31, 2025, and other information described below, to identify Part D high spend drugs. In accordance with section 1192(d)(1)(B) of the Act, CMS will use Total Expenditures[62] under Part B of Title XVIII of the Act for these qualifying single source drugs, calculated using Medicare Fee-for-Service (FFS) Part B claims data and Medicare Advantage (MA) encounter data for Part B items or services (hereinafter collectively referred to as "Part B data") for the dates of service between November 1, 2024 and October 31, 2025, and other information described below, to identify Part B high spend drugs. In these steps, CMS will also exclude certain qualifying single source drugs in accordance with sections 1192(d)(2) and (3) of the Act.

For purposes of calculating Total Expenditures under Part D of Title XVIII of the Act, PDE data will be included in the calculation of total gross covered prescription drug costs for these qualifying single source drugs when the PDE record meets the following additional requirements: (1) total gross covered prescription drug costs on the PDE record is greater than $0; (2) the PDE record is considered final action;[63] (3) the drug coverage status code indicates the PDE record is for a drug covered under Part D; and (4) the compound code indicates the PDE record is not for a compounded drug.[64]

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[61] For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) of the Act as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)) of the Act. The term "gross covered prescription drug costs" is also defined in the Part D regulations at 42 C.F.R. § 423.308.

[62] For the purposes of the Negotiation Program, section 1191(c)(5) of the Act specifies that Total Expenditures under Part B of title XVIII excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

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

[64] As described in section 40.4.2.1 of this final guidance, CMS provides that, for operational reasons at this time, for 2026, 2027, and 2028, MFP refunds will not be required for PDE records for selected drugs that were billed as compounds. For alignment, CMS provides in sections 30.1.2, 30.2, 30.2.1, 60.2.1, 60.3.2, and 60.5 of this final guidance that, for initial price applicability year 2028, PDE records with a compound code indicating the PDE record is for a compounded drug will be excluded from the PDE data used to calculate the low-spend Medicare drug exclusion (section 30.1.2), the ranking of negotiation-eligible drugs (section 30.2), the Small Biotech Exception Total Expenditure calculations (section 30.2.1), the ceiling for the MFP (section 60.2.1), the Net Part D Plan Payment and Beneficiary Liability of therapeutic alternative(s) (section 60.3.2), and the application of the MFP across dosage forms and strengths (section 60.5). 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." CMS will only use PDE records with a compound code field equal to "1=Not a Compound."

CMS will calculate Total Expenditures under Part B of Title XVIII of the Act using a combination of total allowed charges from FFS 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 will reflect the amount that would have been applicable under FFS. To do so, CMS will 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.[65] Because Medicare Administrative Contractors apply these edits to FFS Part B claims, this will bring the MA encounter data for Part B items and services into closer alignment. CMS will then multiply the adjusted units by the appropriate published payment limit (e.g., Average Sales Price (ASP)[66]-based) or payment rate (e.g., Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center (ASC)) to calculate what would have been applicable for the Part B items and services under Medicare FFS.

For the purposes of calculating Total Expenditures under Part B of Title XVIII of the Act for these qualifying single source drugs, FFS Part B claims data will be included when the claims meet the following additional requirements: (1) the claim type is 40, 71, 72, 81, or 82 (claim type codes associated with separately payable drugs eligible for reimbursement under Part B); (2) 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; (3) the claim is considered final action;[67] and (4) the claim is not billed as a compounded drug.[68] CMS has 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. CMS will exclude such separately billed claims.

For the purposes of calculating Total Expenditures under Part B of Title XVIII of the Act for these qualifying single source drugs, MA encounter data for Part B items and services will be included when the MA encounter data meet the following additional requirements: (1) the claim type is 4012, 4013, 4014, 4022, 4023, 4032, 4034, 4071, 4072, 4073, 4074, 4075, 4076, 4077, 4079, 4083, 4085, 4087, 4089, 4700, or 4800; (2) the reported total number of units on the MA encounter data record line is greater than 0; (3) the encounter data record is considered final action;[69] (4) the encounter data record is not denied; (5) it is not a chart review record; (6) the encounter data record line is not for a supplemental benefit; and (7) the encounter data record is

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

[66] "Average Sales Price" means the price calculated and reported by a manufacturer under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2)(A) of the Act, as applicable.

[67] A FFS Part B claim is considered final action based on the final action indicator for the claim and claim line.

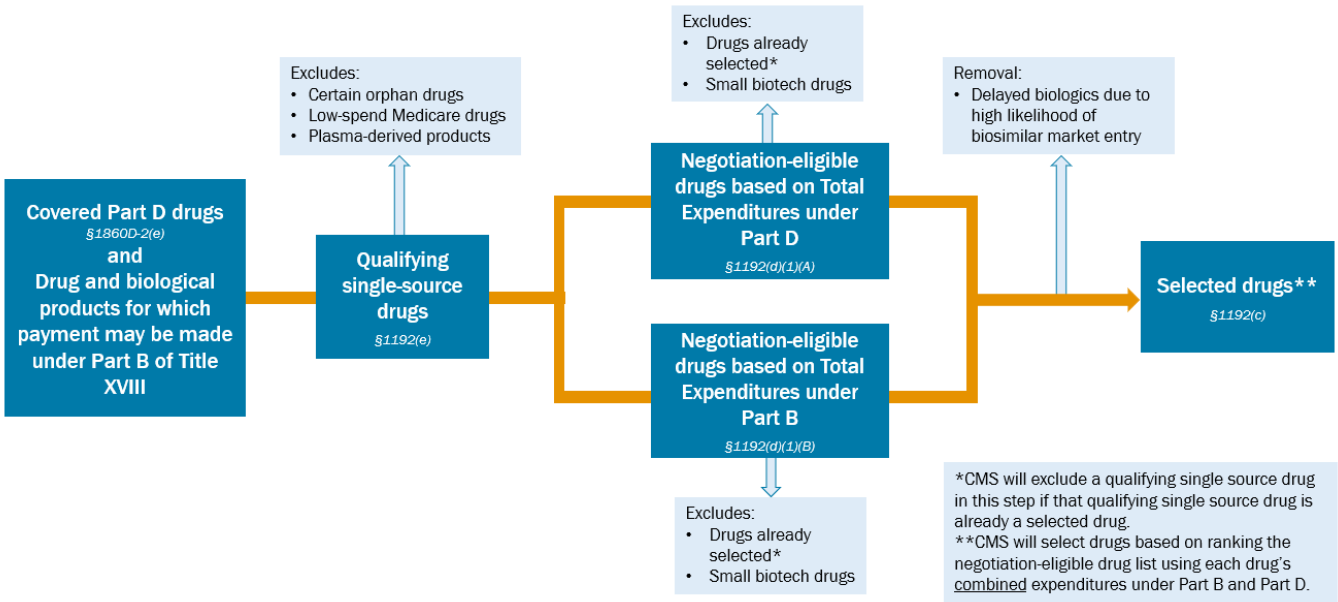
[68] For consistency with the treatment of compounded drugs covered under Part D, CMS will also exclude FFS Part B claims data billed as compounded drugs and MA encounter data for Part B items and services reported as a compounded drug when calculating the low-spend Medicare drug exclusion (section 30.1.2), the ranking of negotiation-eligible drugs (section 30.2), the Small Biotech Exception Total Expenditure calculations (section 30.2.1), the ceiling for the MFP (section 60.2.1), and the application of the MFP across dosage forms and strengths (section 60.5). Compounded drugs payable under Part B are typically reported with HCPCS code J7999 or other Not Otherwise Classified HCPCS codes. As stated in section 40.4 of this final guidance, CMS is not providing detailed policy on providing access to the MFP for selected drugs for which payment may be made under Part B at this time.

[69] 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.

not reported as a compounded drug. CMS will exclude MA encounter data for Part B items and services that are typically payable only as part of a bundled payment.[70]

In accordance with sections 1192(b)(1)(A) and (d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2028 according to the Total Expenditures for such drugs under Part B and Part D of Title XVIII for the 12-month period (defined above), as described in section 30.3 of this final guidance. In accordance with section 1192(a) of the Act and subject to the Special Rule to delay the selection and negotiation of biological products for biosimilar market entry described in section 1192(f) of the Act, CMS will select up to 15 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 2028 (described in section 30.3 of this final guidance). CMS will publish a list of up to 15 selected drugs, a list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D, and the list of drugs selected for renegotiation, if any, not later than February 1, 2026 (described in section 30.4 of this final guidance). Figure 1 provides a visual depiction of this process. Detailed guidance pertaining to this process for initial price applicability year 2028 is included further below.

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2028



[70] Throughout this final guidance, CMS refers to the criteria described in this section 30 of final guidance as the "inclusion and exclusion criteria" for PDE and Part B data.

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2028

For initial price applicability year 2028, in accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) (hereinafter "a drug covered under Part D") or a drug or biological product for which payment may be made under Part B of Title XVIII of the Act (hereinafter "a drug payable under Part B") that meets the following criteria:

- For drug products, a qualifying single source drug is a drug: (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("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;[71] 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.
- For biological products, a qualifying single source drug is a biological product: (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;[72] 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.

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 biologics license applications (BLAs) under section 351 of the PHS Act, effective March 23, 2020, pursuant to section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 ("BPCI Act") that are currently licensed and marketed as biological products under section 351 of the PHS Act (hereinafter "deemed biologics"), 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)(ii) of the Act.[73] 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 New Drug Application (NDA)[74] 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.

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

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[71] As described in section 1194(e)(4) of the Act, different timing requirements will apply to certain former orphan drugs. See section 30.1.1 of this final guidance for more information.

[72] As noted above, see section 30.1.1 of this final guidance for more information on the different timing requirements for certain former orphan drugs.

[73] For a biological product with an approved application under section 505(c) of the FDC&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.

[74] As described in 21 C.F.R. 314.3(b).

release formulation, and not based on the specific formulation, package size, or package type of the drug for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act and applying the exception for small biotech drugs under section 1192(d)(2) of the Act. 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 section 60 of this final guidance, 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.

Identifying potential qualifying single source drugs:
In accordance with the statutory language cited above, for purposes of the Negotiation Program, CMS will identify a potential qualifying single source drug[75] using:

- For drug products, all dosage forms and strengths of the drug with the same active moiety and the same holder of a 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, CMS 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 U.S. Food and Drug Administration (FDA) sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug will 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[76] that are marketed pursuant to such NDA(s); (2) authorized generic drugs (defined in section 1192(e)(2)(B)(i) of the Act and described further below) that are marketed pursuant to such NDA(s); or (3) multi-market approval (MMA)[77] products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);[78]
- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a BLA,[79] inclusive of products that are marketed pursuant to different BLAs. If there are multiple BLAs with the same active ingredient that include non-identical names reported for the BLA holder, including situations where it appears the BLA holder name has not yet been updated, CMS may

[75] Throughout this final guidance, a qualifying single source drug means the specific constituent dosage forms and strengths (at the NDC-9 or NDC-11 level) that are identified as aggregated under the New Drug Application (NDA(s)) / Biologics License Application (BLA(s)) for the active moiety / active ingredient as outlined in section 30.1 of this final guidance.
[76] For purposes of the Negotiation Program, the terms "repackage" and "relabel" have the meaning specified in 21 C.F.R. § 207.1.
[77] See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-and.
[78] 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 will also be aggregated in the potential qualifying single source drug of that holder of the NDA.
[79] As described in section 351(a) of the PHS Act.

> 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 will 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) unbranded biological products (see section 1192(e)(2)(B)(ii) of the Act and the description further below) 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).[80]

CMS will identify the active moiety or active ingredient of the drug using public sources such as RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file. CMS may also consult with FDA as appropriate to, for example, clarify whether a suffix or prefix in an ingredient name represents a genuine difference in active ingredient. CMS clarifies that in the context of vaccines for infectious disease(s), CMS will identify a potential qualifying single source drug on the basis of such vaccines' antigen component(s) as reflected on such vaccines' labeling, as accessed in public sources.

Table 1 below provides an example to illustrate how CMS will identify a potential qualifying single source drug. As illustrated in Table 1, Entity A holds three NDAs for drug products with the same active moiety approved in NDA-1, NDA-2, and NDA-3. Entity A manufactures and markets three different strengths as an immediate release tablet pursuant to NDA-1, three different strengths as an extended-release tablet pursuant to NDA-2, and three different strengths as an oral solution pursuant to NDA-3. Additionally, under an agreement with Entity A, Entity B repackages three strengths of the immediate release tablets manufactured by Entity A and markets them pursuant to NDA-1. Each of these 12 drug products has a unique 9-digit National Drug Code (NDC-9). In this scenario, all 12 of these drug products, including the repackaged products, will be aggregated as a single potential qualifying single source drug for purposes of identifying negotiation-eligible drugs.

Table 1: Example Application of NDAs Containing the Same Active Moiety to Identification of a Potential Qualifying Single Source Drug

NDAs containing the same active moiety	**NDCs marketed by Entity A (holder of NDA-1, NDA-2, and NDA-3)**	**NDCs repackaged and marketed by Entity B**
NDA-1	NDC #1, NDC #2, NDC #3	NDC #10, NDC #11, NDC #12
NDA-2	NDC #4, NDC #5, NDC #6	
NDA-3	NDC #7, NDC #8, NDC #9	
12 Total NDCs included in this single potential qualifying single source drug		

[80] 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 will also be aggregated in the potential qualifying single source drug of that holder of the BLA.

This approach to identifying a potential qualifying single source drug aligns with the requirement in section 1192(d)(3)(B) of the Act to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. Consistent with this statutory instruction, this approach is also appropriate because CMS is aware that existing NDA / BLA holders have obtained approval for new dosage forms or different routes of administration of the same active moiety / active ingredient under different NDAs or BLAs.

Section 1192(e)(2)(A) of the Act states that 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. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as: (1) in the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act); and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act[81] 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.

If a drug is a fixed combination drug[82] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs. Therefore, all formulations of this distinct combination offered by the same NDA / BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not all) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will 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.

CMS believes that treating distinct combinations of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs is generally appropriate. However, CMS acknowledges 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. Accordingly, the current fixed combination drug policy could create a gaming opportunity in which a Primary Manufacturer may attempt to avoid the aggregation of its products, thereby decreasing the likelihood of or avoiding their selection for negotiation, thus undermining the integrity of the Negotiation Program. An example might include the addition of active moiety / active ingredient X to a different active moiety / active ingredient Y, where active moiety / active ingredient X

[81] 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.

[82] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 C.F.R. § 300.50.

affects the bioavailability of active moiety / active ingredient Y but is not biologically active against the disease state that active moiety / active ingredient Y is indicated for. In this scenario, CMS believes that aggregating the combination of active moiety / active ingredient X and active moiety / active ingredient Y with other formulations of active moiety / active ingredient Y may be consistent with the direction in 1192(d)(3)(B) of the Act to aggregate across "new formulations" of a potential qualifying single source drug. CMS intends to address this program integrity risk and is continuing to consider the appropriate policy to implement in rulemaking beginning in initial price applicability year 2029.

Applying statutory criteria for qualifying single source drugs:
In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, at least 7 years (for drug products) or 11 years (for biological products) must have elapsed between the FDA date of approval or licensure of the potential qualifying single source drug, as applicable, and the selected drug publication date.[83] To determine the date of approval for a potential qualifying single source drug that is a drug product with more than one FDA application number, CMS will use the earliest date of approval of the initial FDA application number assigned to the NDA holder for the active moiety (or in the case of fixed combination drugs, for the distinct combination of active moieties). To determine the date of licensure for a potential qualifying single source drug that is a biological product (subject to the clarification described below regarding vaccines for infectious disease(s)) with more than one FDA application number, CMS will use the earliest date of licensure of the initial FDA application number assigned to the BLA holder for the active ingredient (or in the case of fixed combination drugs, for the distinct combination of active ingredients). The selected drug publication date for initial price applicability year 2028 is February 1, 2026, as specified in section 1191(b)(3) of the Act. As such, for initial price applicability year 2028, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before February 1, 2019, and the date of initial licensure for a biological product to be considered a qualifying single source drug must have been on or before February 1, 2015.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and February 1, 2026, then the potential qualifying single source drug defined above would meet this statutory criterion for qualifying single source drugs (even if less than seven years had elapsed between the approval dates for NDA-2 or NDA-3 and February 1, 2026), consistent with the statutory directive in section 1192(d)(3)(B) of the Act to aggregate data across dosage forms and strengths of the drug, including new formulations of the drug.

CMS is aware that some manufacturers of vaccines for infectious disease(s) update the antigen component(s) of their products through supplemental BLAs. For each unique potential qualifying single source drug that CMS identifies based on its antigen component(s), CMS clarifies that it will use the earliest date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of determining time eligibility.

In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, a product cannot be the listed drug for any drug approved and marketed under an ANDA

[83] For certain former orphan drugs described in section 1194(e)(4) of the Act, different timing requirements as described in section 1194(e)(4) of the Act will apply. See section 30.1.1 of this final guidance for more information.

under section 505(j) of the FD&C Act (i.e., a generic drug[84]), and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act (i.e., a biosimilar biological product[85]). CMS will use FDA reference sources, including the Orange Book[86] and Purple Book,[87] to determine whether a generic drug or biosimilar biological product has been approved or licensed for any of the strengths or dosage forms of the potential qualifying single source drugs for initial price applicability year 2028.

CMS will consider a generic drug or biosimilar to be marketed when the totality of the circumstances, including the data specified below, reveals that the manufacturer of that approved generic drug or licensed biosimilar is engaging in bona fide marketing of that drug or biosimilar. In accordance with sections 1192(c) and (e) of the Act, for the purpose of identifying qualifying single source drugs for initial price applicability year 2028, CMS will review PDE data for the 12-month period beginning January 16, 2025 and ending January 15, 2026, as well as Average Manufacturer Price (AMP)[88] data for the 12-month period beginning December 1, 2024 and ending November 30, 2025, for a given generic drug or biosimilar for which a potential qualifying single source drug is the listed drug or reference product. CMS has chosen these time periods to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time for such data to inform the selected drug list published no later than February 1, 2026, in accordance with section 1192(a) of the Act. CMS believes that review of additional data sources beyond PDE and AMP data may be merited for assessing utilization, in particular for drugs payable under Part B. Therefore, CMS will additionally review, when available, the ASP data available to CMS for the sales quarters of the fourth quarter of 2024 through the third quarter of 2025 (e.g., the 12-month period beginning October 1, 2024 and ending September 30, 2025) for drugs payable under Part B. CMS may review additional data sources for utilization for drugs payable under Part B and/or covered under Part D for the most recent 12-month period for the applicable data source, when available to CMS. The additional data sources CMS may also review, are Medicaid State Drug Utilization Data (SDUD) and/or data from nationally representative and commercially available databases.

The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry based on the totality of the circumstances. The sources of data described in the preceding paragraph, over the specified intervals, will be informative for that inquiry, but CMS' determination will not necessarily turn on any one source of data. Additional relevant factors may include whether the generic drug or biosimilar is regularly and consistently available for

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[84] As used in this final guidance, the term "generic drug" refers to a drug approved under an ANDA under section 505(j) of the FD&C Act.

[85] The terms "biosimilar biological product" and "biosimilar" mean the same thing for purposes 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. This guidance will use the term "biosimilar" hereinafter unless otherwise noted, such as related to the discussion of the Biosimilar Delay under section 11002 of the IRA in section 30.3.1 of this final guidance. For references to biological products licensed pursuant to an application submitted under section 351(a) of the PHS Act, the term "biological product" is used.

[86] See: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[87] See: https://purplebooksearch.fda.gov/.

[88] "Average Manufacturer Price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period (calendar quarter), the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer, subject to certain exclusions. See section 1927(k)(1) of the Act.

purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer (as defined in section 40 of this final guidance) and a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar, as articulated further in sections 70 and 90.4 of this final guidance.

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, CMS will consider the generic(s) or biosimilar(s) of the potential qualifying single source drug bona fide marketed. As another example, a potential qualifying single source drug might have a newly or recently approved generic 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 or biosimilar manufacturer has successfully launched their product, and there is no evidence of agreements limiting distribution of the generic or biosimilar product, then CMS will consider the generic or biosimilar product of the potential qualifying single source drug as bona fide marketed. As a third example, a potential qualifying single source drug might have an approved generic 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 or biosimilar manufacturer has successfully launched their product, then CMS will consider the generic or biosimilar product of the potential qualifying single source drug as not bona fide marketed. While the circumstances illustrated in these examples weigh in favor of, or against, a determination regarding bona fide marketing, CMS' ultimate determination on any particular drug will be based on the totality of the circumstances and not on the presence, or absence, of any single factor.

If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar products that CMS determines are approved or licensed, as applicable, and bona fide marketed based on the process described in this final guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028. If CMS determines that the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028 because a manufacturer of such generic drug or biosimilar product has engaged in bona fide marketing of the generic drug or biosimilar, CMS will monitor to ensure continued bona fide marketing of the generic drug or biosimilar based on the approach described in section 90.4 of this final guidance.

In identifying qualifying single source drugs, with respect to initial price applicability year 2028, CMS will limit exclusions from qualifying single source drugs to those described throughout section 30.1 above and identified under section 1192(e)(3) of the Act as described below in sections 30.1.1 through 30.1.3 of this final guidance.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

On July 4, 2025, the “Working Families Tax Cuts Act” (P. L. 119-21) was signed into law. Section 71203(a) of the Working Families Tax Cuts Act 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 Cuts Act 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. Therefore, section 30.1.1 of this final guidance includes policy revisions that were not included in the draft guidance for initial price applicability year 2028 but that are required by law to take effect in initial price applicability year 2028.

In accordance with section 1192(e)(3)(A) of the Act, as modified by section 71203(a)(2) of the Working Families Tax Cuts Act, CMS will exclude certain orphan drugs when identifying qualifying single source drugs as described in section 30.1 of this final guidance ("the Orphan Drug Exclusion"). Specifically, CMS will exclude 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) 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). To be considered for the Orphan Drug Exclusion, 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). CMS will consider only active designations and active approvals when evaluating a drug for the Orphan Drug Exclusion; that is, CMS will not consider withdrawn orphan drug designations or withdrawn approvals when determining whether a drug meets the Orphan Drug Exclusion.[89]

To determine whether a potential qualifying single source drug qualifies for the Orphan Drug Exclusion, CMS will consider all dosage forms and strengths of the potential qualifying single source drug, as described in section 30.1 of this final guidance. CMS will use the FDA Orphan Drug Product designation database[90] and information on FDA-approved indications from other publicly available databases and documents (such as FDALabel, FDA Online Label Repository, Drugs@FDA, and NLM DailyMed[91]) to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the Orphan Drug Exclusion. CMS will also consult with FDA, as appropriate, including to determine 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.

In accordance with section 71203(a)(3) of the Working Families Tax Cuts Act and section 1192(e)(4) of the Act, if, as of the date of a drug or biological product's earliest approval or licensure identified under section 1192(e)(1)(A)(ii) or 1192(e)(1)(B)(ii) of the Act and described in section 30.1 of this final guidance, such drug or biological product met or meets the criteria for the Orphan Drug Exclusion, as described in section 1192(e)(3)(A) and this section 30.1.1 of this final guidance, CMS will measure the 7- and 11-year periods described in sections 1192(e)(1)(A)(ii) and 1192(e)(1)(B)(ii) of the Act, respectively, starting from the first day after such earliest 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 will identify this day as the earlier of

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[89] For purposes of the Negotiation Program, CMS uses 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 C.F.R. § 316.24 or a revoked orphan drug designation as described at 21 C.F.R. § 316.29.

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

[91] FDALabel: https://nctr-crs.fda.gov/fdalabel/ui/search; FDA Online Label Repository: https://labels.fda.gov/; Drugs@FDA: https://www.accessdata.fda.gov/scripts/cder/daf/; NLM Daily Med: https://dailymed.nlm.nih.gov/dailymed/.

(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.[92]

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(B) of the Act, CMS will exclude low-spend Medicare drugs or biological products with combined expenditures under Medicare Part B and Part D less than the inflation-adjusted threshold for the previous initial price applicability year,[93] increased by the annual percentage increase in the consumer price index for all urban consumers (CPI-U)[94] for the 12-month period ending on September 30, 2025, when identifying qualifying single source drugs ("the Low-Spend Medicare Drug Exclusion"). For initial price applicability year 2028, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify PDE data and Part B data for each potential qualifying single source drug for dates of service during the 12-month period beginning November 1, 2024 and ending October 31, 2025 using the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance. To allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that are available by December 1, 2025. To allow a reasonable amount of time for providers and suppliers to submit FFS Part B claims data and Medicare Advantage Organizations (MAOs) to submit MA encounter data for Part B items and services, CMS will use Part B data for the dates of service described above that are available by December 1, 2025.
- For each potential qualifying single source drug as described in section 30.1 of this final guidance, CMS will calculate the Total Expenditures under Part D and Total Expenditures under Part B using the methodology described at the beginning of section 30 of this final guidance. Payment for drugs and biological products payable under Part B is made on the basis of claims for units of a drug or biological product's Healthcare Common Procedure Code System (HCPCS) code. 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 potential qualifying single source drug is assigned to a HCPCS code with other products. In such cases, CMS will use ASP sales volume data to apportion Part B expenditures based on the ratio of reported sales volume of the potential qualifying single source drug compared to reported sales volume

[92] 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, CMS will 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.

[93] The inflation-adjusted threshold for initial price applicability year 2027 was $206,680,891. (Note: this threshold number has been corrected by CMS after an error in the number was identified in the originally published version of this final guidance.)

[94] The "CPI-U" means the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (https://www.bls.gov/cpi/data.htm).

of all products assigned to the HCPCS code to calculate the Total Expenditures under Part B for the purposes of implementing the Low-Spend Medicare Drug Exclusion.[95]

- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2028 any drugs for which the sum of Total Expenditures under Part B and Part D is 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, 2025.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(C) of the Act, CMS will exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1 of this final guidance ("the Plasma-Derived Product Exclusion"). For purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. CMS will refer to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[96] and will refer to databases such as FDALabel and the FDA Online Label Repository[97] to verify if the product is derived from human whole blood or plasma. CMS also will consult with FDA, as appropriate.

30.2 Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2028

In accordance with sections 1192(a) and 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2028 is a qualifying single source drug 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. CMS will identify the negotiation-eligible drugs for initial price applicability year 2028 as follows:

- CMS will identify all qualifying single source drugs for initial price applicability year 2028 using the process described in section 30.1 of this final guidance. CMS will exclude any drugs that qualify for the exclusions listed in sections 30.1.1 through 30.1.3 of this final guidance.
- CMS will identify Part D high spend drugs described in section 1192(d)(1)(A) of the Act using the following steps:
    - CMS will identify PDE data for each 11-digit National Drug Code (NDC-11)[98] of a qualifying single source drug for dates of service during the 12-month period beginning November 1, 2024 and ending October 31, 2025. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that are available in CMS' data repository by

[95] As described in sections 30.2 and 30.2.1 of this final guidance, CMS similarly will use ASP sales volume data to apportion Part B expenditures for the purpose of identifying whether a qualifying single source drug is a negotiation-eligible drug based on Total Expenditures under Part B and whether a qualifying single source drug qualifies for the Small Biotech Exception in Part B, in cases where a qualifying single source drug is assigned to a HCPCS code with other products.

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

[97] FDALabel: https://nctr-crs.fda.gov/fdalabel/ui/search; FDA Online Label Repository: https://labels.fda.gov/.

[98] NDC-9 and NDC-11 numbers are identical except for two numbers in NDC-11s that indicate package size. Because of this, NDC-11 is more granular than NDC-9, and multiple NDC-11 numbers can aggregate under a single NDC-9 number.

December 1, 2025. CMS will use the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance to identify these PDE data.

- CMS will use this PDE data to calculate the Total Expenditures under Part D for each qualifying single source drug during the 12-month applicable period. CMS will: (1) remove qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act; (2) remove qualifying single source drugs CMS determines qualify for the exception for small biotech drugs, in accordance with section 1192(d)(2)(A)(ii) and as described in section 30.2.1 of this final guidance; (3) rank the remaining qualifying single source drugs by Total Expenditures under Part D during the applicable 12-month period; and (4) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part D during the applicable 12-month period.
- When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part D, and such Total Expenditures are the 50th highest among qualifying single source drugs under Part D, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients, until CMS has identified 50 Part D high spend drugs.

- CMS will identify Part B high spend drugs described in section 1192(d)(1)(B) of the Act using the following steps:
  - CMS will identify Part B data for each qualifying single source drug for dates of service during the 12-month period beginning November 1, 2024 and ending October 31, 2025. To allow a reasonable time for providers and suppliers to submit FFS Part B claims data and MAOs to submit MA encounter data for Part B items and services, CMS will use Part B data for the dates of service described above that are available in CMS' data repository by December 1, 2025. CMS will also use the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance to identify the Part B data.
  - CMS will use these Part B data to calculate the Total Expenditures under Part B for each qualifying single source drug during the 12-month applicable period. 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, CMS will use ASP sales volume data to apportion Part B 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.
  - CMS will: (1) remove qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act (in accordance with section 1192(d)(3)(B) of the Act, this removal will encompass qualifying single source drugs that have been selected for initial price applicability years 2026 and 2027 based on Part D expenditures, as discussed in more detail below in this section 30.2 of final guidance); (2) remove qualifying single source drugs CMS determines qualify for the exception for small biotech drugs, in accordance with

section 1192(d)(2)(A)(ii) of the Act and as described in section 30.2.1 of this final guidance; (3) rank the remaining qualifying single source drugs by Total Expenditures under Part B during the applicable 12-month period; and (4) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part B during the applicable 12-month period.
    - When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part B, and such Total Expenditures are the 50th highest among qualifying single source drugs under Part B, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients, until CMS has identified 50 Part B high spend drugs.
- CMS will consider these 50 Part D high spend drugs and 50 Part B high spend drugs to be the negotiation-eligible drugs for initial price applicability year 2028.

In accordance with section 1192(d)(1) of the Act, beginning with initial price applicability year 2028, the assessment of negotiation-eligibility for each qualifying single source drug is determined based on Total Expenditures for that qualifying single source drug under both Part D and Part B. In keeping with this inclusive assessment of the negotiation-eligibility of a qualifying single source drug, and in accordance with sections 1192(d)(3)(A)(i) and 1192(d)(3)(B) of the Act, CMS will not include a qualifying single source drug on the list of negotiation-eligible Part D high spend drugs or Part B high spend drugs if that qualifying single source drug is already a selected drug.

30.2.1 Exception for Small Biotech Drugs

In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception" or "SBE"). The statute requires that CMS evaluate whether a qualifying single source drug qualifies for the SBE based on Total Expenditures under Part B or Part D. CMS will make separate determinations with respect to the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"), and the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track"). For initial price applicability year 2028, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE. A manufacturer that would like an SBE determination on multiple qualifying single source drugs must submit a unique application for each qualifying single source drug.

To apply the criteria that comprise the Part B Track and Part D Track of the SBE, CMS needs to identify qualifying single source drugs. CMS will define a qualifying single source drug based on the aggregation policies outlined in section 30.1 of this final guidance for initial price applicability year 2028. This ensures the qualifying single source drug reflects initial price applicability year 2028 concepts and avoids potential inconsistencies in the calculations that comprise the Part B Track.

For the purposes of the SBE, CMS needs to collect information to accurately identify: the "Part D 2021 Manufacturer," which is the entity that had the 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; and the "Part B 2021 Manufacturer," which is the entity that held the NDA(s) / BLA(s) for the qualifying single source drug on December 31, 2021. This information is used in the Part B Track and Part D Track considerations outlined in 1192(d)(2)(A)(ii)(II) and 1192(d)(2)(A)(i)(II), respectively. In addition, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all corporations or partnerships, sole proprietorships, and other entities that, on December 31, 2021, were treated as a single employer (i.e., part of the same controlled group) under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 (IRC) with the Part B 2021 Manufacturer or Part D 2021 Manufacturer. The controlled group of the Part D 2021 Manufacturer comprises all entities 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. The controlled group of the Part B 2021 Manufacturer comprises all entities that, as of December 31, 2021, were treated as a single employer with 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 or the Part D 2021 Manufacturer under the applicable IRC provisions and the Treasury regulations thereunder. Therefore, a manufacturer that seeks the SBE for its qualifying single source drug(s) ("Submitting Manufacturer") must submit information to CMS about the Part B 2021 Manufacturer and/or the Part D 2021 Manufacturer, its controlled group (e.g., P number, labeler code(s)), and its products (e.g., NDA(s) and/or BLA(s)) in order for the drug to be considered for the exception. To the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s) / BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. CMS is setting forth this policy to ensure that only the entity with which CMS would negotiate in the event that the qualifying single source drug is selected for negotiation, as described in section 40 of this final guidance, is able to seek the SBE.

In applying the Part D Track of the SBE, the statute requires that CMS consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the qualifying single source drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021.[99] To identify and exclude drugs eligible for the SBE, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures during 2021 under Part D for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and (2) equal to at least 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.

[99] As stated in section 50.1.1 of the Revised Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available at https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf (hereinafter, the "Manufacturer Discount Program Final Guidance"): "A manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP Agreement would be considered to have had an agreement in effect during 2021."

Likewise, in applying the Part B Track of the SBE, the statute requires that CMS consider Total Expenditures under Part B during 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the qualifying single source drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group. To identify and exclude drugs eligible for the SBE, CMS will consider whether, for Part B data with dates of service in calendar year 2021, the Total Expenditures under Part B, as determined using Part B data as described in this final guidance, during 2021 for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid 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.

Additionally, the limitation at section 1192(d)(2)(B)(ii) of the Act states that a qualifying single source drug is not eligible for an SBE 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, or January 1, 2026, for acquisitions occurring during 2025.[100] For initial price applicability year 2028, in order for the Submitting Manufacturer to have its qualifying single source drug(s) considered for an SBE, CMS must consider whether the Submitting Manufacturer was acquired after 2021, and if so, whether the acquiring entity is a manufacturer that will not meet the definition of specified manufacturer effective January 1, 2025 or January 1, 2026, for acquisitions occurring during 2025. For purposes of implementing this limitation, CMS will use the determinations of the Medicare Part D Manufacturer Discount Program ("Manufacturer Discount Program") as to whether the acquiring entity met the definition of specified manufacturer in the applicable period. CMS will consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount Program as either a specified manufacturer under section 1860D-14C(g)(4)(B)(ii) of the Act or a specified small manufacturer under section 1860D-14C(g)(4)(C)(ii) of the Act.[101] For an acquisition of a manufacturer to be relevant to the limitation, and therefore to potentially preclude a drug from being considered a qualifying single source drug that could be eligible for an SBE, the transaction must occur after 2021 and must involve the acquisition of the Submitting Manufacturer after the Submitting Manufacturer held the NDA(s) / BLA(s) for the qualifying single source drug.

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[100] See section 50.1 of the Manufacturer Discount Program Final Guidance; see also the November 17, 2023 CMS Health Plan Management System ("the CMS HPMS") memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers" for more information.

[101] For purposes of the SBE 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).

CMS published the "Negotiation Program Drug Selection Information Collection Request for Initial Price Applicability Year 2028" (CMS-10844, OMB 0938-1443) (hereinafter the "Drug Selection ICR"), which includes the form to submit an SBE, on May 13, 2025, for a 60-day public comment period. CMS is publishing revisions to the Drug Selection ICR for a 30-day public comment period concurrent with the publication of this final guidance.[102]

The Drug Selection ICR Form addresses the collection of information for initial price applicability year 2028 only. A manufacturer seeking to have the SBE apply to its drug(s) for initial price applicability year 2028 must submit a request for an SBE for initial price applicability year 2028 regardless of whether the manufacturer submitted a request for a prior initial price applicability year and irrespective of CMS' determination in a prior initial price applicability year. For initial price applicability year 2028, section 1192(d) of the Act requires CMS to evaluate whether a qualifying single source drug qualifies for the SBE based on Total Expenditures under Part B or Part D; the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE.

As specified in the Drug Selection ICR Forms, CMS anticipates that the Submitting Manufacturer will submit a request for a Small Biotech Exception using the CMS Health Plan Management System ("the CMS HPMS") by the date specified by CMS.[103] CMS will provide a deadline that CMS believes is necessary to allow sufficient time for manufacturers to complete the activities required to apply for the SBE, as well as provide CMS with time to make a determination prior to the initial price applicability year 2028 selected drug publication date. CMS will provide the submission deadline once the Drug Selection ICR for initial price applicability year 2028 is finalized. After reviewing a submitted SBE request, CMS may request additional information from the Submitting Manufacturer as necessary to make a determination with respect to an SBE request. CMS plans to make any such follow-up request in writing to the Submitting Manufacturer via email. Information submitted in a request for an SBE 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)).

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[102] The currently approved CMS-10844, OMB 0938-1443 package is available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016. The 30-day notice will be available in the Federal Register and the revised materials will be available on CMS' Paperwork Reduction Act website at: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10844.

[103] As specified in the Drug Selection ICR Forms available for a 30-day public comment, CMS will provide the deadline for submissions upon approval of the Drug Selection ICR from the Office of Management and Budget. Access to the SBE functionality to request an SBE will be granted automatically to active manufacturer users in HPMS. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program" PDF, available at: https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

CMS will not consider incomplete submissions. Upon receipt of a complete request for an SBE, CMS will take the following steps to identify whether a qualifying single source drug qualifies for the Small Biotech Exception:

1. CMS will first analyze whether the qualifying single source drug for which the Submitting Manufacturer requests an SBE is excluded from SBE consideration under the limitation set forth in section 1192(d)(2)(B)(ii) of the Act. If the Submitting Manufacturer was acquired after 2021 by another manufacturer, CMS will rely on the determination by CMS under the Manufacturer Discount Program as to whether the acquiring entity will meet the definition of a "specified manufacturer" effective January 1, 2025 or January 1, 2026, for acquisitions occurring during 2025. If the acquiring entity is a manufacturer that does not meet the definition of a "specified manufacturer," the limitation applies, and the Submitting Manufacturer's qualifying single source drug cannot qualify for the SBE for initial price applicability year 2028.
2. Provided the limitation does not apply, CMS will identify the Part B 2021 Manufacturer and/or the Part D 2021 Manufacturer of the qualifying single source drug on December 31, 2021 based on information submitted in the request for an SBE.

If the limitation set forth in section 1192(d)(2)(B)(ii) of the Act does not apply, and the manufacturer submits a complete request for an SBE pertaining to a qualifying single source drug covered under Part D, CMS will take the following steps to identify whether a qualifying single source drug qualifies for the Small Biotech Exception Part D Track:

1. CMS will identify the complete set of NDC-11s for which the Part D 2021 Manufacturer and its controlled group as of December 31, 2021 had a CGDP Agreement in effect as of December 31, 2021.
2. Using the complete set of NDC-11s for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021, CMS will identify PDE data for dates of service during the 12-month period beginning January 1, 2021, and ending December 31, 2021.
3. Using the PDE data for: (1) the qualifying single source drug; (2) the complete set of drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect as of December 31, 2021; and (3) all drugs covered under Part D, CMS will determine whether:
    - The Total Expenditures under Part D for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part D for all drugs covered under Part D; and
    - The Total Expenditures under Part D for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part D for all drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect as of December 31, 2021.

The Total Expenditures under Part D for the qualifying single source drug will be determined using calendar year 2021 PDE data for the qualifying single source drug for initial price applicability year 2028, as defined by the aggregation policies outlined in section 30.1 of this final guidance. The Total Expenditures under Part D for all drugs covered under Part D will be determined using calendar year 2021 PDE data for all drugs covered under Part D. The Total Expenditures under Part D for all drugs covered under Part D for which the Part D 2021

Manufacturer and its controlled group had a CGDP Agreement in effect as of December 31, 2021 will only include PDE data for NDC-11s with labeler codes associated with the Part D 2021 Manufacturer or any member of the Part D 2021 Manufacturer's controlled group. CMS will use the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance to identify the PDE data used in these Total Expenditures calculations.

If the limitation set forth in section 1192(d)(2)(B)(ii) of the Act does not apply, and the manufacturer submits a complete request for an SBE pertaining to a qualifying single source drug paid under Part B, CMS intends to take the following steps to identify whether a qualifying single source drug qualifies for the Small Biotech Exception Part B Track:

1. CMS will identify the complete set of NDC-11s for all qualifying single source drug(s) for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021.
2. Using the HCPCS codes associated with the complete set of NDC-11s for qualifying single source drugs for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021, CMS will identify Part B data for dates of service during the 12-month period beginning January 1, 2021, and ending December 31, 2021.
    - 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, CMS will use ASP sales volume data to apportion Part B 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 for the qualifying single source drug.
3. Using the Part B data for: (1) the qualifying single source drug; (2) the complete set of qualifying single source drugs for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021; and (3) all qualifying single source drugs paid under Part B, CMS will determine whether:
    - The Total Expenditures under Part B for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B; and
    - The Total Expenditures under Part B for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021.

The Total Expenditures under Part B for the qualifying single source drug and Total Expenditures under Part B for all qualifying single source drugs payable under Part B will be determined using calendar year 2021 Part B data for the qualifying single source drugs in initial price applicability year 2028, as defined by the aggregation policies outlined in section 30.1 of this final guidance. The Total Expenditures under Part B for all qualifying single source drugs payable under Part B for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021 will include Part B data for NDC-11(s) associated with

qualifying single source drug(s) that correspond to the NDA(s) / BLA(s) held by the Part B 2021 Manufacturer or any member of its controlled group. CMS will use the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance to identify the Part B data used in these Total Expenditures calculations.

If a manufacturer submits a complete request for an SBE for both the Part B Track and the Part D Track pertaining to a qualifying single source drug payable under Part B and covered under Part D, respectively, CMS will make separate determinations under the Part B Track and Part D Track of the SBE. For initial price applicability year 2028, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE.

A determination by CMS that a given qualifying single source drug qualifies for the SBE for initial price applicability year 2028 does not determine if the drug will qualify for the temporary floor for a small biotech drug that is selected for initial price applicability years 2029 or 2030 as described in section 1194(d) of the Act. CMS will provide information about section 1194(d) of the Act in future guidance or rulemaking.

CMS anticipates notifying the Submitting Manufacturer by February 2026 of its SBE determination for initial price applicability year 2028. This information will only be shared after the selected drug list for initial price applicability year 2028 has been published. CMS will publish the number of drugs that receive the SBE for initial price applicability year 2028 as part of publishing the selected drug list no later than February 1, 2026. For initial price applicability year 2027, CMS received SBE requests which resulted in CMS determining four qualifying single source drugs qualified for the SBE. The determination that these drugs qualified for the SBE applied only to initial price applicability year 2027.[104]

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under sections 1192(b) or 1192(d) of the Act.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2028

In accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 15 (or all, if such number is less than 15) negotiation-eligible drugs for negotiation for initial price applicability year 2028 as follows:

1. CMS will rank the list of negotiation-eligible drugs identified, as described in section 30.2 of this final guidance, 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 will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part B and Part D will be listed last. If a negotiation-eligible drug appears on both high-spend lists, it will receive only one ranking for purposes of selection, according to its combined Total Expenditures under both Part D and Part B. If a negotiation-eligible drug appears on only one high-spend list, CMS will also combine Total Expenditures under both Part B and Part D.

[104] Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027 Fact Sheet, available at https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf.

2. CMS will remove any biological products that qualify for delayed selection under section 1192(f) of the Act, as described in section 30.3.1 of this final guidance.
3. CMS will select for negotiation the 15 (or all, if such number is less than 15) highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2028.
    - In the event that two or more negotiation-eligible drugs have the same combined Total Expenditures under Part B and Part D to the dollar, and such combined Total Expenditures are the 15th highest among negotiation-eligible drugs, CMS will rank those negotiation-eligible drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the initial FDA application number for its active moiety / active ingredient, and select based on that ranking until there are 15 selected drugs (or until all drugs are selected, if the number of negotiation-eligible drugs is less than 15).

30.3.1 Delay in the Selection and Negotiation of Certain Biological Products with High Likelihood of Biosimilar Market Entry

In accordance with section 1192(b)(1)(C) of the Act, CMS will remove from the ranked list of negotiation-eligible drugs described in section 30.3 of this final guidance any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. This section 30.3.1 describes the implementation of section 1192(f) of the Act (the "Biosimilar Delay").

Under section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is hereinafter a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by FDA. 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. CMS believes 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 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 request for a Biosimilar Delay, as described in this section 30.3.1 of this final guidance.

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in 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") as stated in 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." CMS did not grant any Initial Delay Requests for initial price applicability year 2027; therefore, Additional Delay Requests are not

relevant for initial price applicability year 2028. As explained in the draft guidance, CMS is providing more information about the Additional Delay Request process within this final guidance to respond to previous comments requesting information about this topic. CMS will provide more information in rulemaking applicable to future initial price applicability years.

CMS published the Drug Selection ICR, which includes the form to request a Biosimilar Delay, on May 13, 2025 for a 60-day public comment period. CMS is publishing revisions to the Drug Selection ICR for a 30-day public comment period concurrent with the publication of this final guidance. As specified in the Drug Selection ICR Forms available for a 30-day public comment, CMS anticipates that a Biosimilar Manufacturer will submit an Initial Delay Request using the CMS HPMS by the date specified by CMS.[105] CMS anticipates providing a 30-day submission window. Information regarding the submission of an Initial Delay Request is addressed in detail within the Drug Selection ICR Forms. Because CMS did not grant any Initial Delay Requests for initial price applicability year 2027, CMS is not including a specific data collection request within the Drug Selection ICR Forms for an Additional Delay Request. CMS anticipates including specific questions necessary for CMS to gather the information for an Additional Delay Request in a future revision to the Drug Selection ICR Forms and will provide opportunity for public comment on those proposed revisions at that time. This section 30.3.1 and the following subsections of this section 30.3.1 include details on the policies for implementation of Initial Delay Requests for initial price applicability year 2028. As discussed above in this section, while Additional Delay Requests are not relevant for initial price applicability year 2028, CMS is providing information about the Additional Delay Request process within this final guidance to respond to previous comments requesting information about this topic and to receive feedback for CMS consideration in rulemaking applicable to future initial price applicability years.

Information submitted in a Biosimilar Delay Request 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 FOIA (5 U.S.C. § 552(b)(3), (4)).

30.3.1.1 Procedures for Submission of Initial Delay Requests and Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2028

Procedures for Submission

CMS will not consider late or incomplete submissions. Upon receipt of a complete Initial Delay Request, CMS will take the following approach to identify whether an Initial Delay Request may be granted for a negotiation-eligible drug:

[105] As specified in the Drug Selection ICR Supporting Statement – Part A, available for a 30-day public comment, CMS intends to provide the opening date for submissions after approval of the Drug Selection ICR by the Office of Management and Budget (refer to the Drug Selection ICR Supporting Statement – Part A for additional information). Access to Initial Delay Request functionality will be granted automatically to active manufacturer users in the CMS HPMS. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program" PDF, available at: https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

- First, if an Initial Delay Request includes all required elements and was timely submitted, CMS will review the Initial Delay Request to determine if it meets all statutory requirements described in section 30.3.1.1 of this final guidance, with the exception of the high likelihood requirement (which refers collectively to the requirements described in section 30.3.1.3 of this final guidance).
- Second, if the Initial Delay Request meets all statutory requirements other than the high likelihood requirement, CMS will review the Initial Delay Request to determine whether it demonstrates that there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the statutorily-defined selected drug publication date for the initial price applicability year (hereinafter the "High Likelihood Deadline"), which is February 1, 2028 for Initial Delay Requests for initial price applicability year 2028. For purposes of its review of marketing in the context of the Biosimilar Delay, CMS intends to consider whether the totality of the circumstances, including the data specified below, demonstrates a high likelihood that the Biosimilar Manufacturer will engage in bona fide marketing of that Biosimilar.

In considering an Initial Delay Request, CMS will cease consideration upon finding that the Initial Delay Request has failed to meet any of these requirements. For example, if CMS determines an Initial Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements. If CMS determines an Initial Delay Request fails to meet one or more of the statutory requirements described in section 30.3.1.1 of this final guidance, with the exception of the high likelihood requirement, CMS will not consider whether that Initial Delay Request demonstrates a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028.

In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Initial Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request. For Initial Delay Requests for initial price applicability year 2028, CMS plans to make any such follow-up request in writing to the Biosimilar Manufacturer via email. Any such written request will specify the additional information required, the format and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information.

The one exception to the ICR submission deadline and the follow-up information that may be requested by CMS for an Initial Delay Request for initial price applicability year 2028 is as follows: per section 30.3.1.3 of this final guidance, for CMS to determine that there is a high likelihood of the Biosimilar being licensed and marketed prior to February 1, 2028, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than January 15, 2026. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 PM PT on January 15, 2026, in order to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list to be published no later than February 1, 2026, in accordance with section 1192(a) of the Act.

The list of selected drugs published for initial price applicability year 2028 will reflect the results of CMS' determinations with respect to any Initial Delay Requests that are submitted, i.e., a Reference Drug that, absent a successful Initial Delay Request, would have been selected, will not appear on the selected drug list published no later than February 1, 2026, if it is named in a successful Initial Delay Request.

After completing its review, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2028 in writing of CMS' determination regarding such request. This notification will occur on or after the date that the selected drug list for initial price applicability year 2028 is published, but no later than February 28, 2026, and will include a brief summary of CMS' determination, including:

- Whether the Initial Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined the Initial Delay Request was unsuccessful, including but not limited to:
    - failure to submit all elements of the Initial Delay Request by the applicable deadline;
    - 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 initial price applicability year 2028 absent the Initial Delay Request; or
    - failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028.

CMS will also notify each Primary Manufacturer (as defined in section 40 of this final guidance) of the Reference Drug ("Reference Manufacturer") named in a successful Initial Delay Request using the CMS HPMS to identify the relevant point(s) of contact. Such notification will be in writing and will identify the Reference Drug that would have been a selected drug in initial price applicability year 2028, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests will not be notified. CMS will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2028, absent successful Initial Delay Requests, as part of publishing the selected drug list no later than February 1, 2026.

Requirements for Granting an Initial Delay Request

The statute specifies that the following requirements must be met in order for CMS to grant an Initial Delay Request:

1. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be, absent the Biosimilar Delay, a selected drug for the initial price applicability year.
    - Biosimilar Manufacturers that believe that a Reference Drug for their Biosimilar may be a selected drug for initial price applicability year 2028 may submit an Initial Delay Request, and CMS will disregard that application if the Reference Drug would not, in fact, be a selected drug for initial price applicability year 2028. 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[106] and the Medicare Part D Drug Spending Dashboard,[107] which may allow them to determine the likelihood that a given drug may be a selected drug.

2. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests submitted with respect to initial price applicability year 2028, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2012, and January 1, 2016.
    - 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. 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, CMS believes the exception to the definition of "extended-monopoly drug" in section 1194(c)(4)(B)(ii) of the Act will not apply at the time that a delay would be requested for initial price applicability years 2026 through 2029. Accordingly, CMS believes that the Biosimilar Delay under section 1192(f) of the Act is applicable for initial price applicability year 2028. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2028, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years[108] prior to the start of the initial price applicability year on January 1, 2028.
3. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product[109] identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by FDA or accepted for review.
    - Note that in order for CMS to grant an Initial 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.
4. In accordance with section 1192(f)(2)(D)(iii) of the Act, an Initial Delay Request cannot be granted if more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to 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 IRC, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.

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

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

[108] Section 1194(c)(4)(A) of the Act defines "extended-monopoly drug."

[109] 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 as the reference product.

- For the purposes of this determination, "partnership" 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.

6. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that:
   - requires or incentivizes the Biosimilar Manufacturer to submit an Initial 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. For Initial Delay Requests submitted with respect to initial price applicability year 2028, CMS will 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 February 1, 2026, as violating this requirement.
7. In accordance with section 1192(f)(1)(A) of the Act and as described in section 30.3.1.3 of this final guidance, CMS must determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.

30.3.1.2 Procedures for Submission of Additional Delay Requests and Requirements for Granting an Additional Delay Request After the Initial Delay Period

Procedures for Submission

Upon receipt of a complete Additional Delay Request, CMS will take the following approach to identify whether an Additional Delay Request may be granted for a negotiation-eligible drug.

- First, if an Additional Delay Request includes all required elements and was timely submitted, CMS will review the Additional Delay Request to determine if it meets all statutory requirements described in this section 30.3.1.2 of this final guidance, with the exception of the high likelihood and the significant amount of progress towards licensure and marketing requirements;
- Second, if the Additional Delay Request meets all statutory requirements other than the high likelihood requirement and significant amount of progress requirement, CMS will review the Additional Delay Request to determine whether:
  1. it demonstrates a high likelihood that the Biosimilar will be licensed and marketed prior to the date that is two years after the selected drug publication date for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request, as described in section 30.3.1.3 of this final guidance. For purposes of its review of marketing in the context of the Biosimilar Delay, CMS will consider whether the totality of the circumstances, including the data specified below, demonstrates a high likelihood that the Biosimilar Manufacturer will engage in bona fide marketing of that Biosimilar; and

2. it demonstrates that a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar as described in section 30.3.1.4 of this final guidance.

In considering an Additional Delay Request, CMS will cease consideration upon finding that the Additional Delay Request has failed to meet any of these requirements. For example, if CMS determines an Additional Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements. If CMS determines an Additional Delay Request fails to meet one or more of the statutory requirements described in this section 30.3.1.2 of this final guidance, with the exception of the high likelihood requirement or significant amount of progress requirement, CMS will not consider whether that Additional Delay Request demonstrates (1) a high likelihood that the Biosimilar will be licensed and marketed prior to the date that is two years after the selected drug publication date for which the Reference Drug would have been included as a selected drug on the selected drug list but for the successful Initial Delay Request, as described in section 30.3.1.3 of this final guidance; or (2) a significant amount of progress has been made by the Biosimilar Manufacturer toward licensure and marketing of the Biosimilar, as described in section 30.3.1.4 of this final guidance.

In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Additional Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Additional Delay Request. With respect to any Additional Delay Requests submitted for future initial price applicability years, CMS will provide information in future rulemaking about the specific dates, similar to the dates included above for a determination of an Initial Delay Request, such as notification of CMS' determination of an Additional Delay Request. At this time, after completing its review for Additional Delay Requests, CMS will notify each Biosimilar Manufacturer that submits an Additional Delay Request for an applicable initial price applicability year in writing of CMS' determination regarding such request. This notification will occur on or after the date that the selected drug list for an applicable initial price applicability year is published and will include a brief summary of CMS' determination, including:

- Whether the Additional Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined the Additional Delay Request was unsuccessful, including but not limited to:
    - failure to submit all elements of the Additional Delay Request by the applicable deadline;
    - failure to meet another statutory requirement for granting a request (other than the high likelihood and significant progress requirements);
    - failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed prior to the date that is two years after the selected drug publication date for which the Reference Drug would have been included as a selected drug on the selected drug list but for the successful Initial Delay Request, as described in section 30.3.1.3 of this final guidance; or
    - failure to show clear and convincing evidence that a significant amount of progress towards both licensure and marketing of the Biosimilar has occurred since the Biosimilar Manufacturer's submission of the successful Initial Delay Request for the Biosimilar.

Requirements for Granting an Additional Delay Request

The statute specifies that the following requirements must be met in order for CMS to grant an Additional Delay Request for the Biosimilar:

1. In accordance with section 1192(f)(2)(B)(i) of the Act, the Secretary must have determined that, for the biological product identified in a successfully granted Initial Delay Request, licensure and marketing under section 351(k) of the PHS Act has not commenced 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.
2. In accordance with section 1192(f)(1)(A) of the Act, 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 by FDA or accepted for review.
3. In accordance with section 1192(f)(2)(D)(iii) of the Act, no more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
4. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that:
    - requires or incentivizes the Biosimilar Manufacturer to submit an Additional 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.[110]
6. In accordance with section 1192(f)(2)(B)(i)(I) of the Act and as described in section 30.3.1.3 of this final guidance, CMS must reevaluate to determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.
7. In accordance with section 1192(f)(2)(B)(i)(II) of the Act and as described in section 30.3.1.4 of this final guidance, CMS 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.
8. In accordance with section 1192(f)(2)(D)(ii) of the Act, a Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is not eligible for an Additional Delay Request if there would have been a change in status to a long-monopoly drug, as defined in section 1194(c)(5) of the Act, with respect to the initial price applicability year for which the Biosimilar Manufacturer is submitting an Additional Delay Request.

30.3.1.3 High Likelihood

In accordance with section 1192(f)(1)(A) and section 1192(f)(2)(B)(i)(I) of the Act, CMS will review Biosimilar Delay Requests to determine whether there is a high likelihood that the

[110] CMS will provide information in future rulemaking about the specific dates, similar to the dates included for a determination of an Initial Delay Request, such as notification of CMS' determination of an Additional Delay Request.

Biosimilar will be licensed and marketed before the High Likelihood Deadline. For purposes of application of this section to an Additional Delay Request, as explained in the draft guidance, CMS is providing information about the Additional Delay Request process within this final guidance to respond to previous comments requesting information about this topic. CMS will provide additional information in rulemaking applicable to future initial price applicability years.

Accordingly, for Initial Delay Requests submitted with respect to initial price applicability year 2028, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028, in order to grant the request. If CMS does not find that there is a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028, based on the criteria described below, CMS will deny the Initial Delay Request. For an Additional Delay Request, CMS must reevaluate to determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline for the successful Initial Delay Request submission for such Biosimilar. If CMS reevaluates and does not find that there is a high likelihood that the Biosimilar will be marketed before the High Likelihood Deadline for the successful Initial Delay Request submission for the Biosimilar, CMS will deny the Additional Delay Request.

In accordance with section 1192(f)(3) of the Act, Biosimilar Delay Requests must demonstrate both of the following in order to meet the high likelihood threshold:

1. An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by FDA.[111]
    - For Initial Delay Requests submitted with respect to initial price applicability year 2028, the Biosimilar's application for licensure must be approved or accepted for review by FDA no later than January 15, 2026 in order to permit CMS time to review the information and finalize the selected drug list prior to publishing the selected drug list for initial price applicability year 2028.
        i. Note that if the Biosimilar's application for licensure has not been accepted for review by January 15, 2026, 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, CMS will deny the Initial Delay Request for initial price applicability year 2028.
    - CMS will provide information about the specific timing for an Additional Delay Request for specific initial price applicability years in future rulemaking.
2. Clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, based on the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act that has been submitted to CMS.

To demonstrate clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, CMS will require that the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS by the Biosimilar

[111] CMS will consider an application for licensure under section 351(k) of the PHS Act that has been accepted for review and that has received a complete response letter 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.

Manufacturer as part of its request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date, and so CMS believes 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, 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 for the successful Initial Delay Request submission for the Biosimilar. CMS 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 would not be considered to be "applicable to the Biosimilar." Specifically, CMS will consider this requirement met if (1) there will be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar; (2) 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 patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar, or neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer's legal 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 clearly specified a launch date for the Biosimilar that is a calendar date before the High Likelihood Deadline; further, this launch date must not be contingent on the outcome of pending litigation; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without imposing improper constraints on the Biosimilar Manufacturer.[112]

Second, the Biosimilar Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline for the successful Initial Delay Request submission for the Biosimilar (which is February 1, 2028 for Initial Delay Requests for initial price applicability year 2028). To assess this requirement, CMS will 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 February 1, 2028; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. CMS chose these

[112] Pursuant to section 1192(f)(2)(D)(iv) of the Act and described in section 30.3.1.1 of this final guidance, an Initial Delay Request will not be granted if the Biosimilar Manufacturer enters into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request or directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after February 1, 2026. CMS will provide information about the specific timing requirements related to Additional Delay Request for specific initial price applicability years in future rulemaking.

criteria because 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 determining whether a Biosimilar Delay Request satisfies the high likelihood threshold, CMS may use all the information described in sections 30.3.1.1 and 30.3.1.2 of this final guidance to determine whether an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA. In accordance with section 1192(f)(3)(B) 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 will be marketed before the High Likelihood Deadline:

- 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;
- 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 (e.g., 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 biological product.

CMS provides three examples of "clear and convincing evidence" that might be included in the documentation required at section 1192(f)(3)(B) of the Act to potentially demonstrate that the Biosimilar has a high likelihood of being marketed before the High Likelihood Deadline. These examples are illustrative but alone may not always constitute "clear and convincing evidence" of a high likelihood of marketing. First, CMS provides 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 legal 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 FTC or AAG 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 legal 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 clearly specifies a 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, CMS provides 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 (e.g., 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 a biosimilar delay necessary to demonstrate "clear and convincing evidence."

30.3.1.4 Significant Amount of Progress

As discussed above and explained in the draft guidance, CMS is providing information about the Additional Delay Request process, including information in this section, within this final guidance to respond to previous comments requesting information about this topic. CMS will provide additional information in rulemaking applicable to future initial price applicability years.

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:

- 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
- 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).

Recognizing that approximately one year has passed since submission of the successful Initial Delay Request, CMS will consider whether the Biosimilar Manufacturer demonstrates that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. Specifically, 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, which includes the documentation in any follow-up requests.

CMS will consider if the Biosimilar Manufacturer can demonstrate affirmative progress towards being operationally ready to market the Biosimilar.

CMS will 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 both any updates or supplements to the documents specified in section 1192(f)(1)(B)(ii)(III) of the Act. The documents specified in section 1192(f)(1)(B)(ii)(III) of the Act include (1) disclosures about

capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before February 1, 2028; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations.

30.3.1.5 Failure of the Biosimilar to Be Licensed and Marketed

In accordance with section 1192(f)(2)(B) of the Act, CMS must determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. For successful Initial Delay Requests submitted with respect to initial price applicability year 2028, CMS 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 by November 5, 2026. If CMS determines that the Biosimilar is not licensed and marketed during the initial delay period, the Biosimilar Manufacturer will have the opportunity to submit an Additional Delay Request.

For purposes of application of this section to an Additional Delay Request, as explained in the draft guidance, CMS is providing information about the Additional Delay Request process within this final guidance to respond to previous comments requesting information about this topic. CMS will provide additional information for purposes of this section to an Additional Delay Request in rulemaking for future initial price applicability years.

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, CMS will (subject to the circumstances discussed below) include the Reference Drug on the selected drug list for the initial price applicability year that is one 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 (e.g., the selected drug list for initial price applicability year 2029 for successful Initial Delay Requests for initial price applicability year 2028). If a different biosimilar product is marketed before the publication of the selected drug list for the applicable initial price applicability year, CMS could also determine, in accordance with section 1192(c) of the Act and sections 30.1, 60.7, 70, and 90.4 of this final guidance, 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, CMS must determine whether each Biosimilar named in a successful Additional Delay Request is licensed and marketed during the second delay period. CMS will specify the date by which CMS will notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Additional Delay Request is licensed and marketed during the second delay period in future rulemaking. If CMS determines that the Biosimilar is not licensed and marketed during the second delay period, CMS will (subject to the circumstances below) 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 of the successful Initial Delay Request. CMS could also determine, in accordance with section 1192(c) of the Act and sections 30.1, 60.7, 70, and 90.4 of this final guidance, 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.

In accordance with sections 1192(f)(2)(B)(ii), 1192(f)(2)(C), and 1192(f)(4)(A) of the Act, if CMS delayed the selection and negotiation of a Reference Drug for one or two years in accordance with sections 30.3.1.1 or 30.3.1.2 of this final guidance, respectively, the Biosimilar was not licensed and marketed, and 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.

Section 1192(f)(4)(B) of the Act specifies that the rebate owed by the Reference Manufacturer, for the price applicability year for which an Initial Delay Request was granted will be calculated as follows:

- 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; and
- 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.

For the price applicability year for which an Additional Delay Request was granted, CMS will adjust the MFP as described in section 1195(b)(1)(A) of the Act to account for changes in the CPI-U.

Before applying a rebate, CMS 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 that is the year after the successful Initial Delay Request or successful Additional Delay Request, as applicable, and CMS has determined that the Biosimilar was not licensed or marketed. 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, 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-Federal Average Manufacturer Price ("non-FAMP") (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 or the Additional Delay Request. For example, if inclusion of the Reference Drug on the selected drug list is delayed until initial price applicability year 2029 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 2028 (September 2025) for the purposes of adjusting for inflation the average non-FAMP for 2021.

In accordance with section 1192(f)(4)(B) of the Act, CMS intends 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 delay. For example, if the Reference Drug would have been on the list for initial price applicability years 2028 and 2029 but for the approval of an Initial Delay Request and an Additional Delay Request and the Biosimilar was not licensed and marketed, CMS will use the MFP agreed to for initial price applicability year 2030 to calculate the rebate amount for initial price applicability years 2028 and 2029.

In accordance with section 1192(f)(4)(D) of the Act, the rebates paid for drugs payable under Part B will 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 will 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. CMS will provide additional information about 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.

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1192(f) of the Act.

30.4 Publication of the Selected Drug List

In accordance with sections 1191(b)(3) and 1192(a) of the Act, CMS will publish the selected drug list for initial price applicability year 2028 no later than February 1, 2026. This list will include the 15 (or all, if such number is less than 15) drugs payable under Part B and/or covered under Part D selected for negotiation for initial price applicability year 2028, including the active moiety / active ingredient (or in the case of fixed combination drugs, the distinct combination of active moieties / active ingredients) for each selected drug and the NDC-9s, NDC-11s, and HCPCS codes for the selected drug, as applicable. CMS will also publish a list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D, as described in section 30.3 of this final guidance, and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable. Because section 1192(d)(2)(A) of the Act excludes a qualifying single source drug that receives the SBE from the definition of a negotiation-eligible drug, a qualifying single source drug that receives the SBE will not be included in this list of the up to 50 top negotiation-eligible drugs. To promote greater transparency into the process for identifying selected drugs, this list of top drugs based on combined Total Expenditures will not include those negotiation-eligible drugs that qualify for the Biosimilar Delay; however, because section 1192(f)(1)(A) of the Act specifies that a biological product may only qualify for the Biosimilar Delay if the biological product would be included on the selected drug list but for the Biosimilar Delay, the list of the up to 50 top negotiation-eligible drugs will reflect the removal of any biological product that qualified for the Biosimilar Delay solely as it relates to the 15 top negotiation-

eligible drugs. Additionally, CMS will publish the list of drugs selected for renegotiation, if any, no later than February 1, 2026, as described in section 130.2.2 of this final guidance.

The NDC-9s and NDC-11s for each selected drug will be identified by compiling all NDC-11s belonging to the selected drug associated with HCPCS codes that appear on NDC-HCPCS code crosswalks published by CMS for each quarter in the 12-month period beginning November 1, 2024 and ending October 31, 2025, and all NDC-11s belonging to the selected drug that had Part D PDE utilization in this same 12-month period. CMS will also identify any additional NDC-11s associated with the NDA(s) / BLA(s) of the selected drugs 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) and remove any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B (e.g., NDC-11s for which there are no PDE records with a coverage status code of "C" and which are not associated with any HCPCS codes). CMS will post the selected drug list, including the NDC-9s, NDC-11s, and HCPCS codes (as applicable) for each selected drug, on the CMS website and update this information in accordance with section 40.2 of this final guidance. CMS may revise the selected drug list published pursuant to this section prior to or after the publication of any agreed-upon MFP as described in section 60.6 of this final guidance.

40. Requirements for Manufacturers of Selected Drugs

In accordance with section 1193(a) of the Act, the Secretary shall enter into agreements with manufacturers of selected drugs. 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, and renegotiate, as applicable, an MFP with "the manufacturer" of the selected drug (section 130 of this final guidance discusses renegotiation with "the manufacturer" in accordance with section 1193(a)(2) of the Act). To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2028, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer").[113]

Likewise, for initial price applicability year 2028, CMS will 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." A Secondary Manufacturer will include any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meet these criteria. A manufacturer that is not listed as a manufacturer on the NDA / BLA and without an agreement in place with the Primary Manufacturer would not be considered a Secondary Manufacturer. Examples of agreements that could result in a Secondary Manufacturer relationship may include, but are not limited to, royalty agreements, licensing

[113] In sections 40.2-40.5, 40.7, 50, 60-60.6, 60.8, 90, 100-100.2, 100.5, and 130 of this final guidance, all references to a "Primary Manufacturer" refer to any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program.

agreements, revenue sharing agreements, marketing agreements, supply agreements, purchasing agreements, or parent / affiliate agreements.

In the example described in section 30.1 of this final guidance, if the potential qualifying single source drug described was selected for negotiation, Entity "A" would be considered the Primary Manufacturer while Entity "B" would be considered a Secondary Manufacturer either because it was listed as a manufacturer in NDA-1 or if it was not listed as a manufacturer in NDA-1 because it markets the three strengths of the immediate release tablets manufactured by Entity A pursuant to an agreement with Entity A.

CMS will sign an agreement (the "Medicare Drug Price Negotiation Program Agreement," hereinafter also referred to as an "Agreement") with the willing Primary Manufacturer of each selected drug and believes this approach aligns with the statute's requirement to negotiate to determine an MFP with "the manufacturer" of a selected drug in accordance with section 1193(a) of the Act. This Agreement, as described in this section 40 of this final guidance, will set forth requirements of the Primary Manufacturer with respect to its participation in the Negotiation Program, including with respect to section 1193(a)(5) of the Act, which requires the Primary Manufacturer to comply with requirements set forth in this final guidance, which CMS has determined are necessary for purposes of administering and monitoring compliance with the Negotiation Program.

CMS will not enter into an Agreement with any Secondary Manufacturer of a selected drug with respect to that drug. As such, under section 1193(a)(4) of the Act, a Primary Manufacturer that enters into an Agreement must collect and report necessary information applicable to any Secondary Manufacturer(s) as described in section 40.2 of this final guidance. As the entity that is party to the Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Agreement and will be accountable for ensuring compliance with respect to units of the selected drug manufactured by the Secondary Manufacturer or marketed by any Secondary Manufacturer pursuant to an agreement with the Primary Manufacturer. In accordance with section 1193(a)(1) of the Act and section 40.4 of this final guidance, the Primary Manufacturer must ensure that any Secondary Manufacturer(s) make the MFP available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug. The scope of a Primary Manufacturer's responsibility to provide access to the MFP for the selected drug is limited to units of such drug sold by the Primary Manufacturer or a Secondary Manufacturer. CMS emphasizes that the requirement for Primary Manufacturers to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug, as described in section 80 of this final guidance. Failure to comply with obligations to make the MFP available may result in CMPs being assessed on the Primary Manufacturer pursuant to section 1197(a) of the Act.

CMS will require that for initial price applicability year 2028, the Primary Manufacturer of a selected drug is the entity that does each of the following:

1. Signs the Agreement with CMS, as described in section 40.1 of this final guidance;
2. Collects and reports all data required for negotiation, and if applicable, renegotiation under section 1193(a)(4) of the Act, including the negotiation data elements, as described in section 40.2, section 50.1, and Appendix A of this final guidance;
3. Negotiates an MFP with CMS, as described in section 40.3 of this final guidance, and if applicable, renegotiates an MFP with CMS, as described in section 130 of this final guidance;
4. Ensures the MFP, or renegotiated MFP, as applicable, is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities, with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug, as described in section 40.4 of this final guidance; and
5. Responds to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities; and pays any CMPs for violations, including: violating the terms of the Agreement; providing false information to CMS for use in applying the aggregation rule for the Small Biotech Exception or the Biosimilar Delay; failing to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but which has since undergone negotiation as described in section 1192(f)(4) of the Act; or not providing access to the MFP to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug, as described in sections 40.5, 90, and 100 of this final guidance.

Termination of an Agreement for the Negotiation Program is described in section 40.6 of this final guidance, and other relevant provisions from the Agreement are described in section 40.7 of this final guidance.

40.1 Entrance into an Agreement with CMS and Alternatives

Section 1193(a) of the Act instructs CMS to enter into agreements with manufacturers of selected drugs for a price applicability period. The deadline for the Primary Manufacturer of a selected drug to enter into an Agreement for initial price applicability year 2028 is February 28, 2026. The Primary Manufacturer must use the CMS HPMS to identify the relevant authorized representative(s) and effectuate the Agreement.[114]

To be eligible to sign the Agreement, and obtain electronic signature access within the CMS HPMS Negotiation Program module, which is necessary to sign the Agreement, an authorized representative must be the Primary Manufacturer's Chief Executive Officer, Chief Financial Officer, an individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer, or an individual that has been granted delegated authority to perform electronic

[114] See: https://hpms.cms.gov/app/ng/home/.

signatures on behalf of one of the individuals previously noted by a senior official of the Primary Manufacturer. To make a request to obtain electronic signature access, an authorized representative must prepare an official letter that states the user's name(s), role(s) (e.g., Chief Executive Officer), CMS user ID, the P number that will 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. CMS anticipates providing additional instructions related to requesting electronic signature authorization prior to the publication of the selected drug list for initial price applicability year 2028. Once additional instructions are provided, CMS recommends taking action as soon as possible to facilitate timely communication and effectuation of the Agreement. The authorized representative(s) must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Agreement, including any Addenda. CMS notes that it is a requirement of the CMS HPMS that the person accessing the CMS HPMS have a Social Security Number (SSN). An authorized representative of the Primary Manufacturer must access the CMS HPMS and sign the Agreement by February 28, 2026.

The negotiation period for initial price applicability year 2028 will begin on the earlier of two dates: the date on which the Agreement is executed (i.e., signed by both CMS and the Primary Manufacturer) or February 28, 2026. If an Agreement is fully executed before February 28, 2026, the negotiation period (as defined in section 1191(b)(4) of the Act) will begin on the date on which the Agreement is signed by the last party to sign it. If the Agreement is not fully executed by February 28, 2026, then pursuant to 26 U.S.C. § 5000D(b)(1), a period will begin on March 1, 2026, during which the Primary Manufacturer could be exposed to potential excise tax liability. Instructions for the Agreement and a template of the Agreement are available on the CMS website.[115]

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 CGDP,[116] and the Manufacturer Discount Program. If a Primary Manufacturer decides it is unwilling to enter into an Agreement for the Negotiation Program, it may expedite its exit from the Manufacturer Discount Program by submitting to CMS a notice (herein "Request to Terminate") that incorporates both: (1) a notice of decision not to participate in the Negotiation Program; and (2) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program.[117] If CMS determines the Primary Manufacturer's Request to Terminate complies with these requirements, the Primary Manufacturer's request will constitute good cause to terminate the Primary Manufacturer's agreement(s) under the Manufacturer

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

[116] 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, CMS has removed references to the CGDP in discussion of Primary Manufacturer termination. CGDP requirements are codified in Subpart W of 42 C.F.R. Part 423.

[117] See also section 80.1.3.1 of Manufacturer Discount Program Final Guidance, which describes termination of applicable agreements in the context of Medicare Part D. See: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.

Discount Program, pursuant to section 1860D-14C(b)(4)(B)(i) of the Act, to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14C of the Act. CMS has determined (and hereby provides notice) that it will automatically grant such Request to Terminate upon receipt, and that it will expedite the effective date of the Primary Manufacturer's termination of its Manufacturer Discount Program agreements consistent with the statutory limitation that termination shall not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination.

If a Primary Manufacturer decides it is unwilling to enter into an Agreement for the Negotiation Program and has submitted a Request to Terminate as described above, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning the termination of the Primary Manufacturer's applicable agreements under the Manufacturer Discount Program, in accordance with section 1860D-14C(b)(4)(B)(i) of the Act. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers. 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. Therefore, 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 the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its Request to Terminate.

If CMS determines the Primary Manufacturer's Request to Terminate complies with the requirements above, the Primary Manufacturer's request also will constitute good cause for CMS to terminate the Primary Manufacturer's applicable agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and section VII(b) of the Medicaid National Drug Rebate Agreement (NDRA). The Primary Manufacturer's applicable agreements include all the NDRAs of the Primary Manufacturer. Consistent with section 1927(b)(4)(B)(i) of the Act and section VII(b) of 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. CMS shall, upon request from the Primary Manufacturer, provide a hearing concerning the termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program, in accordance with section 1927(b)(4)(B)(i) of the Act. Consistent with the procedures described above in the context of the Manufacturer Discount Program, such a hearing will be held solely on the papers and if the manufacturer has asked to rescind its Request to Terminate prior to the effective date of the termination, CMS will automatically grant such request.

For clarity, if the request to rescind termination of the applicable 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.

40.2 Submission of Manufacturer Data to Inform Negotiation

After entering into an Agreement with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug must submit to CMS the following information with respect to the selected drug: information on the non-FAMP, as described in section 50.1.1 and Appendix A of this final guidance, and any information that CMS requires 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, as described in section 50.1 and Appendix A of this final guidance. This information must be submitted by the Primary Manufacturer to CMS no later than March 1, 2026 for initial price applicability year 2028.

The Agreement must be fully executed, meaning both the Primary Manufacturer and CMS have signed the Agreement, before the Primary Manufacturer may submit the data elements described in this section. While these data elements may not be submitted prior to execution of the Agreement, Primary Manufacturers will be able to access the data elements template in the CMS HPMS, and CMS believes Primary Manufacturers will be able to gather these data elements prior to the Agreement being executed. By signing the Agreement, a Primary Manufacturer agrees to use the CMS HPMS and comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system.

Certain data, as described in section 50.1, section 130.4, and Appendix A of this final guidance, must reflect any NDCs included in the selected drug marketed by any Secondary Manufacturer(s). The Primary Manufacturer is responsible for collecting such data from such Secondary Manufacturer(s) and including this information in its submission to CMS.

For each selected drug for initial price applicability year 2028, CMS will populate the CMS HPMS with the NDC-11s published in accordance with section 30.4 of this final guidance, including those NDC-11s of the selected drug with Part D PDE utilization or NDC-11s of the selected drug that are associated with HCPCS codes in Part B data in the 12-month period beginning November 1, 2024 and ending October 31, 2025, as well as any additional NDC-11s associated with the NDA(s) / BLA(s) of the selected drug as found in recent updates of the NSDE file, the NDC Directory (including its NDC Excluded Drugs Database file), and removing any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B (e.g., NDC-11s for which there are no PDE records with a coverage status code of "C" and which are not associated with any HCPCS codes). This list will include any NDC-11s of the selected drug marketed by the Primary Manufacturer or any Secondary Manufacturer. CMS will transmit this list to the Primary Manufacturer of the selected drug. In connection with the data submission described in section 50.1 of this final guidance, the Primary Manufacturer must provide CMS with information regarding NDC-11s that may be appropriate to ensure the list is complete and accurate. This includes but is not limited to:

- whether any NDC-11s associated with the NDA(s) / BLA(s) of the selected drug are missing from the list (e.g., because they are new NDC-11s), including any missing NDC-11s of a Secondary Manufacturer of the selected drug;
- whether any of the listed NDC-11s are for products distributed by or under the name of a private label distributor;
- whether any of the listed NDC-11s are neither marketed nor controlled by the Primary Manufacturer or a Secondary Manufacturer;

- whether any of the listed NDC-11s represent a sample package;
- whether any of the listed NDC-11s represent an inner package or an outer package; and
- whether any of the listed NDC-11s have been discontinued.

CMS will collect this information in the CMS HPMS as part of the collection of the other data elements described in section 50.1 of this final guidance and update this list as necessary (e.g., based on supplements from the Primary Manufacturer or other updates).

CMS may use this submitted information to revise the list of NDC-11s for each selected drug maintained on the CMS HPMS as well as information published pursuant to section 30.4 of this final guidance. For example, CMS will remove NDC-11s that are sample packages or that are marketed and controlled solely by a manufacturer that is not the Primary Manufacturer or Secondary Manufacturer(s).

This list of NDC-11s constitutes the baseline of NDCs[118] of the selected drug as described in section 30 of this final guidance that will be subject to the negotiation process for initial price applicability year 2028. The NDC-11s on this list will be included in ceiling calculations for initial price applicability year 2028 as described in section 60.2 of this final guidance, to the extent data is available to support such calculations. CMS will also use the NDC-11s on this list for the calculations used to apply the MFP across dosage forms and strengths of the selected drug for initial price applicability year 2028 as described in section 60.5 of this final guidance. CMS will use other information about the NDC-11s supplied by the Primary Manufacturer as additional context for the data elements described in section 50.1 of this final guidance (e.g., notice that an NDC-11 has been discontinued may explain why a Primary Manufacturer submitted partial year data for a particular NDC-11 of a selected drug; notice that an NDC-11 is for a drug distributed by or under the name of a private label distributor may explain why a Primary Manufacturer did not report Wholesale Acquisition Cost (WAC) for a particular NDC-11 of a selected drug).

The Primary Manufacturer has an ongoing obligation to timely report any changes in this information to ensure the list of NDC-11s of the selected drug in the CMS HPMS remains complete and accurate consistent with this final guidance and any future guidance and regulations. For example, 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. If CMS believes these new NDC-11s are not likely to have Part B utilization, including MA utilization, or Part D utilization in the future, these NDC-11s will not be added to the list of NDC-11s of the selected drug. As another example, a Primary Manufacturer must report to CMS any NDC-11s of the selected drug that the Primary Manufacturer previously indicated as being marketed and controlled solely by a manufacturer that is not the Primary Manufacturer or Secondary

[118] This list will include NDCs of the selected drug that are associated with HCPCS codes. CMS will organize data at the NDC-11 level because CMS groups NDC-11s for aggregation purposes via identification of the holder of the associated NDA / BLA and identification of the active moiety/active ingredient. The data Primary Manufacturers are required to report under section 1194(e)(1) is also generally maintained at the NDC-11 level. CMS will identify the HCPCS codes with which selected drugs are associated and for which payment may be made under Part B of Title XVIII via published NDC-HCPCS crosswalks.

Manufacturer, but that are newly marketed or controlled by the Primary Manufacturer or a Secondary Manufacturer. Failure of the Primary Manufacturer to provide timely information material to the accuracy of the list of NDC-11s of the selected drug as described in this section 40.2 may be considered a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs per section 1197(c) of the Act.

40.2.1 Confidentiality of Proprietary Information

Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. Information that is deemed proprietary shall 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. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).[119]

CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information of Primary Manufacturers, including Exemptions 3 and/or 4 of the FOIA, and that strikes an appropriate balance between: (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program; and (2) avoiding treating information that does not qualify for such protection as proprietary. Thus, for initial price applicability year 2028, CMS will treat information on non-FAMP as proprietary.

For initial price applicability year 2028, CMS will also treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 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. CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat 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 as non-proprietary. Within a Primary Manufacturer's response to a particular data element required in the Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS-10844, OMB 0938-1452)[120] (hereinafter the "Drug Price Negotiation ICR"), the response may include information that is non-proprietary because it is publicly available or otherwise 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, if a Primary Manufacturer provides a Common Technical File or Drug Master File, that is what is commonly titled "a drug dossier," within the manufacturer's submission of data submitted to CMS in accordance with section 1194(e)(2) of

[119] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

[120] As discussed in section 50 of this final guidance, CMS published the Drug Price Negotiation ICR in the Federal Register for a 60-day public comment period that ended on August 29, 2025. CMS intends to publish a revised version of the ICR for a 30-day comment period in late Fall 2025.

the Act, CMS will treat the submission of a drug dossier as proprietary because CMS understands that this type of document is typically not publicly available. In the Primary Manufacturer's submission of information in response to the Drug Price Negotiation ICR, the Primary Manufacturer may identify 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 in this section as proprietary by CMS. For example, the Primary Manufacturer would have an opportunity to specify any information included in a drug dossier that the Primary Manufacturer believes is proprietary and should be protected from disclosure.

Pursuant to section 1195(a)(2) of the Act and as discussed in section 60.6.1 of this final guidance, CMS is required to publish the explanation of the MFP by March 1, 2027, for initial price applicability year 2028. In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer for their selected drug (and submitted by the public as discussed in more detail in section 50.2.1 of this final guidance) that are determined to be non-proprietary and will not disclose any protected health information (PHI), personally identifiable information (PII), or information that is protected from disclosure under other applicable law. Public submissions of section 1194(e)(2) data may also include submissions from a Primary Manufacturer that do not pertain to the selected drug of the Primary Manufacturer (see section 50.2.1 of this final guidance for more information about use and disclosure of public submissions).

Within the explanation of the MFP, CMS may also make public high-level comments about the section 1194(e)(1) and section 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. For example, CMS will not make public the research and development costs reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say "the manufacturer has recouped its research and development costs." Any proprietary information obtained during an audit will also remain confidential, except as necessary to use that information in the course of a judicial enforcement proceeding.

Similar to the approach taken for publication of the public MFP explanations for initial price applicability year 2026, for each drug, CMS will make available on the CMS website redacted versions of section 1194(e)(1) and section 1194(e)(2) submitted data.

40.2.2 Data and Information Use Provisions and Limitations

CMS will not publicly discuss ongoing negotiations with a Primary Manufacturer, except as outlined below. As described in section 60.6.1 of this final guidance, CMS will make public a narrative explanation of the negotiation process and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. 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.

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, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. 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 will no longer consider that material proprietary consistent with section 40.2.1 of this final guidance. For example, if a Primary Manufacturer chooses to publicly disclose the unit cost of production, CMS will no longer consider the unit cost of production to be proprietary. If the Primary Manufacturer chooses to disclose proprietary information prior to the explanation of the MFP, then it will not be redacted in the explanation of the MFP. Primary Manufacturers negotiating an MFP with CMS pursuant to the process set forth in section 60 of this final guidance are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Information exchanges concerning confidential and strategic business negotiations may violate the antitrust laws under certain circumstances and lead to other anticompetitive agreements. Primary Manufacturers should consider the antitrust implications of any such actions.

CMS will prohibit audio or video recording of any negotiation meetings between CMS and a Primary Manufacturer. CMS will 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 can maintain its own written record of the negotiation process.

40.2.3 Opportunity for Corrective Action Following Information Submission

Recognizing the substantial role that manufacturer-submitted information will play in the Negotiation Program and in administering and monitoring the Negotiation Program, CMS will provide Primary Manufacturers with an opportunity for corrective action in the event a submission is incomplete or inaccurate. Upon receipt of Primary Manufacturer-submitted information—for example, information on the section 1194(e)(1) factors—CMS will review the submission for completeness and accuracy. Should CMS determine that a submission is incomplete or contains inaccurate information, CMS will 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. Following resubmission, CMS may follow up with the Primary Manufacturer to clarify any information included in the resubmission and confirm full accuracy and completeness of the required information.

If the Primary Manufacturer has failed to clarify its submission or if CMS determines the submission remains incomplete or inaccurate, CMS may issue a Request for Corrective Action outlining the needed action and establishing a five business-day deadline for the Primary Manufacturer to correct the submission and/or provide additional information to validate the accuracy/completeness of the original submission. CMS will make efforts to be available to engage with the Primary Manufacturer about the specifics of a request for corrected information and to answer questions and provide clarification. Note that the information required under

section 1193(a)(4) of the Act, including the section 1194(e)(1) factors, is information required by CMS to administer and monitor the Negotiation Program in accordance with section 1193(a)(5) of the Act; as such, failure to provide complete and accurate section 1194(e)(1) data, initially or in response to CMS' initial questions or Request for Corrective Action, may result in the Primary Manufacturer being subject to a CMP as authorized under section 1197(c) of the Act and as described in section 100.2 of this final guidance. If CMS decides to assess a CMP, the process established in section 100.5 of this final guidance will be followed.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years

CMS will use the CMS HPMS to share the initial offer and concise justification, to share any subsequent written offer(s), and to receive any written counteroffer(s) from the Primary Manufacturer of a selected drug. A Primary Manufacturer that signs the Agreement will be required to adhere to the process and deadlines described in section 60 of this final guidance. CMS will also use the CMS HPMS to share and receive an Addendum to the Agreement, as applicable, in order for CMS and the Primary Manufacturer to effectuate agreement upon any MFP that results from the negotiation process. For example, concurrent with the agency's provision of the initial offer, CMS will populate an Addendum in the CMS HPMS containing the MFP identified in the initial offer; if a Primary Manufacturer wishes to accept CMS' initial offer, it can sign the Addendum in the CMS HPMS. Similarly, concurrent with the Primary Manufacturer's submission of a statutory written counteroffer, the Primary Manufacturer will populate an Addendum in the CMS HPMS containing the MFP identified in the statutory written counteroffer and sign the Addendum; if CMS wishes to accept the statutory written counteroffer, it will countersign the Addendum in the CMS HPMS. CMS will determine that negotiations have concluded upon execution by both parties of the Addendum setting forth the agreed-upon MFP.

Pursuant to section 1194(f) of the Act, for initial price applicability year 2028, CMS may select for renegotiation selected drugs for initial price applicability years 2026 and 2027 if such drugs meet certain eligibility and selection criteria (described further in section 130 of this final guidance). If a drug is selected for renegotiation for initial price applicability year 2028, and if agreement is reached with respect to a renegotiated MFP, the Primary Manufacturer will be obligated to make the renegotiated MFP available as described in sections 40.4 and 130 of this final guidance.

40.4 Providing Access to the MFP in 2026, 2027, and 2028

After entering into an Agreement with CMS and in accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must, for 2026, 2027, and 2028, as applicable, provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act and section 80 of this final guidance) and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed that selected drug during a price applicability period. Beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028 per section 130 of this final guidance, such Primary Manufacturers must also provide access to the MFP, or renegotiated MFP, as applicable, to hospitals, physicians, and other providers of services and suppliers with respect to MFP-eligible individuals (described in section 1191(c)(2)(B) of the Act and section 80 of this final guidance) who are furnished or administered that selected drug

during a price applicability period. That is, the Primary Manufacturer is required to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug included on the list maintained on the CMS HPMS and published in accordance with sections 30.4 and 60.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable. The Primary Manufacturer is also required to provide access to the MFP for any additional dosage forms, strengths, and package sizes of the selected drug that may be introduced into the market, if coverage is being provided for such dosage forms, strengths, and package sizes under a prescription drug plan under Medicare Part D or an MA-PD plan under Medicare Part C (including an Employer Group Waiver Plan) or, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, if payment may be made for such dosage forms, strengths, and package sizes under Medicare Part B.

Although the Primary Manufacturer is obligated to provide access to the MFP for these dosage forms, strengths, and package sizes of the selected drug that are dispensed, furnished, or administered to MFP-eligible individuals, the Primary Manufacturer is not obligated to make any sales of the selected drug. As described in section 40.2 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable, the Primary Manufacturer has an ongoing obligation to timely report any changes to the NDC-11s for the selected drug to ensure the list of NDC-11s of the selected drug in the CMS HPMS remains complete and accurate. As described in section 60.6 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 and this final guidance, CMS will update the MFP file as needed. For initial price applicability year 2028, the MFP file will contain the single MFP for a 30-day equivalent supply of the selected drug, the NDC-9 per unit price and the HCPCS code dosage price, and will be updated annually to show the inflation-adjusted MFP for the selected drug. Sections 60.5 and 60.6 of this final guidance contain more details related to the MFP file.

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 such drug.[121] In Part D, the negotiated price of a drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point-of-sale. That is, in the case of a selected drug for which an MFP is in effect, the MFP-eligible individual's Part D cost-sharing is based on a negotiated price that cannot exceed the MFP plus any dispensing fees for such drug. Therefore, the requirement that the price used for MFP-eligible individual cost-sharing and benefit administration cannot exceed the applicable MFP (plus dispensing fees) helps to ensure that MFP-eligible individuals will have access to the MFP at the point-of-sale for selected drugs covered under Part D. While section 1193(a) of the Act requires the Primary Manufacturer to provide access to the MFP to MFP-

[121] CMS notes that Part D plan sponsors have flexibility to negotiate additional price concessions, similar to any other Part D covered drug. A Primary Manufacturer that negotiates additional price concessions with a Part D plan sponsor will still be responsible for providing access to the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed that selected drug.

eligible individuals, meeting this obligation to make the MFP available to MFP-eligible individuals will be facilitated by Part D plan sponsors in the normal course of operations.

However, section 1193(a) of the Act also requires that the Primary Manufacturer provide access to the MFP for the selected drug to pharmacies, mail order services, and other dispensing entities (hereinafter "dispensing entities") with respect to MFP-eligible individuals who are dispensed such drugs and, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, to hospitals, physicians, and other providers of services and suppliers (hereinafter "Part B providers") with respect to MFP-eligible individuals who are furnished or administered such drugs. CMS requires that Primary Manufacturers establish processes to ensure that dispensing entities that dispense drugs and Part B providers that furnish or administer drugs to MFP-eligible individuals have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in this section and section 90.2 of this final guidance. CMS defines "providing access to the MFP" as ensuring that the acquisition cost of the dispensing entity or Part B provider for the selected drug (as discussed in more detail in section 40.4.1 of this final guidance) is no greater than the MFP.

A Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity or Part B provider when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity or Part B provider's acquisition cost and the MFP. For selected drugs dispensed to MFP-eligible individuals, this means that, unless the dispensing entity's acquisition cost for the selected drug is equal to or less than the MFP, or, as detailed in section 40.4.5 of this final guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, CMS requires that the Primary Manufacturer transmit payment of an amount that provides access to the MFP within 14 calendar days of when the MTF sends data to the Primary Manufacturer that verify the selected drug was dispensed to an MFP-eligible individual (hereinafter the "14-day prompt MFP payment window").

A Primary Manufacturer must effectuate any agreed-upon MFPs for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028 when dispensed, furnished, or administered to MFP-eligible individuals on or after January 1, 2028. CMS is not at this time including detailed policy on providing access to the MFP for selected drugs payable under Part B. To the extent appropriate and feasible, CMS intends to align the policies and operations for providing access to the MFP for selected drugs payable under Part B with those for selected drugs covered under Part D. Unless otherwise specified, the MFP effectuation policies described hereinafter apply only to selected drugs covered under Part D and dispensed to MFP-eligible individuals as defined by section 1191(c)(2)(A) of the Act and described in section 80 of this final guidance.

While Primary Manufacturers and dispensing entities participating in Part D plan networks will be required to enroll in the MTF Data Module ("MTF DM"), and we expect that Primary Manufacturers and dispensing entities will use the MTF platform (including the voluntary MTF Payment Module ("MTF PM")) to support access to the MFP for selected drugs starting January 1, 2026, it is possible that the private sector could develop alternative solutions for sharing

verified data or for routing refund payments from manufacturers to dispensing entities. CMS intends to monitor potential private sector alternative solutions for sharing verified data or for routing MFP refund payments from manufacturers to dispensing entities.

The MTF could be expanded to support MFP effectuation for drugs payable under Part B beginning with initial price applicability year 2028. CMS will provide detailed policy on providing access to the MFP for selected drugs payable under Part B in the future and will consider comments and recommendations related to MFP effectuation for drugs payable under Part B in CMS' policy development.

If a retrospective refund is necessary to effectuate the MFP, CMS notes that the Primary Manufacturer must *transmit* (as described in section 40.4.2.1 of this final guidance) an MFP refund amount within 14 days, as opposed to ensuring the dispensing entity has *received* the MFP reimbursement within 14 days, in order to comply with the 14-day prompt MFP payment window. As noted in the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS intends for the 14-day prompt MFP payment window to align with the timing requirement in the longstanding prompt pay rules in Part D for plan sponsors.[122] Clarifying that the 14-day prompt MFP payment window requires the MFP refund payment to be transmitted within 14 days provides for greater consistency with the Part D prompt pay rules, which establish a required timeframe for plan sponsors to issue, mail, or otherwise transmit payment, as opposed to a deadline by which plan sponsors must ensure pharmacies have received payment. Additionally, this definition should provide interested parties and CMS with a clear standard by which to monitor whether Primary Manufacturers have made the MFP available on a timely basis, especially with respect to payment methods (e.g., paper checks) where it might be difficult for parties to ensure that the payment amount has been received by the dispensing entity before the end of the 14-day prompt MFP payment window. While the 14-day prompt MFP payment window is intended to align with the timing requirements in the Part D prompt pay rules, dispensing entities should be aware that they may not receive payment from a Part D plan sponsor for the Part D claim on the same date that the Primary Manufacturer provides a retrospective MFP refund to the dispensing entity. Due to operational differences between the Part D program and the Negotiation Program, the respective prompt payment windows for a particular dispense may start on different dates for the Part D plan sponsor and the Primary Manufacturer.

CMS reiterates that section 1193(a)(3)(A) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to dispensing entities that dispense the selected drug to MFP-eligible individuals. Similarly, section 1193(a)(3)(B) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to Part B providers that furnish or administer the selected drug to MFP-eligible individuals. The Primary Manufacturer is also obligated to ensure that the MFP is available for units of the selected drug that are marketed and sold by any Secondary Manufacturer(s) and dispensed, furnished, or administered to MFP-eligible individuals. Commercial and other payers continue to have discretion to consider Medicare payment rates, including the MFP, in establishing their own payment policies.

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[122] See 42 C.F.R. § 423.520, Prompt Payment by Part D Sponsors, which requires the Part D sponsor to transmit payment to pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.

CMS received extensive feedback from interested parties and, based upon that feedback, has completed an MTF data exchange acquisition process to engage an MTF Contractor[123] for the Negotiation Program to facilitate the exchange of data between Primary Manufacturers and dispensing entities. The MTF DM will support the verification that the selected drug was dispensed to an MFP-eligible individual, as described in section 40.4.2 of this final guidance. As described in section 40.4.2 of this final guidance, CMS believes mandatory participation for Primary Manufacturers and dispensing entities in the MTF's data exchange functionality is necessary to administer the Negotiation Program and Part D program, as well as to promote compliance and oversight. CMS intends for the MTF DM to serve a similar purpose for drugs payable under Part B.

CMS conducted listening sessions and reviewed comments regarding payment options outlined in draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027. Interested parties were generally supportive of payment facilitation in addition to data exchange. Therefore, CMS also completed an acquisition process to engage a separate MTF Contractor to support the MTF PM. The MTF PM will facilitate pass through of payments from Primary Manufacturers that elect to use the MTF PM that will complement the data-related activities of the MTF DM. CMS intends that the MTF PM will also be available to Primary Manufacturers for drugs payable under Part B.

CMS hosts frequent MTF systems and technical calls to engage with manufacturers and dispensing entities on implementation details and operational topics such as system integration, secure data exchange protocols, system user experience, and other components to inform the design and functionality of the MTF DM and MTF PM and to share information and hear feedback on technical and operational aspects of the Negotiation Program.

While CMS is committed to helping to facilitate exchange of data and pass through of payment, the Primary Manufacturer is ultimately responsible for calculating the appropriate amount to effectuate the MFP and ensuring that timely payment is made to the dispensing entity or Part B provider, as applicable. Stakeholders using the MTF should also remain mindful of their obligations to comply with all applicable laws, regulations and guidance including, but not limited to, fraud and abuse laws such as the Anti-Kickback Statute. CMS may refer potential fraud and abuse concerns to law enforcement, including the Department of Justice and the Office of Inspector General, as applicable.

The MFP effectuation policies established for 2026 and 2027 in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 are final policies that remain in effect for 2026 and 2027. In this final guidance, CMS describes updates to, and includes supplemental information regarding, these policies for 2026 and 2027, and also addresses extending these same policies to 2028 for drugs covered under Part D. For ease of reference, CMS is restating the MFP effectuation sections from final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 in this final

[123] For the purposes of this guidance, CMS uses the term "MTF Contractor" or "MTF Contractors" to refer generally to the contractors that CMS has engaged to provide services in connection with the MTF, including the MTF DM and MTF PM.

guidance so that the changes and updates to those policies can more easily be read in context with the policies in the prior final guidance that CMS is modifying or supplementing.

CMS understands that changes to the MFP effectuation process described in section 40.4 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 may impact the development of interested parties' MFP effectuation implementation solutions. CMS highlights that the following key changes from the final guidance for initial price applicability year 2027 are made in sections 40.4.1 through 40.4.5 of this final guidance: (1) the inclusion of new claim-level data elements and clarification on how the MTF DM will handle and process specific claim edits in CMS' Drug Data Processing System (DDPS) (section 40.4.2); (2) additional and updated information about the Medicare Transaction Facilitator Data Module User Agreement (hereinafter the "MTF DM User Agreement"), including the impact of transfer of ownership of a selected drug or termination of participation in the Negotiation Program on the MTF DM User Agreement and surviving responsibilities (section 40.4.2.1); (3) clarification that the MTF DM will produce remittances for all MFP refund payments facilitated by the MTF PM or for claims for which the Primary Manufacturer indicates to the MTF DM that the MFP was provided prospectively (section 40.4.2); (4) further clarification on the issuance and timing of payment to dispensing entities that elect to receive MFP refund payments from the MTF PM in the form of paper checks and details related to situations in which a paper check is not deposited by the dispensing entity (section 40.4.3); (5) clarification on Primary Manufacturers' responsibilities when terminating participation in the MTF PM (section 40.4.3); (6) addition of a Justification Code to Table 5 to address scenarios described in section 1193(d)(2) of the Act (section 40.4.3.1); (7) additional information for how Primary Manufacturers should respond to adjustments to original claims that are received within the 14-day prompt MFP payment window (section 40.4.3.2); (8) clarification regarding MFP refund payments issued through the MTF PM when a claim is submitted by a dispensing entity that is not enrolled in the MTF DM (section 40.4.3.3); and (9) the inclusion of a new claim-level payment element and separation of date and time payment elements in Table 6 for MFP refund payments made outside of the MTF PM (section 40.4.4.2). Additionally, CMS provides clarification that the claim-level data elements and claim-level payment elements shall be returned in a single response file to the MTF DM. CMS will consider the comments and recommendations related to the MFP effectuation process for selected drugs payable under Part B, including how any changes would correspond with MTF data and payment workflows outlined in sections 40.4.2, 40.4.3, and 40.4.4 of this final guidance, in CMS' policy development in the future.

40.4.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount

As described above, a Primary Manufacturer may meet its statutory obligation under section 1193(a)(3) of the Act to make the MFP available to dispensing entities by retrospectively transmitting payment for the difference between the dispensing entity's acquisition cost and the MFP (i.e., the MFP refund amount), within the 14-day prompt MFP payment window. CMS recognizes that dispensing entities and manufacturers may face significant challenges establishing a reliable actual acquisition cost for a selected drug that could be used to determine the MFP refund amount. For example, using each individual dispensing entity's actual acquisition cost for each particular dispensed unit of a selected drug could be challenging due to

differences in purchasing agreements with suppliers that contribute to variable drug costs among dispensing entities, the number of dispensing entities for which to account, pricing variability among individual units of a selected drug within each dispensing entity's inventory, difficulties in reconciling the misalignment in the cost of a drug product when it is acquired for purchase and the changes in cost through the point at which that product is dispensed, and restrictions and sensitivities around sharing proprietary pricing information with third-party vendors. However, a Primary Manufacturer and dispensing entity may choose to calculate the MFP refund using a dispensing entity's actual acquisition cost rather than a standardized pricing metric that serves as a reasonable proxy for the dispensing entity's acquisition cost.

CMS recognizes the significant operational challenges that Primary Manufacturers and dispensing entities may face in calculating a retrospective refund amount based on real-time actual acquisition cost. CMS believes that allowing a Primary Manufacturer flexibility to determine its preferred methodology for calculating its MFP refund payments aligns with the Primary Manufacturer's statutory obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP, as required under section 1193(a)(3) of the Act. CMS outlines in section 90.2 of this final guidance the agency's process for determining when the MFP was made available and the specific information that may be considered when evaluating whether the MFP was made available in individual cases. Primary Manufacturers should consider CMS' MFP effectuation compliance monitoring and enforcement policies and procedures when determining whether an MFP refund is necessary to effectuate the MFP and when calculating the amount of such a refund; please see section 90.2 of this final guidance for more information on these factors. CMS encourages interested parties to use the complaints process within the complaint and dispute system, as outlined in section 90.2.2 of this final guidance, to address issues regarding access to the MFP. CMS intends to review complaints regarding access to the MFP on a case-by-case basis and monitor overall trends and emerging compliance issues reported via the complaints and disputes system, including issues related to determining acquisition costs.

In light of the significant operational challenges associated with calculating real-time actual acquisition cost, manufacturers and dispensing entities may agree to use a standardized pricing metric to approximate acquisition cost for purposes of calculating any MFP refund amount necessary to make the MFP available. CMS believes that WAC will generally best approximate the acquisition costs of dispensing entities and offers a reliable method for calculating a "standard default refund amount" (SDRA) for manufacturers and dispensing entities that agree to use such a standardized pricing metric. WAC, as defined by section 1847A(c)(6)(B) of the Act, is the manufacturer's list price for the drug or biological 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 pricing data. Additionally, the use of WAC as a standardized pricing metric in the calculation of the SDRA addresses concerns raised by interested parties that the use of acquisition cost would create significant administrative burdens and avoids dispensing entities having to share proprietary or confidential pricing information with Primary Manufacturers. WAC is a widely available pricing metric, published and regularly updated in common pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process and would not require the

sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates, between parties. As discussed in section 90.2 of this final guidance, when assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug, absent information available to CMS indicating otherwise, CMS will consider provision of the SDRA (defined as WAC minus the MFP) to meet the Primary Manufacturer's obligation to make MFP available.

The MTF DM will use WAC, as published in pharmaceutical pricing database compendia on the date of service of the Part D claim, as the standardized pricing metric to calculate the SDRA. As described in section 40.4.2 of this final guidance, the MTF DM will provide the Primary Manufacturer with the SDRA (i.e., WAC per unit on the date of service of the Part D claim minus MFP per unit on the date of service of the Part D claim, then multiplied by the quantity dispensed) as part of the transmitted claim-level data elements. The Primary Manufacturer may elect to use the SDRA, as appropriate, to calculate and make the retrospective MFP refund payment to dispensing entities. CMS maintains that WAC is the best option to calculate the SDRA for the MTF DM for the reasons stated above and due to the support expressed by interested parties.[124]

The obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP rests with the Primary Manufacturer. A Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines some other amount is appropriate and sufficient to make the MFP available. A dispensing entity can work with Primary Manufacturers to establish an MFP refund amount using the dispensing entity's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available, and the Primary Manufacturer would indicate such agreed amount when reporting the claim-level payment elements, described in sections 40.4.3 and 40.4.4 of this final guidance, provided by the Primary Manufacturer to the MTF DM. In the exceedingly rare case that the NDC for a Part D claim does not have a published WAC available to CMS for the date of service of the claim, the MTF DM will not provide the Primary Manufacturer with the calculated SDRA and will leave the field null in the transmitted claim-level data elements for the claim. Unless access to the MFP was provided prospectively or, as detailed in section 40.4.5 of this final guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, the Primary Manufacturer remains obligated to pay an appropriate refund amount to ensure the dispensing entity has access to the MFP and is responsible for calculating that refund amount. As for the rare cases where the MTF DM does not provide the Primary Manufacturer with a calculated SDRA, Primary Manufacturers are encouraged to include information on their approach to calculating an MFP refund amount when an SDRA is not provided in the Primary Manufacturer's MFP Effectuation Plan for initial price applicability year 2026 and are required to include this information beginning with initial price applicability year 2027 as outlined in section 90.2.1 of this final guidance.

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[124] In response to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS received comments from interested parties, including manufacturers and dispensing entities, overwhelmingly supporting the use of a standardized proxy for acquisition cost, such as WAC, to calculate the MFP refund amount. See https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

As set forth in section 90.2.1 of this final guidance, the Primary Manufacturer is expected to include in their written plan for making the MFP available that is submitted to CMS whether it will use the dispensing entity's actual acquisition cost or a reasonable proxy for such a cost, such as WAC (i.e., the SDRA). If the Primary Manufacturer and a dispensing entity agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost (e.g., WAC as used in the SDRA), as opposed to the dispensing entity's actual acquisition cost for that particular unit of the selected drug, then CMS intends to consider a retrospective refund paid pursuant to that calculation to be sufficient for the Primary Manufacturer to meet its obligation to make the MFP available to the dispensing entity. Additionally, as described in more detail in sections 40.4.3.1 and 40.4.4.2 of this final guidance, the Primary Manufacturer is required to transmit claim-level payment elements to the MTF DM and, should the Primary Manufacturer pay an amount other than the SDRA, the Primary Manufacturer is required to indicate that an amount other than the SDRA was made available and provide the amount of payment determined to be the MFP refund when reporting claim-level payment elements to the MTF DM. If a dispensing entity believes that they have not received a retrospective refund that effectuates the MFP, CMS recommends the dispensing entity remediate with the Primary Manufacturer directly. If remediation between the parties cannot be reached, interested parties are encouraged to use the complaints process, within the complaint and dispute system outlined in section 90.2.2 of this final guidance in addressing issues regarding access to the MFP.

40.4.2 Medicare Transaction Facilitator Data Facilitation

As discussed in section 40.4 of this final guidance, CMS has engaged an MTF Contractor for the MTF DM to facilitate the exchange of certain claim-level data elements and claim-level payment elements for selected drugs. As discussed in further detail below, CMS requires Primary Manufacturers to participate in the MTF DM for purposes of data exchange to exchange key data files necessary for MFP effectuation. In recent rulemaking, CMS finalized a requirement for Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM.[125] Dispensing entity participation in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and making available remittances (e.g., paper checks) or an Electronic Remittance Advice (ERA) that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act (HIPAA), providing access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are drugs covered under Part D, and ensuring accurate Part D claims information and payment. Neither Primary Manufacturers nor dispensing entities shall be required to pay any fees to participate in the MTF DM, including but not limited to user fees or transaction fees, as CMS intends to bear the cost of operationalizing the MTF. In addition, regardless of whether the MFP refund is passed through the MTF PM or payment is made outside of the MTF PM, neither Primary Manufacturers nor

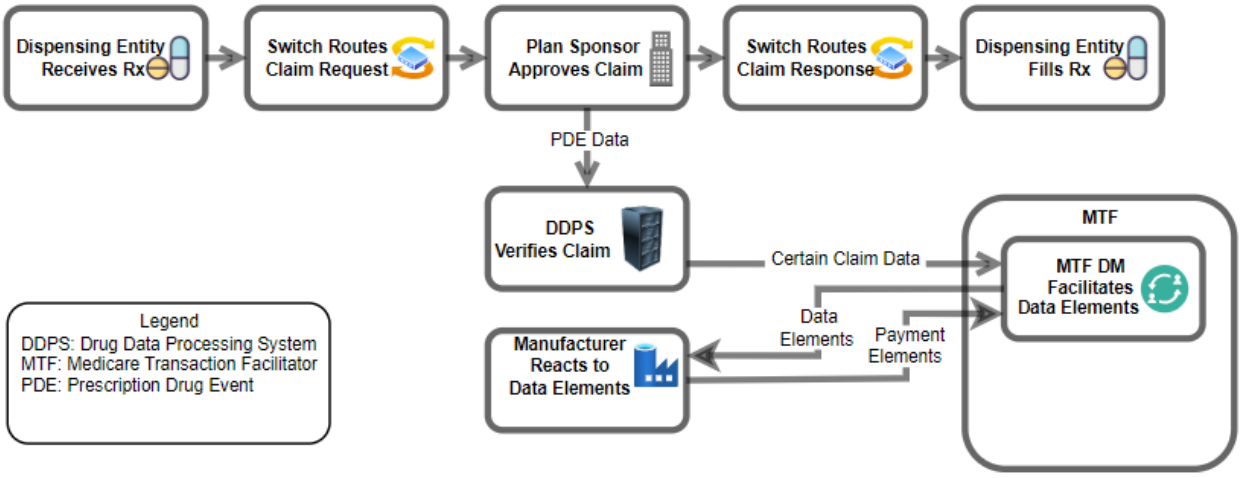
[125] CMS, Final Rule, "Medicare and Medicaid Programs: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," April 15, 2025 (90 Fed. Reg. 15834). See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.

their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

The MTF DM is intended to accomplish the following tasks in the administration of the Negotiation Program: (1) support verification that the selected drug was dispensed to an MFP-eligible individual and furnish the manufacturer with certain claim-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual and identifying the dispensing entity that dispensed the selected drug to the MFP-eligible individual; (2) initiate the 14-day prompt MFP payment window for the Primary Manufacturer to transmit certain claim-level payment elements and, if applicable, the MFP refund for each claim for a selected drug; (3) collect such payment elements for each claim for a selected drug from Primary Manufacturers indicating whether a refund is being paid and the amount of the refund being paid to make the MFP available, if applicable; and (4) make available an ERA for electronic payments or a remittance for payment made by paper check to dispensing entities for payments the Primary Manufacturer passes through the MTF PM.

For illustrative purposes, Figure 2 depicts a basic conceptual overview of the currently anticipated mandatory MTF DM data flow for drugs covered under Part D. CMS will leverage Part D claims data (PDE data) in this data exchange. CMS may revisit the data flow in the future and anticipates technical specifications to evolve as development of the MTF DM's data functionality and information systems progress. Although Figure 2 illustrates data flow for Part D drug claims, as discussed in section 40.4 of this final guidance, CMS intends to also use the MTF to facilitate data exchange for drugs payable under Part B that are furnished or administered to MFP-eligible individuals and will provide more information in the future.

Figure 2: Diagram of MTF Data Flow



40.4.2.1 Primary Manufacturer Participation in the MTF DM

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering and monitoring compliance with the Negotiation Program, participation in the MTF DM is mandatory for Primary Manufacturers. CMS intends to require all Primary Manufacturers that reach an agreed upon MFP for initial price applicability years 2027 and 2028 to register with the

MTF DM by April 1 of the calendar year before the MFP would go into effect, beginning April 1, 2026; for example, Primary Manufacturers with MFPs that will take effect on January 1, 2027 will need to enroll by April 1, 2026. CMS also will require all Primary Manufacturers to maintain the functionality necessary to receive certain claim-level data elements from the MTF DM and return certain claim-level payment elements to the MTF DM. During registration, Primary Manufacturers will be required to furnish information necessary for the MTF DM to complete remittances and ERAs for refunds paid through the MTF PM by the Primary Manufacturer, including but not limited to bank account information if participating in the MTF PM, and to furnish information necessary for the MTF DM to support resolution of complaints and disputes, including circumstances where the Primary Manufacturer chooses not to pass payment through the MTF PM.

Each Primary Manufacturer will be required to sign user agreements to participate in the MTF; all Primary Manufacturers will be required to sign an MTF DM User Agreement[126] with CMS during the MTF DM enrollment process. Primary Manufacturers who elect to participate in the MTF PM will also be required to sign the Medicare Transaction Facilitator Payment Module Contractor Agreement (hereinafter the "MTF PM User Agreement") with the MTF PM Contractor. These MTF agreements establish the rights and responsibilities of all parties involved in the MTF. The MTF agreements contain data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF. The Primary Manufacturer will have one MTF DM User Agreement; if the Primary Manufacturer is the Primary Manufacturer of multiple selected drug(s) for which it agrees to MFPs, including, for example, selected drugs chosen for different initial price applicability years, the Primary Manufacturer will add all such selected drugs to the same signed MTF DM User Agreement. In the event the Primary Manufacturer transfers ownership of all NDAs or BLAs of a selected drug following the process established in section 40.7 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable, the transferring Primary Manufacturer's MTF agreement(s) will terminate as to that transferred selected drug in accordance with the terms of the MTF DM User Agreement and, if applicable, the MTF PM User Agreement. In accordance with the terms of the MTF DM User Agreement, the new acquiring Primary Manufacturer will assume responsibility as the Primary Manufacturer of such selected drug and will be required to sign an MTF DM User Agreement if the Primary Manufacturer does not currently hold an MTF DM User Agreement, or will be required to add the acquired selected drug to an existing MTF DM User Agreement. The transferring Manufacturer must provide CMS at least 30 days written notice before the effective date of any transfer of ownership covered by the MTF DM User Agreement.

If the Medicare Drug Price Negotiation Program Agreement with respect to a selected drug is terminated in accordance with section 40.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable, the MTF DM User Agreement will automatically terminate with respect to such selected drug effective as of the effective date of termination of the Medicare Drug Price Negotiation Program Agreement with

[126] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/medicare-transaction-facilitator-general-resources.

respect to such selected drug. Termination of the MTF DM User Agreement as to a particular selected drug will not affect other selected drug(s) covered by the agreement. Termination of the MTF DM User Agreement as to a selected drug will not affect the Primary Manufacturer's responsibility for effectuating the MFP for dispenses of such selected drug to MFP-eligible individuals with a date of service before the effective date of the termination of the MTF DM User Agreement with respect to such selected drug, except in cases where the Primary Manufacturer has transferred ownership of the selected drug(s) as discussed above (in which case the acquiring Primary Manufacturer is responsible for effectuating MFP for such dispenses).

Notwithstanding the termination of the MTF DM User Agreement with respect to a selected drug, certain requirements and obligations shall survive termination as specified in the MTF DM User Agreement. Because there is a runout of claims for selected drugs dispensed prior to the effective date of termination for which the Primary Manufacturer remains responsible under the statute for providing access to the MFP (except in cases where the Primary Manufacturer has transferred ownership of the selected drug(s) to an acquiring Primary Manufacturer as discussed above), the Primary Manufacturer will still have access to the MTF to address any claims with dates of service prior to termination until such claims are resolved.

As described in sections 40.4.3 and 40.4.4 of this final guidance, all Primary Manufacturers will be required to utilize MTF DM data functionality to report to the MTF DM information (claim-level payment elements) about how the Primary Manufacturer has made the MFP available for each claim for which the Primary Manufacturer received data from the MTF DM, or why no MFP refund payment has been made on a claim. These data exchange requirements apply to each Primary Manufacturer irrespective of how the Primary Manufacturer effectuates the MFP (i.e., through prospective sales of a selected drug to a dispensing entity, either directly or through the supply chain, or through a retrospective refund to a dispensing entity, which may be facilitated by the MTF PM as described in section 40.4.3 of this final guidance or through another payment facilitation method of the Primary Manufacturer's choosing).

CMS acknowledges that a Primary Manufacturer may choose to contract with one or more third-party vendors to perform required operations on behalf of the Primary Manufacturer. Such required operations are discussed in this section 40.4.2.1 of this final guidance on the MTF data exchange and in sections 40.4.3 and 40.4.4 of this final guidance on retrospective refund payment. The Primary Manufacturer remains responsible for compliance with all Negotiation Program requirements notwithstanding any actions that third-party vendors may perform on the Primary Manufacturer's behalf.

Requiring Primary Manufacturers to exchange specified data with the MTF DM is necessary for several reasons. First, exchange of data with the MTF DM ensures a uniform approach to the start of the 14-day prompt MFP payment window for each claim for a selected drug. Second, requiring Primary Manufacturers to exchange claim-level data with the MTF supports the MTF DM in producing ERAs or remittances, as applicable, when the Primary Manufacturer transmits payments through the MTF PM (or to document that dispensed drugs were prospectively purchased at MFP). Third, the Primary Manufacturer exchange of claim-level payment information supports CMS in monitoring the extent to which the Primary Manufacturer has made MFP available, pursuant to CMS' obligation under section 1196(b) of the Act to monitor

Primary Manufacturers' compliance with the terms of the Agreements. Failure by the Primary Manufacturer to register with the MTF DM or to meet the MTF data exchange requirements, including maintaining functionality to receive certain claim-level data elements from the MTF DM and transmission of claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, would be a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act (see section 100.2 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable).

The claim-level data elements for Part D claims for NDCs of a selected drug that the MTF DM will send to the Primary Manufacturer are listed in Table 2. These data will be exclusively transmitted through the MTF DM to the Primary Manufacturer or its designated third-party vendor. In selecting the claim-level data elements that will be sent to Primary Manufacturers, CMS considered numerous data elements recommended by interested parties, such as an encrypted beneficiary identification number and claim reimbursement amounts. CMS believes that the selected data elements provide the minimum necessary information to verify the selected drug was dispensed to an MFP-eligible individual.

Table 2: MTF DM Claim-Level Data Elements

MTF DM Data Elements List	Purpose	Data Source
Record ID	Identifies the type of record, such as claim detail, file header, and file trailer	MTF
MTF Internal Claim Number (ICN)	Identifies the internal unique identifier assigned by the MTF to support claim adjustments	MTF
MTF XRef ICN	Links an adjustment to previous MTF ICN	MTF
Process Date	Identifies MTF processed date	MTF
Transaction Code	Indicates original claim, adjustment, reversal, MTF DM enrollment status of dispensing entity, etc.	MTF
Medicare Source of Coverage	Identifies coverage under Medicare Part B or Part D	MTF
Date of Service	Verifies MFP eligibility	PDE Record

MTF DM Data Elements List	Purpose	Data Source
Service Provider Identifier Qualifier	Verifies MFP eligibility	PDE Record
Service Provider Identifier	Verifies MFP eligibility	PDE Record
Prescription/Service Reference Number	Verifies MFP eligibility	PDE Record
Prescriber ID	Identifies prescriber	PDE Record
Prescriber ID Qualifier	Identifies prescriber	PDE Record
Fill Number	Verifies MFP eligibility	PDE Record
Product/Service Identifier	Verifies MFP eligibility	PDE Record
Quantity Dispensed	Assists the manufacturer in calculating a refund	PDE Record
Days' Supply	Assists the manufacturer in calculating a refund	PDE Record
340B Claim Indicator (as voluntarily reported by dispensing entity)	Assists the manufacturer in assessing applicability of section 1193(d)(1) of the Act	PDE Record
Contract Number	Verifies MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) Per Unit on Date of Service of Claim	Provides list price on claim date of service	MTF
Maximum Fair Price (MFP) Per Unit on Date of Service of Claim	Assists the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (SDRA) ((WAC-MFP) x Quantity Dispensed)	Assists the manufacturer in calculating a refund	MTF
Service Provider Payment Method Preference	Indicates dispensing entity's specified preference for	MTF

MTF DM Data Elements List	Purpose	Data Source
	payment via electronic transfer of funds or paper check	
Previous MFP Refund Paid Product/Service Identifier	Indicates product associated with the Previous MFP Refund Paid Amount, if applicable	MTF
Previous MFP Refund Paid Amount	Indicates refund amount previously paid by manufacturer for the claim, if applicable	MTF
Previous MFP Refund Paid Date	Indicates date associated with the Previous MFP Refund Paid Amount, if applicable	MTF
Previous MFP Refund Paid Quantity	Indicates quantity associated with the Previous MFP Refund Paid Amount, if applicable	MTF
Previous MFP Refund Paid Method for Determining MFP Refund Amount	Indicates basis for determining refund amount associated with the Previous MFP Refund Paid Amount, if applicable	MTF

The combination of "Date of Service," "Service Provider Identifier Qualifier," "Service Provider Identifier," "Prescription/Service Reference Number," and "Fill Number" identify unique Part D claims. Other data elements listed in Table 2 will provide additional information about each claim to the Primary Manufacturer that may be useful in calculating the retrospective refund, if applicable, including "Product/Service Identifier," "Quantity Dispensed," "Days' Supply," "Contract Number," "WAC Per Unit on Date of Service of Claim," and "MFP per unit on Date of Service of Claim."

Beginning January 1, 2025, the "Submission Clarification Code" value of "20" and the "Submission Type Code" value of "AA" was added to the PDE record to indicate a 340B claim.[127] A dispensing entity may voluntarily apply these indicators to a Part D claim to indicate the claim is being billed for a 340B drug.[128] The MTF's provision of the "340B Claim Indicator" data element does not represent or imply that CMS verified the 340B status of the claim nor that dispensing entities are required to include this code on claim submissions. The MTF will also

[127] See: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.
[128] In NCPDP *Telecommunications Standard F.2* and higher, the "Submission Clarification Code" 340B value has been moved to a new field ("Submission Type Code") and assigned a new value, "AA". See: https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.

include the field “Service Provider Payment Method Preference” to indicate to Primary Manufacturers if the dispensing entity responsible for the claim has indicated their preference to receive payment via electronic funds transfer or paper check (see section 40.4.3 of this final guidance for services that the MTF PM will provide to facilitate the transfer of funds between participating Primary Manufacturers and dispensing entities). “Prescriber ID” and “Prescriber ID Qualifier” reflect the National Provider Identifier (NPI) of the prescriber as listed on the claim, which may be useful (although not sufficient, as noted in section 40.4.5 of this final guidance) for 340B nonduplication efforts. “Transaction Code” will be populated by the MTF when sending claim-level data elements to Primary Manufacturers and by Primary Manufacturers when sending claim-level payment elements to the MTF. Further detail on use of the Transaction Code field will be provided in future guidance or technical instructions. The MTF will have additional data elements (i.e., “MTF internal claim number (ICN),” “Record ID,” “MTF XRef ICN,” “Process Date,” and “Medicare Source of Coverage”) that will assist in the facilitation of information on claim adjustments and reversals; further detail on claim adjustments and reversals is provided in sections 40.4.3.2 and 40.4.4.4 of this final guidance and will be provided in future guidance or technical instructions.

The claim-level data elements that the Primary Manufacturer will receive from the MTF DM will include the SDRA that will reflect the difference between the WAC per unit and the MFP per unit of the selected drug on the date of service, then multiplied by the quantity dispensed, as described in section 40.4.1 of this final guidance. Regardless of whether the Primary Manufacturer chooses to pass payment through the MTF PM, the Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP. The MTF DM’s provision of the SDRA claim-level data element does not supersede that responsibility or indicate that payment of such an amount will be sufficient for the Primary Manufacturer to meet its statutory obligation to make the MFP available. Rather, this claim-level data element is intended to provide an additional data point to assist the Primary Manufacturer in determining and paying an amount sufficient to make the MFP available consistent with the statute.

Lastly, the claim-level data elements that the Primary Manufacturer will receive from the MTF DM will include information about the previously paid MFP refund, if any, if an adjustment to a previously addressed claim is made. These data elements will show the Primary Manufacturer the MTF record for the immediate prior MFP refund payment made for the specific claim, if any.

See section 40.4.1 of this final guidance for additional detail regarding retrospective refunds and section 40.4.3 of this final guidance for additional detail on the voluntary MTF PM payment pass through services. As the approach for effectuating retrospective MFP refunds is further developed, additional data elements may be added to improve efficiency in processing these data.

The MTF DM will provide Primary Manufacturers with data that has been verified by both the Part D plan sponsor and DDPS, a CMS system used to process all Medicare PDE records and related data, resulting in dual verification of both an individual’s eligibility for Part D and Part D coverage of the selected drug for each claim being transmitted. When a Part D plan sponsor receives a claim for a selected drug from a dispensing entity, before making any payment, the Part D plan sponsor verifies that the beneficiary listed on the claim is enrolled in Medicare Part

D and coverage is provided under Part D for the dispensed drug. After the Part D plan sponsor verifies Medicare eligibility and coverage of the selected drug, the plan pays the dispensing entity no more than the MFP plus any dispensing fees for the selected drug. Then, the Part D plan sponsor sends the data on the Part D claim as a PDE record to DDPS.[129]

CMS, using DDPS, also performs verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim. After CMS verifies MFP eligibility for the individual related to the claim, DDPS will transmit the PDE record for the Part D claim for the selected drug to the MTF DM, which will prepare the file of claim-level data elements listed in Table 2 for MFP-eligible claims for transmittal to the applicable Primary Manufacturer.[130] The MTF DM also will confirm that NDCs on PDE records received from DDPS appear on the list of NDCs for the selected drug maintained in the CMS HPMS prior to sending to the Primary Manufacturer. Therefore, because MFP eligibility status of the individual has been twice validated, by the plan sponsor and DDPS, and the selected drug NDC has been validated by the MTF DM before the data elements are sent from the MTF DM to the Primary Manufacturer, the data elements will have been verified as involving a selected drug that was dispensed to an individual who is MFP-eligible.

Data validation edits are applied against PDE data submitted to DDPS to ensure the information accepted by the system is in accordance with statute, regulation, and program guidance and instruction. PDE records are deemed final action once all DDPS edits are resolved. CMS recognizes that certain DDPS edits do not directly relate to verification of the MFP eligibility of a claim for the purposes of the Negotiation Program, such as edits related to the Manufacturer Discount Program. For administrative efficiency and to minimize new reporting obligations on manufacturers and dispensing entities, CMS decided to leverage the existing PDE data flow to support verification of MFP eligibility through the MTF DM data exchange.

While PDEs include a wide range of data that is necessary for Part D plan sponsor payment purposes, only a subset of the PDE data is directly relevant to and necessary for verifying that a selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual. Requiring all DDPS edits to be resolved before the PDE data is used by the MTF DM to generate and transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window would delay transmission to the Primary Manufacturer of claims that have been verified as a dispense of the selected drug to an MFP-eligible individual, which in

[129] Currently, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. CMS finalized in rulemaking a change effective in contract year 2026 to shorten the current 30-day window for plans to submit initial PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities. See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.

[130] At this time for 2026 and 2027, this file transmittal will exclude claim-level data elements from any PDE data with a compound code indicating the PDE record is for a compounded drug. CMS is exploring operational changes to the PDE record layout that would provide CMS with visibility into data on the quantity dispensed for a selected drug when that selected drug is billed as a compound, at which point such PDE record may be used to allow for inclusion in the claim-level data elements that are included in the file transmittal.

turn could cause financial hardship for dispensing entities by delaying payment of an MFP refund on such claim as Part D plans have up to 90 days to resolve DDPS edits.[131]

Therefore, CMS intends to maintain a list of DDPS edits that directly relate to the determination and verification of MFP eligibility for the purposes of the Negotiation Program, such as missing service provider ID or missing or invalid date of service, which will be posted on the CMS website. DDPS edits were identified as related to the determination and verification of MFP eligibility if they directly relate to the data elements listed in Table 2 in this final guidance, impact the verification of an individual as MFP-eligible in accordance with section 1191(c)(2) of the Act, or identify duplicate PDE records. The current list of DDPS edits CMS has identified as related to the determination and verification of MFP eligibility is in Appendix B of this final guidance.

CMS intends to process claims in the following manner:

1. If a claim does not have any DDPS edits, the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window.
2. If a claim, through DDPS processing, cleared all of the DDPS edits that are on CMS' list of edits directly related to MFP eligibility and only has DDPS edits that are not on such CMS list, the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window because it has been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual.
3. If a claim has DDPS edits that are on CMS' list of edits directly related to MFP-eligibility or has not yet cleared all of the DDPS edits that are on such CMS list of edits, the MTF DM will not transmit the claim-level data elements to the Primary Manufacturer because it has not been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual. The MTF DM will monitor for resolution of these edits. If all such edits directly related to MFP-eligibility are resolved within 90 days of the rejection, then the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window. If the edits are not resolved within this timeframe and the Primary Manufacturer participates in the MTF PM, the MTF DM will notify the dispensing entity that no refund payment has been paid for the claim through a remittance. If the edits are not resolved within this timeframe and the Primary Manufacturer does not participate in the MTF PM, the MTF DM will transmit claim-level data elements from the PDE record to the Primary Manufacturer and indicate it has unresolved DDPS edits directly related to MFP-eligibility. In this case, the claim-level data elements are transmitted for informational purposes only and therefore do not initiate the 14-day prompt MFP payment window and do not require the Primary Manufacturer to respond with claim-level payment elements. However, the Primary Manufacturer may notify the dispensing entity that no refund payment has been paid for the claim. If a subsequent PDE record for the claim indicates these edits are resolved, the

[131] In accordance with the timeliness standards established in 90 Fed. Reg. 15827 which appeared in the April 15, 2025 Federal Register, Part D sponsors must resolve rejected PDE records within 90 calendar days following the receipt of rejected record status from CMS. See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.

MTF DM will transmit the claim's data elements to the Primary Manufacturer and initiate the 14-day prompt MFP payment window.

Primary Manufacturers may not impose additional reporting requirements on dispensing entities to support MFP eligibility verification, regardless of whether the Primary Manufacturer utilizes the MTF PM. The provision of additional patient information (such as an encrypted "Medicare Beneficiary Identifier") by the MTF DM will not help the Primary Manufacturer to verify the selected drug was dispensed to an MFP-eligible individual because the Primary Manufacturer would also need access to the individual's Medicare eligibility status to verify eligibility. That information is stored with the Medicare plans and DDPS. As stated above, the claim-level data elements will be derived from claims that have been verified for Medicare eligibility by both the Part D plan and DDPS, obviating the need for additional verification by the Primary Manufacturer. In addition, providing additional specific information on individual beneficiaries that constitutes PII or PHI could increase privacy and security risks, even with the use of an encrypted identifier. As a point of reference, the Manufacturer Discount Program, which also sends data elements to manufacturers for the purposes of determining manufacturers' payment obligations, does not provide specific information that identifies individual enrollees.

Once the data has been verified by the Part D plan sponsor and DDPS, and the MTF DM has verified that a claim has no DDPS edits directly related to MFP-eligibility, the MTF DM will make the claim-level data elements listed in Table 2 available to the Primary Manufacturer to notify them that the selected drug was dispensed to an MFP-eligible individual. Claim-level data will be batched across all claims available to the MTF DM as received for all NDCs for the selected drug.

The MTF DM's transmission of the claim-level data elements to the Primary Manufacturer starts the 14-day prompt MFP payment window, within which the Primary Manufacturer must transmit the claim-level payment elements (described further in sections 40.4.3 and 40.4.4 of this final guidance) for each claim identified in the claim-level data elements that the MTF DM transmits to the Primary Manufacturer and, if applicable, must transmit payment of an amount that provides access to the MFP when an MFP refund is appropriate. The date of transmission of the claim-level data elements from the MTF DM to the Primary Manufacturer is considered day 0 of the 14-day prompt MFP payment window. If a retrospective refund is required to effectuate the MFP, the Primary Manufacturer must transmit payment no later than 11:59 PM PT on day 14. The Primary Manufacturer will be considered to have transmitted payment within the 14-day prompt MFP payment window if either (1) when payment is passed through the MTF PM, the Primary Manufacturer sends the claim-level payment elements to the MTF DM on or before day 14 authorizing payment to the dispensing entity; or (2) when payment is made outside of the MTF PM, the Primary Manufacturer sends the claim-level payment elements to the MTF DM and sends the MFP refund amount to the dispensing entity on or before day 14.

Regardless of whether the Primary Manufacturer uses the MTF PM or not to make the MFP refund payment, under this definition, the transmission of payment is considered to have occurred when the Primary Manufacturer takes the last step on its part to make payment to the dispensing entity. In cases where the MTF PM is used, this final step for payment is the authorization via the payment elements for the MTF PM to send along payment to the dispensing

entity in the amount directed by the Primary Manufacturer. In cases where payment is made outside of the MTF PM, the final step is the Primary Manufacturer sending the MFP refund amount to the dispensing entity (e.g., electronically or by mailing a paper check) because the submission of payment elements alone will not result in the dispensing entity being paid without further action by the Primary Manufacturer. Failure to meet these obligations may cause the Primary Manufacturer to be subject to CMPs (see section 100 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable). If a Primary Manufacturer believes that there is an error with the claim-level data received, it can submit a dispute by following the process outlined in section 90.2.2 of this final guidance.

The Primary Manufacturer will be the sole manufacturer authorized to receive this claim-level data directly from the MTF DM about its selected drug and will be responsible for receiving such data for all NDCs of the selected drug subject to an MFP, including those marketed and sold by a Secondary Manufacturer. The Primary Manufacturer must ensure that any data sharing with and any activity by Secondary Manufacturer(s) or third-party vendors contracted by the Primary Manufacturer comply with applicable privacy and security laws, regulations, and CMS requirements to protect the claim-level data elements received from the MTF DM. The Primary Manufacturer also must ensure any activity by Secondary Manufacturer(s) complies with the requirements for the Primary Manufacturer to provide access to the MFP by ensuring an MFP refund reaches the dispensing entity when an MFP refund is appropriate, and the Primary Manufacturer must transmit reports with claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window.

Table 3 describes the timing and required actions of Primary Manufacturers to comply with the 14-day prompt MFP payment window based on the Primary Manufacturer's elected MFP effectuation method when making the MFP available through retrospective refunds. If the Primary Manufacturer has made the MFP available prospectively, then no subsequent payment is needed; however, the Primary Manufacturer is still required to submit its claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window.

Table 3: Primary Manufacturer Payment Approaches to MFP Effectuation

	Payment Passed Through MTF Payment Module (PM)	**Payment Made Outside the MTF Payment Module (PM)**	
Pathway Description	Passing MFP refund payments through the MTF PM	Typically passing MFP refund payments through the MTF PM, but has a mutually agreed upon separate payment arrangement with a dispensing entity	Not passing MFP refund payments through the MTF PM
Action to meet the 14-day prompt MFP payment window	Transmit claim-level payment elements to the MTF DM authorizing electronic fund transfer to and transmission of MFP refund payment by the MTF PM	Transmit the MFP refund payment to the dispensing entity, and transmit payment elements to the MTF DM once payment has been transmitted	
Deadline For Action	No later than 11:59 PM PT on Day 14 after the MTF DM transmits the claim-level data elements to the Primary Manufacturer, with the clock beginning (Day 0) on the day the MTF DM transmits the claim-level data to the Primary Manufacturer.		
Payment Transmission Date Recorded as:	The system-generated date and time the payment elements sent by the Primary Manufacturer are received by the MTF DM, authorizing electronic funds transfer to and transmission of MFP refund payment by the MTF PM	The date and time the MFP refund payment is transmitted from the Primary Manufacturer to the dispensing entity, as reported by the Primary Manufacturer in the claim-level payment elements*	
Result Following Action	MTF PM transmits MFP refund payment to the dispensing entity (electronically or via paper check)	MFP refund payment is required to be transmitted by the Primary Manufacturer prior to submission of claim-level payment elements. No required action by the MTF.	

* For MFP refunds via paper check, the payment transmission date should be recorded as the date on which the paper check was mailed.

40.4.2.2 Dispensing Entity Enrollment in the MTF DM

CMS finalized in rulemaking a requirement that Part D plan sponsors, starting in contract year 2026, include in their pharmacy agreements provisions requiring the pharmacy to be enrolled in

the MTF DM.[132] Dispensing entity enrollment in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and making available remittances or ERAs, maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are drugs covered under Part D, and ensuring accurate Part D claims information and payment. The MTF DM will provide dispensing entities with remittances or ERAs to reconcile MFP refund payments when a Primary Manufacturer chooses to pass payment through the MTF PM. For payments made outside of the MTF PM, CMS also plans to provide Primary Manufacturers with access to view information through the MTF portal, such as a dispensing entity's banking information, in order to support the Primary Manufacturer in making available to the dispensing entity an ERA or remittance, as applicable. Interested parties strongly requested that MFP refunds be accompanied by an ERA or remittance. The ERA or remittance connects claims payment determination and amount with how the payment was made, including the electronic funds transfer information, if applicable. Dispensing entities need an ERA or remittance to close out open accounts receivable for each claim for which a Primary Manufacturer owes an MFP refund.

CMS has developed a flexible, efficient enrollment process that accommodates various structures to (1) provide the MTF DM with bank account information and a secure location for creating and making available the ERA or remittance, as applicable; (2) maintain the accuracy of that information over time; and (3) maintain the functionality necessary to receive ERAs or remittances, as applicable. Information collected from the dispensing entity will support payment pass through both for the MTF PM and Primary Manufacturers choosing to operate their own payment arrangements. Information that dispensing entities will provide will include but not be limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or NPI; (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) deposit or account number with financial institution; (6) type of registered financial account; and (7) secure location for making available the ERA or remittance, as applicable.[133] Dispensing entities will also indicate their election of whether they prefer receiving payments through electronic funds transfers, which will be the default election for dispensing entities at the time of enrollment, or paper checks. This preference will be included on the claim-level data elements transmitted to all Primary Manufacturers, regardless of whether they participate in the MTF PM or not. If the MFP refund payment is passed through the MTF PM, then the MTF PM will transmit the Primary Manufacturer's payment to the dispensing entity in accordance with the dispensing entity's indicated preference. If the Primary Manufacturer declines to participate in the MTF PM and elects to establish its own payment

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[132] CMS, Final Rule, "Medicare and Medicaid Programs: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," April 15, 2025 (90 Fed. Reg. 15834). See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.

[133] CMS issued an information collection request titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" on October 28, 2024 for a 60-day comment period. In this ICR, CMS solicited feedback on all data fields necessary to provide accurate, timely ERAs or remittances for all MFP refund transactions and conduct general program administration and oversight. See: http://federalregister.gov/documents/2024/10/28/2024-25009/agency-information-collection-activities-proposed-collection-comment-request.

facilitation methods, then the Primary Manufacturer is required to provide an electronic reimbursement mechanism for dispensing entities that have indicated their preference to receive electronic transfer of funds. For dispensing entities that have indicated their preference to receive payment via paper check, the Primary Manufacturer would need to, at a minimum, ensure that paper checks are provided as a reimbursement mechanism. CMS published the Medicare Transaction Facilitator for Initial Price Applicability Year 2026 and 2027 ICR for a 60-day public comment period that closed on December 27, 2024. The ICR included details on information that dispensing entities will be required to provide. CMS published this revised ICR for 30-day public comment period on April 1, 2025.[134]

In response to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS received several comments from dispensing entities and their representatives expressing concern that the operations of the MTF and the timeline for the 14-day prompt MFP payment window would create delays in cashflow compared to the existing requirements for Part D prompt payment by plan sponsors. Commenters particularly noted that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund. Based on comments received, it has been described to CMS that this challenge will be most acute in the transition period when MFPs for selected drugs first become effective in January 2026 and at the start of each subsequent initial price applicability year when MFPs for new selected drugs first become effective (i.e., at the start of a price applicability period with respect to a selected drug). CMS does not anticipate this challenge to continue with respect to a selected drug once MFP refunds for that selected drug are flowing and dispensing entities become accustomed to the 14-day prompt MFP payment window.

CMS recognizes that the success of the Negotiation Program is, in part, dependent on Medicare beneficiaries' access to selected drugs through dispensing entities, which in turn necessitates that dispensing entities—particularly those that rely primarily on prescription revenue to maintain business operations—are able to timely access the MFP. Therefore, during the MTF DM enrollment, CMS will ask dispensing entities to self-identify whether they are a dispensing entity that anticipates having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. This information will be provided to Primary Manufacturers to assist in the development of their MFP Effectuation Plans, as described in section 90.2.1 of this final guidance. Consistent with section 1193(a)(5) of the Act and as described in section 90.2.1 of this final guidance, CMS will require Primary Manufacturers to include their approach to mitigating material cashflow concerns in their MFP Effectuation Plans.

Prior to the deadlines for the submission of MFP Effectuation Plans, CMS will provide Primary Manufacturers with a list of dispensing entities that have self-identified as anticipating material cashflow challenges. Primary Manufacturers may use this list to inform development and implementation of their mitigation processes for addressing material cashflow concerns. For example, CMS expects dispensing entities of the types that have raised material concerns about

[134] See: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202503-0938-001.

cashflow related to the effectuation of MFP—such as sole proprietor rural and urban pharmacies with high volume of Medicare Part D prescriptions dispensed, pharmacies who predominantly rely on prescription revenue to maintain business operations, long-term care pharmacies, 340B covered entities with in-house pharmacies, and Indian Health Service, Tribal, and Urban Indian (I/T/U) pharmacies—may self-identify through this process. CMS expects that the requirement that Primary Manufacturers establish mitigation processes for addressing these material cashflow challenges will better enable them to work with dispensing entities to ensure continued beneficiary access to their selected drugs. CMS will evaluate the degree to which this pharmacy self-identification process provides useful data for Primary Manufacturers in developing MFP Effectuation Plans and may reconsider this approach in the future.

Dispensing entities will need to certify that information provided to the MTF DM is accurate and up to date. CMS will require each dispensing entity enrolling in the MTF DM to sign an MTF DM User Agreement with CMS during the enrollment process. This agreement will include provisions such as data use, privacy, and security requirements for engaging with the MTF DM. This agreement also will include requirements for collecting, using, sharing, and safeguarding financial information. During enrollment, independent dispensing entities may elect to receive payment through a third-party vendor, such as a pharmacy services administrative organization (PSAO) or reconciliation vendor, and will be required to indicate that payment should be issued to such party as part of the enrollment process.

CMS expects that dispensing entities would maintain records accounting for any refunds owed to them by a Primary Manufacturer should there be a payment discrepancy for which they engage in the dispute or complaint resolution process set forth in section 90.2.2 of this final guidance. As the approach for creating and making available ERAs or remittances, as applicable, to dispensing entities is further developed, additional requirements for dispensing entities may be necessary to support making this information available.

To assist dispensing entities in reconciling MFP refund payments, regardless of a Primary Manufacturer's election to use the MTF PM to pass through payment, CMS expects Part D plan sponsors to include SDRAs on all Part D claims for selected drugs with a negotiated MFP in effect. The National Council for Prescription Drug Programs (NCPDP) provides instruction to Part D plans sponsors regarding this new message, which will furnish dispensing entities with an estimate of the manufacturer MFP refund amount equal to the SDRA as calculated by the plan sponsor. If the SDRA accurately reflects the dispensing entity's acquisition costs, a dispensing entity may use this estimated amount to create an accounts receivable. NCPDP furnishes additional direction to plan sponsors on implementing the SDRA on the claim response. The SDRA is an estimate and is not a guarantee of payment of an MFP refund by a Primary Manufacturer or an indication that payment of a refund amount equal to the SDRA will be sufficient to provide access to the MFP. The Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP, and there are situations where an MFP refund may not be applicable (e.g., the selected drug was purchased prospectively at or below the MFP) or the SDRA may be insufficient to provide access to the MFP.

Dispensing entities are encouraged to remediate with the manufacturer directly if they believe that they have not received a retrospective refund payment that effectuates the MFP. If remediation between the parties cannot be reached, Primary Manufacturers and dispensing entities may use the complaints process, within the complaint and dispute system, as described in section 90.2.2 of this final guidance, so that CMS is alerted to situations where MFP may not have been made available.

40.4.3 MTF Payment Facilitation

CMS has received many requests from a variety of interested parties, including dispensing entities, manufacturers, and other interested parties in the pharmaceutical supply chain, to support the facilitation of MFP refund payments between Primary Manufacturers and dispensing entities. These requests have included the establishment of MTF payment facilitation functionality (i.e., the MTF PM) to assist Primary Manufacturers and dispensing entities in effectuating payment between parties in a reliable, predictable, and consistent manner without incurring significant burden or cost.

Interested parties commented to CMS that drug manufacturers do not generally provide payments directly to dispensing entities and that a direct means to provide payments typically does not exist. Currently, most transactions are processed through third-party vendors, such as wholesalers and distributors. After publication of the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS received significant feedback from interested parties urging the establishment of a payment facilitation mechanism that would create standardization, predictability, and reduced burden for all parties. In response to comments, CMS considered whether a new framework could support manufacturers in furnishing MFP refund payments to dispensing entities on claims for selected drugs to MFP-eligible individuals.

CMS has engaged with an MTF Contractor to develop the MTF payment functionality through the MTF PM as a mechanism to facilitate the transfer of MFP refund payments from participating Primary Manufacturers to dispensing entities. Participation in the MTF PM will be voluntary for Primary Manufacturers, which will have the option of passing MFP refund payments to dispensing entities through the MTF PM or using their own processes outside of the MTF PM. If the Primary Manufacturer participates in the MTF PM, the Primary Manufacturer and dispensing entity remain free to reach an agreement to use a mutually agreed-upon process outside of the MTF PM to pay MFP refunds. As discussed in section 40.4.3.3 of this final guidance, the MTF PM will not require an affirmative election of participation by dispensing entities for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer.

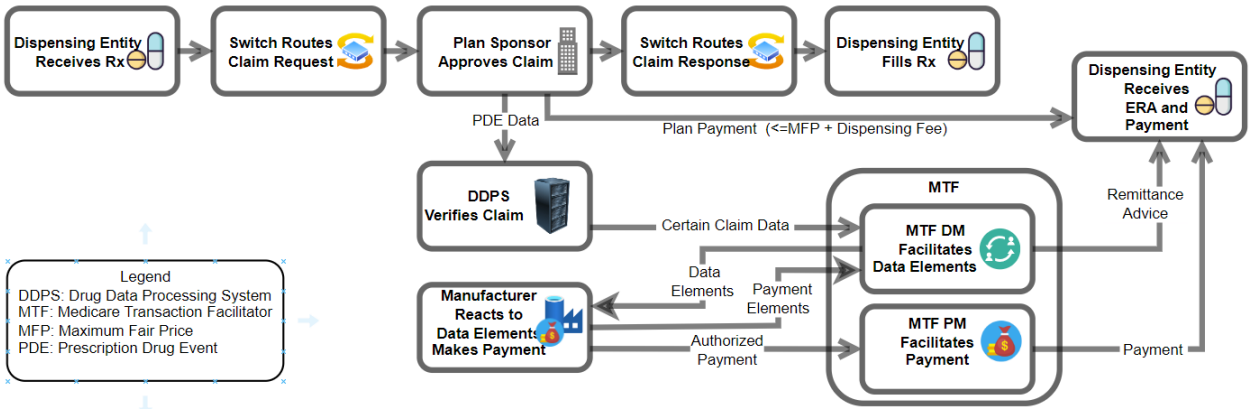
The provision of voluntary MTF payment facilitation services through the MTF PM does not supersede or alter the Primary Manufacturer's obligation under section 1193(a)(3)(A) of the Act to provide access to the MFP to dispensing entities for MFP-eligible individuals who are dispensed selected drugs. While the statute does not provide CMS with an express role in effectuating the MFP, CMS intends for the MTF PM to serve in a ministerial, facilitating role

that would assist Primary Manufacturers in meeting their statutory obligations by passing through refund payments paid by participating Primary Manufacturers to dispensing entities.

The purpose of the voluntary MTF PM is to connect the Primary Manufacturer to the dispensing entity and to facilitate transmission of an MFP retrospective refund on MFP-eligible claims of selected drugs from the Primary Manufacturer to the dispensing entity in accordance with section 1193(a)(3) of the Act. The MTF PM will (1) provide Primary Manufacturers with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments to dispensing entities; and (2) provide Primary Manufacturers with a credit/debit ledger system to track the flow of MFP refunds and to handle reversals, adjustments, and other claim revisions inevitable in a dynamic claim payment system.

CMS expects that most Primary Manufacturers will participate in the MTF PM, given prior feedback requesting a single platform for facilitating MFP refund payments. The combined data and payment facilitation functionality present in the MTF DM and the MTF PM discussed here, and depicted in Figure 3 below, attempts to address the interests expressed by dispensing entities and manufacturers in a single platform for transmitting MFP refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments. Figure 3 represents the flow of data and payment for a claim where the Primary Manufacturer participates in the MTF PM and chooses to pass the MFP refund payment to the dispensing entity through the MTF PM. Even if the Primary Manufacturer elects to participate in the MTF PM, the Primary Manufacturer and dispensing entity may establish a mutually agreed-upon process for effectuating the MFP outside of the MTF PM. The payment process will be different than the payment flow depicted in Figure 3 if the Primary Manufacturer elects not to participate in the MTF PM or if the Primary Manufacturer participates in the MTF PM, but the MFP refund payment for a particular claim is effectuated through a mutually agreed-upon process outside of the MTF PM. Although Figure 3 illustrates the MTF payment flow for Part D drug claims, as discussed in section 40.4 of this final guidance, CMS intends to offer the MTF to facilitate payment exchange for drugs payable under Part B that are furnished or administered to MFP-eligible individuals and will provide more information in the future.

Figure 3: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM



As stated above, the MTF PM's ministerial role as a mechanism for facilitating the pass-through of MFP refund payments from a participating Primary Manufacturer to dispensing entities will not supersede or alter the Primary Manufacturer's statutory obligation to effectuate the MFP. As described in section 90.2 of this final guidance, the Primary Manufacturer is required to establish a process to ensure the MFP is made available to MFP-eligible individuals and dispensing entities, and neither CMS nor its MTF Contractors will determine the amount of payment the Primary Manufacturer chooses to transfer through the MTF PM. Moreover, the MTF PM's transfer of the Primary Manufacturer's authorized MFP refund payment to a dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity and shall not otherwise discharge the Primary Manufacturer's statutory obligation to make the MFP available. Neither CMS nor its MTF Contractors will assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, the MTF Contractors will perform a ministerial function at the behest and direction of the participating Primary Manufacturer with respect to the pass through of the Primary Manufacturer's funds in the amounts and to the dispensing entities identified by the Primary Manufacturer in its claim-level payment elements.

Because the MTF PM will only pass payments between Primary Manufacturers and dispensing entities, under no circumstances will federal funds be used for these transactions or to resolve or make payment related to disputes that may arise between parties when the MTF PM is utilized, including with respect to nonpayment or insufficient payment by a particular party. Additionally, CMS will not float or issue funds to a dispensing entity on the Primary Manufacturer's behalf in anticipation of a future MFP refund payment from the Primary Manufacturer to the dispensing entity. CMS expects and encourages interested parties to work together as necessary to develop mechanisms to ensure timely effectuation of MFP refund payments consistent with statute, CMS' guidance, and all other applicable laws, regulations, and guidance, including without limitation the Anti-Kickback Statute. For example, the following approaches might be pursued by interested parties to provide timely payment, potentially focused on dispensing entities that self-identify as anticipating having material cash flow concerns at the start of the initial price applicability year, and all of which could be paired with retrospective reconciliation once the Primary Manufacturer receives claim-level data elements from the MTF DM: (1) Primary Manufacturers could make prospective sales of selected drugs to dispensing entities at the MFP while leveraging virtual inventory management systems and pharmaceutical wholesaler chargebacks where applicable; (2) Primary Manufacturers could establish pre-funded MFP refund payment accounts directly with dispensing entities; and/or (3) Primary Manufacturers could leverage established relationships between dispensing entities and PSAOs to establish accounts that are pre-funded by the Primary Manufacturer for the PSAOs to use to disburse MFP refund payments to dispensing entities, with the PSAOs facilitating any necessary financial, reconciliation, and administrative services for the dispensing entity, thus minimizing the number of point of contacts for the Primary Manufacturer. Neither CMS nor the MTF Contractors will be responsible for funding or paying the refund amounts owed by the Primary Manufacturer in instances where the Primary Manufacturer does not pay an MFP refund owed to a dispensing entity, including in cases where the Primary Manufacturer may be unable to pay (e.g., bankruptcy, insolvency, etc.). Neither CMS nor its MTF Contractors will accrue any interest on funds held by the MTF PM during the period before the funds are transferred to the dispensing

entity (or returned to the Primary Manufacturer in the event of unclaimed funds, as discussed below). The MTF PM will serve only as a mechanism to transfer funds of the Primary Manufacturer to dispensing entities as directed by the Primary Manufacturer in the amounts authorized by the claim-level payment elements transmitted by the Primary Manufacturer and will not collect funds for any other use. Separately, neither Primary Manufacturers nor dispensing entities shall be required to pay any fees to the MTF PM in connection with the pass through of MFP refund payments, including but not limited to user fees or transaction fees, as CMS intends to bear the cost of operationalizing the MTF PM.

Scenarios may arise where the MTF PM is responsible for temporarily holding unclaimed funds, for example, a dispensing entity ceases operations, yet the MTF PM still receives MFP refund payments designated for that dispensing entity. In the scenario described, unclaimed funds will be returned to the Primary Manufacturer. For Primary Manufacturers that elect to participate in the MTF PM, the return of unclaimed funds may also include scenarios where the MTF PM issues a check to a dispensing entity that has elected to receive MFP refund payments in the form of a paper check, but the dispensing entity has not deposited the issued paper check in the requisite time frame outlined by the MTF PM Contractor. In the described scenario the check shall be made void and funds returned to the Primary Manufacturer. Any disputes related to unclaimed funds will be reconciled directly between the Primary Manufacturer and the dispensing entity.

Primary Manufacturers that elect to use the MTF PM to pass through payments will be required to execute the MTF PM User Agreement with the MTF PM Contractor outlining each party's rights, responsibilities, and potential liabilities associated with the transfer and receipt of funds through the MTF PM.[135] Issues arising from the operational work of facilitating MFP refund payments via the MTF will be resolved in accordance with MTF technical instructions and user guides, and aligned with the applicable MTF agreements. CMS does not assume responsibility for any liability arising from the performance of MTF PM activities.

To participate in the MTF PM, a Primary Manufacturer will indicate to CMS its intention to use the MTF PM as part of the Primary Manufacturer's written plan for effectuating the MFP, described in section 90.2.1 of this final guidance. At the time of enrollment in the MTF DM,[136] the Primary Manufacturer will be provided with an opportunity to participate in the MTF PM. If the Primary Manufacturer elects to enroll in the MTF PM, it will participate in the MTF PM for all its selected drugs and typically with all dispensing entities. However, if a Primary Manufacturer elects to participate in the MTF PM, nothing about the MTF PM User Agreement precludes a Primary Manufacturer from establishing a mutually agreed-upon process for effectuating the MFP outside of the MTF PM with dispensing entities. The Primary Manufacturer will transmit MFP refund payments through the MTF PM Contractor and agree to the MTF PM terms and conditions as outlined in the MTF PM User Agreement. The Primary Manufacturer will also have the option to delegate to a third-party vendor the function of issuing MFP refund payments via the MTF PM and reporting claim-level payment elements, as

[135] See: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program.

[136] As outlined in section 40.4.2 of this final guidance, enrollment in the MTF DM is required of Primary Manufacturers to receive claim-level data elements and to report claim-level payment elements back to the MTF.

described in section 40.4.3.1 of this final guidance, if the manufacturer intends to contract out the management of those activities to a third-party vendor to interface with the MTF PM. However, the Primary Manufacturer will be the sole entity authorized to participate in the MTF PM for its selected drug, and it will be the sole entity permitted to authorize a contracted third-party vendor to support it in performing its required activities of reporting claim-level payment elements and transmitting MFP refund payments through the MTF PM. Notwithstanding any delegation to a third-party vendor, the Primary Manufacturer remains ultimately responsible for calculating the appropriate amount to effectuate the MFP and ensuring that timely access to the MFP is made available to dispensing entities.

Section 40.4.3 of this final guidance addresses what is required of a Primary Manufacturer that elects to pass payments through the MTF PM and section 40.4.4 of this final guidance addresses what is required of a Primary Manufacturer when the MFP refund payment is not passed through the MTF PM either because the Primary Manufacturer chooses not to participate in the MTF PM or the Primary Manufacturer participates in the MTF PM, but has an agreement with the dispensing entity to make payments outside the MTF PM with respect to that dispensing entity. Sections 40.4.3 and 40.4.4 of this final guidance discuss the Primary Manufacturer's reporting requirements under each scenario, respectively.

40.4.3.1 Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When Primary Manufacturer Passes Payment through the MTF PM
Reporting of claim-level payment elements is required regardless of whether the Primary Manufacturer elects to participate in the MTF PM. This section outlines the reporting of claim-level payment elements to the MTF DM that is required of a Primary Manufacturer when passing MFP refund payments through the MTF PM. The reporting of claim-level payment elements that is required of a Primary Manufacturer that does not elect to participate in the MTF PM and issues payments outside of the MTF PM is described in section 40.4.4 of this final guidance. If a Primary Manufacturer and dispensing entity establish a mutually agreed-upon method for effectuating the MFP outside of the MTF PM, regardless of the Primary Manufacturer's participation status in the MTF PM, the Primary Manufacturer will be required to provide the claim-level payment elements described in section 40.4.4 of this final guidance for transactions made outside of the MTF PM.

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering the Negotiation Program and monitoring compliance with the requirement to provide access to the MFP, the Primary Manufacturer will be required to transmit claim-level payment elements to the MTF DM within 14-days after the MTF DM sends the claims-level data elements in Table 2 to the Primary Manufacturer regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer, or whether access to the MFP is provided prospectively or retrospectively. Among other things, the claim-level payment elements will be used to create an ERA or remittance, as applicable, that the MTF DM will make available to the dispensing entity for Primary Manufacturers that pass payments through the MTF PM (unless the MFP is effectuated between parties outside of the MTF PM, in which case the MTF DM will not make an ERA or remittance available). Due to the anticipated high volume of claims for selected drugs, CMS anticipates that Primary Manufacturers may engage a third-party vendor and/or automate the transmission of claim-level payment elements to the MTF DM. Primary

Manufacturers remain responsible for ensuring that reported claim-level payment element information is accurate and submitted on a timely basis.

For all claim-level data elements that are transmitted by the MTF DM to the Primary Manufacturer (regardless of whether a refund is paid, and regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer), Primary Manufacturers will be required to report claim-level payment elements that include: (1) the corresponding claim-level data elements previously transmitted by the MTF DM, listed in Table 2 in section 40.4.2 of this final guidance; and (2) the claim-level payment elements listed in Table 4 below associated with each claim within 14 days of receipt of the claim-level data elements in Table 2. The claim-level data elements and corresponding claim-level payment elements for each MFP eligible claim shall be returned in a single response file to the MTF DM. Claim-level payment elements will include the MTF PM facilitation indicator, the method for determining the MFP refund amount, the amount of payment sent as the MFP refund, and claim-level data elements for inclusion in the ERA or remittance made available to dispensing entities when Primary Manufacturers choose to pass payment through the MTF PM. CMS notes that two claim-level payment elements, NPI of the Entity Receiving the MFP Refund and Quantity of Selected Drug, established in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 were removed from this final guidance to eliminate redundancy with the two corresponding claim-level data elements. As CMS further develops the approach for creating and making available ERAs and remittances to dispensing entities and operational technical specifications, CMS may add claim-level payment elements.

If the Primary Manufacturer is unable to transmit the claim-level payment elements, for example, if there is a technical breakdown in the transmission process, the Primary Manufacturer must continue to attempt to transmit the claim-level payment elements in good faith until successful transmission of the claim-level payment elements and must maintain documentation of the Primary Manufacturer's good faith effort in case there is a related complaint or dispute.

The Primary Manufacturer's transmission of claim-level payment elements to the MTF DM will indicate to the MTF PM the amount of MFP refund payment that the Primary Manufacturer authorizes for the MTF PM to pass through to the dispensing entity following receipt of the claim-level data elements received. The claim-level payment elements also act as the Primary Manufacturer's authorization for the MTF DM to send the payment instruction to the MTF PM to pass through payment for applicable claims. CMS expects MFP refund payments for MFP-eligible claims paid through the MTF PM to occur following Primary Manufacturer authorization of such payment by transmitting the claim-level payment elements. Additional information on timing of MTF PM payment processing will be available as CMS continues to evolve technical specifications. CMS intends to prioritize expeditious pass through of payment to the dispensing entity as it builds the MTF PM and engages the MTF PM Contractor. For payments made through the MTF PM, the MTF DM will timestamp the receipt of the claim-level payment elements when transmitted by the Primary Manufacturer to the MTF DM. Failure by the Primary Manufacturer to transmit all claim-level payment elements to the MTF DM consistent with the timing of the 14-day prompt MFP payment window will be considered a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act (see section 100 of the revised guidance for

initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable).

Table 4: Example Manufacturer Claim-Level Payment Elements List for Primary Manufacturers Passing Payment through the MTF PM[137]

Payment Elements	Purpose
MTF PM Facilitation Indicator	Indicates whether transmission of the MFP refund should be facilitated through the MTF PM
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5).
Amount of Payment to be Transmitted as the MFP Refund by the MTF PM	Indicates the amount the MTF PM should pay to the dispensing entity, prior to the application of any credits.
Transaction Code[138]	Indicates if the MFP refund payment is in response to an original claim, or if it is an adjustment or reversal to a previously submitted set of claim-level payment elements.

CMS understands there are several reasons why a given claim provided to the Primary Manufacturer may not receive a retrospective MFP refund or may receive an MFP refund equal to an amount other than the SDRA. For example, the Primary Manufacturer and the dispensing entity may have an arrangement in place where the selected drug is prospectively purchased by the dispensing entity at or below the MFP. To account for such scenarios, the Primary Manufacturer will be required to report a mandatory claim-level payment element, "Method for Determining MFP Refund Amount," to be populated with one of several pre-identified justification codes indicating whether the MFP refund payment was made using the SDRA, a different amount, or the reason an MFP refund payment was not provided.[139] Examples of these justification codes, listed in Table 5, include codes indicating the drug was prospectively purchased at or below the MFP; the Primary Manufacturer and dispensing entity have a separately negotiated refund amount distinct from the SDRA; or the claim is excluded from MFP refunds under section 1193(d)(1) of the Act. CMS believes that identifying standardized justifications for the claim-level payment elements will allow Primary Manufacturers to establish

[137] These elements are representative examples only, and CMS will provide the exact claim-level payment elements in forthcoming guidance or technical instructions as operations develop.

[138] Transaction Code is the same field received in the claim-level data elements from the MTF DM. Primary Manufacturers will update the Transaction Code field before submitting claim-level payment elements to the MTF DM.

[139] Nothing in this section precludes a Primary Manufacturer and a dispensing entity from reaching agreements outside of the MTF to establish an adjusted refund amount based on the dispensing entity's acquisition costs, which could be paid by the Primary Manufacturer through the MTF PM or through an alternative process outside of the MTF PM that is mutually agreed upon by the parties.

efficient processes to provide such information to the MTF. CMS intends to work with interested parties to add justification codes, if necessary, to meet reporting needs.

When a Primary Manufacturer reports a code other than "1" for the "Method for Determining MFP Refund Amount" claim-level payment element, it will be required to maintain supporting documentation as outlined in section 90.2.1 of this final guidance, demonstrating why the MFP refund was provided at an amount other than the SDRA, or was not provided, for the applicable claim. This documentation is described in further detail in section 90.2 of this final guidance.

Table 5: Examples of Justification Codes and Values for the "Method for Determining MFP Refund Amount" Claim-Level Payment Element for Primary Manufacturers[140]

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this final guidance)
1	Standard Default Refund Amount Transmitted	Record of successful payment to the MTF PM.
2	Amount Other than Standard Default Refund Amount Transmitted	Documentation could include: invoices from the dispensing entity, a contractual outside agreement with the dispensing entity establishing an acquisition cost agreed to between the Primary Manufacturer and the dispensing entity, or other evidence of the dispensing entity's acquisition cost for the selected drug and proof of successful MFP refund payment.
3	No Refund Transmitted – Prospective MFP Access	Invoice documentation of the drug sold at or below MFP, or an outside agreement between the Primary Manufacturer and dispensing entity establishing prospective purchasing of the selected drug at or below MFP.

[140] CMS will issue and maintain the exact codes to be used in future guidance or technical instructions, including further guidance on what to submit if not populating a code in a specific field. Some codes will not be relevant for payments transmitted through the MTF PM and will only apply to payments transmitted outside the MTF PM, or situations where payment is not made, as discussed in section 40.4.4 of this final guidance.

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this final guidance)
4	No Refund Transmitted – Section 1193(d)(1) Exception	• At a minimum, either records from the Primary Manufacturer's process for ensuring 340B nonduplication of claims and the conclusion reached for the claim, where the process has demonstrated a valid and reliable method to accurately identify 340B eligibility, or demonstrated confirmation from a 340B covered entity or from any vendor/third-party administrator that the 340B covered entity employs to determine 340B eligibility status. • Documentation that the 340B ceiling price is less than MFP and the "Service Provider Identifier" matching the claim-level data elements the MTF DM transmitted to the Primary Manufacturer is for the covered entity or its contract pharmacy.
5	No Refund Transmitted – Payment Transmission Attempted but Unsuccessful	This code would be available in the event a Primary Manufacturer attempts to transmit an MFP refund to a dispensing entity outside of the MTF PM, using an alternative payment method, but is unable to complete the transmission. In these cases, the Primary Manufacturer must maintain documentation of all attempts to demonstrate that a good faith effort to provide an MFP refund was made.
6	No Refund Transmitted – Other	Documentation to justify the reason why no refund was transmitted that does not align with any other justification code.
7	Refund Transmitted Consistent with Alternative Reconciliation	Documentation of the Primary Manufacturer's GAAP-compliant method of accounting for claims reconciliation, and how that was used to calculate any transmitted refund.
8	Amount Other than Standard Default Refund Amount Transmitted – Section 1193(d)(2) Scenario	• At a minimum, either records from the Primary Manufacturer's process for ensuring 340B nonduplication of claims and the conclusion reached for the claim, where the process has demonstrated a valid and reliable method to accurately identify 340B eligibility, or demonstrated confirmation from a 340B covered entity or from any vendor/third-party administrator that the 340B covered entity employs to determine 340B eligibility status.

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this final guidance)
		• Documentation that the 340B ceiling price is greater than MFP and the "Service Provider Identifier" matching the claim-level data elements the MTF DM transmitted to the Primary Manufacturer is for the covered entity or its contract pharmacy.

By transmitting the claim-level payment elements to the MTF DM including the "MTF PM Facilitation Indicator" indicating that payment should be made through the MTF PM, the Primary Manufacturer will authorize the electronic funds transfer of payment equal to the total refunds to be paid through the MTF PM and the transmission of such MFP refund payments by the MTF PM to the dispensing entities identified in the claim-level payment elements (in the amounts directed by the claim-level payment elements). The MTF PM may require additional authorization for fund transfer from the Primary Manufacturer after this step as CMS continues to develop the MTF processes. Once the Primary Manufacturer transmits the claim-level payment elements which authorizes MFP refund payment, and once the MTF PM considers any credits at the dispensing entity NPI-level for each selected drug, for each Primary Manufacturer as part of the credit/debit ledger system described in section 40.4.3.2 of this final guidance, the MTF PM will route the payment provided from the Primary Manufacturer to the corresponding dispensing entities included in the claim-level payment elements using the dispensing entities' documented banking information and preferred payment method (i.e., electronic funds transfer or paper check). The MTF DM and MTF PM will maintain a record documenting whether the claim-level payment elements were sent within the 14-day prompt MFP payment window for every payment passed through the MTF PM to further assist in the dispute and complaint resolution process between interested parties, described in section 90.2.2 of this final guidance. Primary Manufacturers will be able to view the payment status for each claim routed to the MTF PM through their connection to the MTF DM.

The MTF PM will transmit electronic payment or will issue a paper check on behalf of the Primary Manufacturer to the dispensing entity based on whether the dispensing entity has indicated its preference to receive MFP refund payments in the form of electronic funds or a paper check. When a Primary Manufacturer elects to pass payment through the MTF PM and a dispensing entity has indicated a preference to receive payment in the form of a paper check, the MTF PM will issue a paper check using the Primary Manufacturer's funds and on behalf of the Primary Manufacturer, as described in 90.2.1 of this final guidance. In such instance, participating Primary Manufacturers will send claim-level payment elements to the MTF DM authorizing electronic funds transfer to, and transmission of MFP refund payment by, the MTF PM. Whenever payment is passed through the MTF PM, the MTF DM will make an ERA (for electronic transfer of funds) or remittance (for payment made via paper check) available to dispensing entities. For informational purposes, the MTF DM will issue a receipt file to Primary Manufacturers that elect to participate in the MTF PM. This receipt file will provide a notice to the Primary Manufacturer that acknowledges receipt and processing of claim-level payment elements by the MTF DM and the MFP refund payment status including successful payment

transmission and the application of credits as described in section 40.4.3.2 of this final guidance for payments made through the MTF PM.

Primary Manufacturers participating in the MTF PM may still make payments through an MFP effectuation method outside of the MTF PM that is mutually agreed upon with the dispensing entity. When a mutually agreed-upon process is implemented, the Primary Manufacturer will need to abide by the requirements outlined in sections 40.4.4 and 90.2.1 of this final guidance. These requirements include, but are not limited to, including detail on a distinct payment facilitation method in the Primary Manufacturer's plan for effectuating the MFP; following claim-level payment element reporting required when the MTF PM is not used to make payment (as described in section 40.4.4.2 of this final guidance); maintaining generally accepted accounting principles (GAAP) compliant and auditable accounting of payments, credits and debits; maintaining appropriate documentation to support MFP refund amounts; and issuing an ERA for electronic payments or remittance for payments issued by check.

If a Primary Manufacturer decides to terminate participation in the MTF PM, the Primary Manufacturer must update its MFP Effectuation Plan, complying with the notice requirements in section 90.2.1 of this final guidance. The Primary Manufacturer remains responsible for making the MFP available through the transmission of payment via the MTF PM for any claims for which the claim-level payment elements have been transmitted to the MTF DM prior to the effective date of termination, unless the Primary Manufacturer has in place an alternative arrangement for making the MFP available, as documented in the MFP Effectuation Plan.

40.4.3.2 Primary Manufacturer and MTF PM MFP Refund Payment Adjustments due to Claim Amendments Through the MTF PM

For Primary Manufacturers that pass payments through the MTF PM, regardless of whether MFP refund payments are issued to dispensing entities electronically or through paper check, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level, for each selected drug based on information reported by the Primary Manufacturer in the claim-level payment elements. CMS has received many requests to provide clarification on how MFP refunds will be reconciled when MFP refund payment occurs for a claim that is subsequently reversed or adjusted. To address changes in MFP refund payments due to claim reversals, adjustments, or determinations that a claim is not MFP-eligible after the Primary Manufacturer has transmitted claim-level payment elements, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level for each selected drug for Primary Manufacturers that participate in the MTF PM and where payment is facilitated through the MTF PM. The credit/debit ledger system will accommodate a variety of revisions to incoming PDE information, including reversals or adjustments originating from updated PDE information received from DDPS. The Primary Manufacturer is responsible for reviewing all such credit and debit amounts to confirm their accuracy.

- To address adjustments and reversals, whether these occur before the 14-day prompt MFP payment window has elapsed or after the Primary Manufacturer has transmitted the claim-level payment elements to the MTF DM, the MTF DM will transmit updated

claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 2) that links an adjustment to the previous MTF ICN.

- Each set of claim-level data elements, including claim-level data elements associated with an adjusted claim, has a distinct 14-day prompt MFP payment window.
- For adjustments, when a Primary Manufacturer participating in the MTF PM has already transmitted the claim-level payment elements to the MTF DM in response to the original claim, the Primary Manufacturer will identify and authorize the correct payment amount based on the reported claim adjustment in its claim-level payment elements submitted in response to the adjusted claim.
- For adjustments, when a Primary Manufacturer participating in the MTF PM has not transmitted the claim-level payment elements to the MTF DM in response to the original claim, the Primary Manufacturer must respond to the original set of claim-level data elements within the 14-day prompt MFP payment window of the original claim. In such instances, the Primary Manufacturer may transmit the claim-level payment elements based on the adjusted claim-level data elements. CMS will provide further instruction on how Primary Manufacturers may respond in this scenario in future technical instructions.
- When a Primary Manufacturer initiates a reversal or adjustment to claim-level payment elements, the Primary Manufacturer would update the "Transaction Code" from the claim-level data elements (see Table 4) to indicate an "adjustment" to previously transmitted claim-level payment elements. CMS has included additional claim-level data elements (i.e., "MTF ICN," "Record ID," "MTF XRef ICN," "Process Date," and "Medicare Source of Coverage") in Table 2 of section 40.4.2 of this final guidance to support Primary Manufacturer management of claim adjustments.

Upon receiving the claim-level payment elements, the MTF DM will assess whether the claim has been previously paid and will establish a corresponding credit or debit for the Primary Manufacturer's selected drug for the specific NPI of the dispensing entity. The MTF DM's assessment will in no way constitute an endorsement or determination of the appropriateness of any adjusted MFP refund payment made by the Primary Manufacturer. The MTF DM will subsequently instruct the MTF PM to apply the specified credit or debit. The MTF PM will apply credits or debits at the dispensing entity NPI-level for each selected drug. The MTF PM may require additional authorization for fund transfer of the MFP refund, if applicable, from the Primary Manufacturer as technical and operational details develop.

For claims designated as full reversals from DDPS before the Primary Manufacturer has transmitted the claim-level payment elements, the Primary Manufacturer will see the claim removed in its feed of claim-level data elements. For claims designated as full reversals after the Primary Manufacturer has transmitted the claim-level payment elements, for a Primary Manufacturer participating in the MTF PM, the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid MFP refund payment, unless no MFP refund payment was authorized in which case the credit amount would be equal to zero. Primary Manufacturers will not need to submit claim-level payment elements back to the MTF DM for full reversals. Neither CMS nor its MTF Contractors will independently determine, control, or verify the amount of the credit resulting from any claim reversal from DDPS. The Primary Manufacturer is responsible for reviewing all such credit amounts to confirm their accuracy. The MTF DM will issue a record to the Primary Manufacturer to document the occurrence of a full reversal and, in the case

of a credit accrual in the MTF PM as a result of the issuance of a full reversal after the claim-level payment elements have been transmitted, a receipt file will be issued to the Primary Manufacturer to provide notice of the accrued credit.

As part of MFP effectuation, the Primary Manufacturer participating in the MTF PM will authorize the MTF PM, through transmission of the claim-level payment elements, to send to a dispensing entity, a lump sum payment equal to the total refunds to be paid as indicated when reporting the claim-level payment elements. The precise process of authorization surrounding payment transfer continues to be developed. If the Primary Manufacturer has credits accrued with respect to a selected drug for the dispensing entity NPI for which it has authorized an MFP refund payment, the MTF PM will automatically credit the Primary Manufacturer and the MTF PM will indicate to the MTF DM that, for impacted claims, an accrued credit was applied. Primary Manufacturers will not need to provide authorization for the application of credits. The MTF DM will use this information to inform the ERA or remittance, as applicable, that is made available to the dispensing entity. The MTF DM also will update its final database with information from the MTF PM to capture whether a payment was made with credit and the amount of that credit. Primary Manufacturers will have access to the disposition of each claim-level data element claim line to which they responded with claim-level payment elements and the status of MFP refunds through the MTF DM including the result of MTF PM execution. CMS intends that dispensing entities and participating Primary Manufacturers will be able to view the status of available credits and MFP refunds through their MTF portal, however further technical specifications will be outlined in technical guidance. The MTF will not maintain a ledger of credits and debits for Primary Manufacturers that elect not to participate in the MTF PM. Additionally, for Primary Manufacturers that participate in the MTF PM, the MTF credit/debit ledger system will not track credits and debits related to claims where the MFP refund was paid outside of the MTF PM to a dispensing entity through a mutually agreed-upon process. The established MFP effectuation process between the parties will be responsible for reconciling and tracking accrued debits and credits that may result from amended claims. See section 40.4.4 of this final guidance for additional detail.

If a Primary Manufacturer terminates participation in the MTF PM, CMS, or its designated contractor, will communicate new adjustments, including claim adjustments, reversals, and changes to MFP eligibility to the Primary Manufacturer via the claim-level data elements in the MTF DM; however, the Primary Manufacturer will no longer accrue credits and debits related to those adjustments. Additionally, CMS, or its designated contractor, will provide the Primary Manufacturer with an accounting of any outstanding credits remaining in the credit/debit ledger system as of the date of termination, at a time and in a manner to be described by CMS in upcoming guidance or technical instruction. It is the responsibility of the Primary Manufacturer to work with dispensing entities if a Primary Manufacturer believes funds are owed for the outstanding credits and to continue to make payments to dispensing entities outside of the MTF PM in order to continue to effectuate the MFP. Such outstanding credits shall not be treated as unclaimed funds under applicable guidance, regulations, and technical instructions, and claims by the Primary Manufacturer to any outstanding credits are not within the scope of the dispute or complaint process established in applicable guidance and regulations and must be taken up directly with the applicable dispensing entities.

If a Primary Manufacturer transfers ownership of a selected drug, following the process established in section 40.7 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable, and the Medicare Drug Price Negotiation Program Agreement, credits and debits will remain in the credit/debit ledger system and will be transferred to the new Primary Manufacturer.

40.4.3.3 Pass Through Payment to Dispensing Entity When Primary Manufacturer Participates in the MTF PM

Similar to other applications or mechanisms through which a Primary Manufacturer might submit its payment for delivery, the MTF PM will provide participating Primary Manufacturers with a means by which MFP refund payments can be passed through to dispensing entities at the Primary Manufacturer's election. Accordingly, the MTF PM will not require an affirmative election of participation by dispensing entities for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer.

As outlined in section 40.4.2.2 of this final guidance, at the time of enrollment in the MTF DM, dispensing entities will be required to register bank account information to facilitate making the ERA or remittance, as applicable, available to the dispensing entity. Also, at the time of enrollment into the MTF DM, the dispensing entity will have the opportunity to indicate whether it prefers to receive MFP refund payments through the electronic transfer of funds, which will be the default election for dispensing entities at the time of enrollment, or in the form of a paper check, if such type of payment is preferred by the dispensing entity. Due to the operational need to print, package, and mail paper checks, dispensing entities that elect to receive MFP refund payments in the form of paper checks should expect longer delivery of MFP refund payments as compared with the timing for electronic payment transmission. If the Primary Manufacturer participates in the MTF PM and transmits MFP refund payments through the MTF PM to be passed through to the dispensing entity, then the MTF PM will pass through the payment to the dispensing entity in accordance with the dispensing entity's selected payment method preference (i.e., electronic funds transfer or paper check). However, this does not preclude a dispensing entity from reaching an outside agreement with a Primary Manufacturer participating in the MTF PM for a separate arrangement to pay MFP refunds outside of the MTF PM. For MFP refund payments made by the Primary Manufacturer outside of the MTF PM—because either the Primary Manufacturer and dispensing entity have established a mutually agreed-upon process outside of the MTF PM or the Primary Manufacturer does not participate in the MTF PM—the MTF DM will include the dispensing entity's selected payment method preference among the claim-level data elements transmitted to the Primary Manufacturer. Regardless of whether the MFP refund is passed through the MTF PM or outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

If payment is passed through the MTF PM, the MTF PM's transfer of the Primary Manufacturer's authorized MFP refund payment to the dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity. Additionally, the receipt of the MFP refund payment by the dispensing entity (either

electronically or via paper check) does not constitute the dispensing entity's agreement that access to the MFP has been provided by the Primary Manufacturer.

CMS received feedback from dispensing entities that they prefer having the option to identify a reconciliation vendor to access an ERA, or a remittance if payment is issued by paper check, on their behalf. Additionally, dispensing entities under the same parent organization requested the ability to receive payment through a single entity and to allow for groups of pharmacies to enroll together instead of each pharmacy being required to enroll individually, to streamline both the disbursement of funds and the enrollment process. In response to this feedback, enrollment in the MTF DM will provide the dispensing entity with the option to have a PSAO, reconciliation contractor, or other vendor as indicated during the enrollment process, access the ERA or remittance, as applicable, and receive MFP refund payments on behalf of the dispensing entity, as well as the option for chains to designate a single or central pay option for dispensing entities under common ownership. CMS has issued instructions on enrollment procedures, with considerations for the ability for chains to enroll groups of dispensing entities and functionality for integrating PSAOs, reconciliation vendors, and other third-party vendors in the enrollment process. Designation by the dispensing entity of a third-party vendor will require the dispensing entity's attestation of designation during the enrollment process in the MTF DM. CMS may provide further guidance or technical instructions to ensure effective transfer of MFP refund payments through PSAOs, reconciliation vendors, or aggregated payment to a single entity if necessitated.

For Primary Manufacturers that utilize the MTF PM, once the MTF DM has sent claim-level data elements to the Primary Manufacturer, and the Primary Manufacturer sends the claim-level payment elements to the MTF and, if applicable, pays the MFP refund amount to the dispensing entity through the MTF PM, then the MTF DM will generate an ERA or remittance for the dispensing entity for purposes of reconciling the Primary Manufacturer's retrospective MFP refunds with previously created accounts receivable. The MTF DM will produce ERAs that use the X12 835 standard adopted under HIPAA.

As described above in section 40.4.3 of this final guidance, CMS established the MTF PM to assist Primary Manufacturers and dispensing entities in effectuating MFP refund payment between parties in a reliable, predictable, and consistent manner without incurring significant burden or cost. Despite the respective enrollment obligations of Primary Manufacturers and dispensing entities in the MTF DM as articulated in sections 40.4.2.1 and 40.4.2.2 of this final guidance, based on CMS' review of comments and other feedback from stakeholders, CMS has determined to extend availability of the MTF PM to Primary Manufacturers for use in instances in which a dispensing entity has not enrolled in the MTF DM. Specifically, a Primary Manufacturer that participates in the MTF PM may elect to utilize the MTF PM to pass through MFP refund payments to dispensing entities that have not enrolled in the MTF DM. In such cases, as described further below, the MTF PM will send a paper check for the MFP refund amount, in the amount authorized by the Primary Manufacturer's claim-level payment elements, to the registered mailing address that is listed in the NCPDP database for the dispensing entity.

If the MTF DM receives a PDE record for a dispensing entity that has not enrolled in the MTF DM, the MTF DM will indicate through inclusion of a transaction code on the claim-level data

elements transmitted to the Primary Manufacturer that the dispensing entity is not enrolled in the MTF DM. For Primary Manufacturers that participate in the MTF PM, if the Primary Manufacturer elects to utilize the MTF PM to make any MFP refund payment necessary to effectuate the MFP with respect to a claim from a dispensing entity that is not enrolled in the MTF DM, the Primary Manufacturer can, in accordance with the requirements of section 40.4.3 of this final guidance, transmit the claim-level payment elements within the 14-day prompt MFP payment window, indicating, if applicable, the MFP refund payment amount and authorizing an MFP refund payment amount to be transmitted through the MTF PM to the dispensing entity. In this scenario, after receipt of the claim-level payment elements from the Primary Manufacturer, the MTF PM will issue a paper check to the registered mailing address that is listed in the NCPDP database for the dispensing entity not enrolled in the MTF DM. If the dispensing entity that is not enrolled in the MTF DM wishes to obtain the associated remittance advice that corresponds to the paper check issued to the dispensing entity's registered address in the NCPDP database, the dispensing entity has the option to do the following: (1) enroll with the MTF DM to receive access to the remittance(s) for the issued paper check(s) and establish a secure delivery location for remittances associated with future MFP refund payments or (2) contact the MTF Helpdesk and provide the necessary information to facilitate the issuance of a remittance via a secure delivery method for the issued paper check.

If a Primary Manufacturer that is enrolled in the MTF PM elects not to utilize the MTF PM to make an MFP refund payment necessary to effectuate the MFP with respect to a claim from a dispensing entity that is not enrolled in the MTF, the Primary Manufacturer must transmit payment to the dispensing entity outside of the MTF PM when provided with notice from the MTF DM that a dispensing entity is not enrolled in the MTF DM. If payment is transmitted outside of the MTF PM, Primary Manufacturers must transmit claim-level payment elements to the MTF PM in accordance with section 40.4.4 of this final guidance.

40.4.4 MFP Refund Payments When Primary Manufacturer Makes Payment Outside of the MTF PM

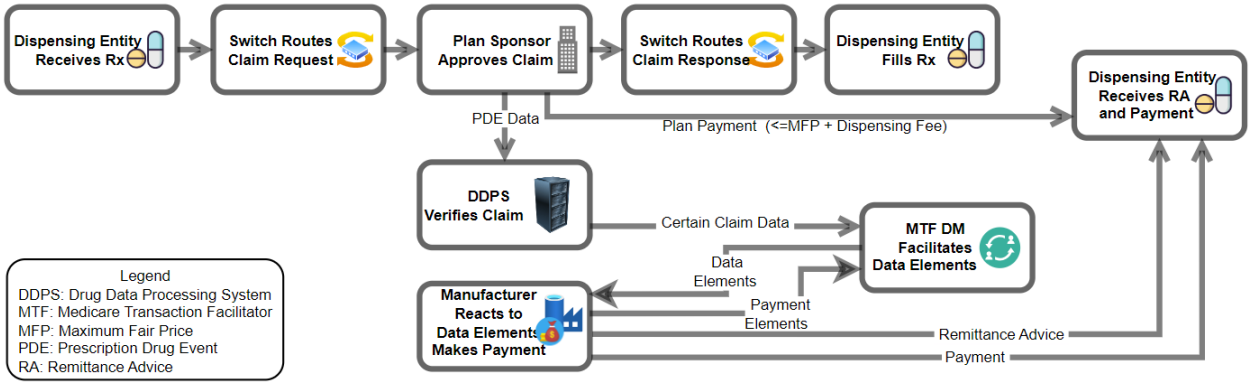
As discussed in section 40.4.3 of this final guidance, the Primary Manufacturer may choose not to pass payment through the MTF PM for facilitation of MFP refund payments. If the Primary Manufacturer chooses not to pass payment through the MTF PM, then the Primary Manufacturer is responsible for paying the MFP refund to the dispensing entity outside of the MTF PM; as described in section 90.2.1 of this final guidance, Primary Manufacturers are required to describe the details of their approach to MFP effectuation outside of the MTF PM, including any specific arrangements with dispensing entities outside of the MTF, in their MFP Effectuation Plans. This section discusses differences in data received from and transmitted to the MTF DM for MFP refund payments made when payments are passed through the MTF PM as compared to payments not passed through the MTF PM, such as when the Primary Manufacturer is not participating in the MTF PM or when the Primary Manufacturer is participating in the MTF PM and mutually agrees with a dispensing entity on a payment arrangement outside of the MTF.

40.4.4.1 Primary Manufacturer Payment Outside of the MTF PM

Table 2, in section 40.4.2 of this final guidance, lists the claim-level data elements the MTF DM will send to Primary Manufacturers to start the 14-day prompt MFP payment window for each claim for an MFP-eligible drug. For Primary Manufacturers that make payments outside of the

MTF PM, CMS plans to make available through the MTF DM the bank account information and designated destination for ERAs or remittances for dispensing entities enrolled in the MTF DM to support the Primary Manufacturer's creation and transmission of an ERA or remittance to the dispensing entity based on the preferred payment method indicated by the dispensing entity during MTF DM enrollment. For electronic transfer of funds, it is the responsibility of the Primary Manufacturer to ensure that the ERA created and transmitted to the dispensing entity uses the X12 835 standard adopted under HIPAA. For funds issued via paper check, it is the responsibility of the Primary Manufacturer to ensure that the remittance is created and made available to the dispensing entity. Figure 4 represents the flow of data and payment if the Primary Manufacturer makes payment outside of the MTF PM. Although Figure 4 illustrates data flow for Part D drug claims, as discussed in section 40.4 of this final guidance, CMS intends to use the MTF to facilitate data exchange for drugs payable under Part B that are furnished or administered to MFP-eligible individuals and will provide more information in the future.

Figure 4: Diagram of MTF Data Flow when Primary Manufacturers Make Payment Outside of the MTF PM



In instances in which the Primary Manufacturer does not use the MTF PM to facilitate payments to a dispensing entity, the Primary Manufacturer must establish a process by which the MFP refund payment can be made. While CMS is not involved in the establishment or facilitation of MFP refund payment processes formed between the Primary Manufacturer and dispensing entities outside of the MTF PM, Primary Manufacturers will be required to submit claim-level payment elements to the MTF DM that detail MFP refund payments made directly to dispensing entities, which CMS intends to use to monitor the Primary Manufacturer's compliance with its requirement to provide access to the MFP. The claim-level data elements the MTF DM will transmit to Primary Manufacturers include the dispensing entity's preferred method by which to receive payment (electronic funds transfer or paper check) as indicated by the dispensing entity during MTF DM enrollment. As discussed in section 40.4.2 of this final guidance, these retrospective refund payments by the Primary Manufacturer to the dispensing entity would be provided through a process that is agreed to by the Primary Manufacturer and the dispensing entity and described in the Primary Manufacturer's MFP Effectuation Plan required under section 90.2.1 of this final guidance.

Any payment system established by a Primary Manufacturer to facilitate these payments outside of the MTF must adhere to GAAP standards and procedures. Payments made without MTF PM facilitation are subject to the 14-day prompt MFP payment window and other applicable

requirements for MFP effectuation in this final guidance. MFP refund payments must be made in a manner that complies with applicable data privacy and security laws. As mentioned in section 40.4.2 of this final guidance, regardless of whether the MFP refund is facilitated through the MTF PM or made outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

40.4.4.2 Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When Primary Manufacturer Makes Payment Outside of the MTF PM
As stated in section 40.4.3 of this final guidance, regardless of whether the Primary Manufacturer elects not to participate in the MTF PM or participates in the MTF PM and makes payment to a dispensing entity outside of the MTF PM, the Primary Manufacturer is responsible for providing claim-level payment elements to the MTF DM for each MFP-eligible claim indicating whether a refund was paid and the amount of the refund paid to make the MFP available. The following discussion outlines the reporting of claim-level payment elements to the MTF DM that is required of a Primary Manufacturer for each MFP refund payment made outside of the MTF PM. Some of the reporting requirements differ from requirements for MFP refund payments passed through the MTF PM, which are described in section 40.4.3 of this final guidance.

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering the Negotiation Program and monitoring compliance with the requirement to provide access to the MFP, the Primary Manufacturer will be required to transmit claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer or whether access to the MFP is provided prospectively or retrospectively. Due to the anticipated high volume of claims for selected drugs, CMS anticipates that Primary Manufacturers may engage a third-party vendor and/or automate the submission of claim-level payment elements to the MTF DM. Primary Manufacturers remain responsible for ensuring that claim-level payment element information is accurate and submitted on a timely basis.

For all claims that are transmitted by the MTF DM to the Primary Manufacturer (regardless of whether an MFP refund is paid, and regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer), Primary Manufacturers, inclusive of any of the Primary Manufacturer's contracted third-party vendors, will be required to include in the claim-level payment elements: (1) the corresponding claim-level data elements previously transmitted by the MTF DM, listed in Table 2 in section 40.4.2 of this final guidance; and (2) the claim-level payment elements listed in Table 6 below. The claim-level data elements and corresponding claim-level payment elements for each MFP eligible claim shall be returned in a single response file to the MTF DM.

Table 6: Example Manufacturer Claim-Level Payment Elements List when Primary Manufacturers Make Payment Outside of the MTF PM[141]

Payment Elements	Purpose
MTF PM Facilitation Indicator	Indicates whether transmission of the MFP refund should be facilitated through the MTF PM.
MFP Refund Transmission Date	Indicates when the MFP refund was transmitted by the Primary Manufacturer.[142]
MFP Refund Transmission Time	Indicates when the MFP refund was transmitted by the Primary Manufacturer.
Method for Determining MFP Refund Amount	Indicates the basis on which the MFP refund amount was determined (refer to Table 5 in section 40.4.3.1 of this final guidance).
Amount Calculated as the MFP Refund	Documents the amount determined as the MFP refund prior to the application of any credits. Payment element should be populated with the final calculated MFP refund amount if payment was an adjustment to a previous claim.
Amount of Payment Transmitted as the MFP Refund	Documents the amount transmitted to the dispensing entity as the MFP refund.
Transaction Code[143]	Indicates if the MFP refund payment is in response to an original claim, or if it is an adjustment or reversal to a previously submitted set of claim-level payment elements.

Claim-level payment elements in common with required elements for payments made through the MTF PM include the "MTF PM Facilitation Indicator," "Method for Determining MFP Refund Amount," "Amount of Payment Transmitted as the MFP Refund," and "Transaction Code." The Primary Manufacturer would update the "Transaction Code" from the claim-level data elements (see Table 6) prior to sending claim-level payment elements to the MTF. As mentioned in section 40.4.3.1 of this final guidance, two claim-level payment elements, NPI of the Entity Receiving the MFP Refund and Quantity of Selected Drug, proposed in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 were removed from this final guidance to eliminate redundancy with the corresponding claim-level data elements. "Amount Calculated as the MFP Refund" is an additional claim-level

[141] These elements are representative of examples and CMS will provide the exact payment elements in forthcoming guidance or technical instructions as operations develop.
[142] The recipient is the dispensing entity for MFP refund payments transmitted directly between parties outside the MTF PM. For MFP refunds paid via electronic payment, the Primary Manufacturer reports the date and time when electronic payment was transmitted to the dispensing entity. For MFP refunds paid via paper check, the Primary Manufacturer reports the date on which the paper check was mailed to the dispensing entity.
[143] Transaction Code is the same field received in the claim-level data elements from the MTF DM. Primary Manufacturers will update the Transaction Code field before submitting claim-level payment elements to the MTF DM.

payment element in which the Primary Manufacturer documents the amount determined as the MFP refund for the claim prior to the application of any credits. "MFP Refund Transmission Date" and "MFP Refund Transmission Time" are additional claim-level payment elements that are required for MFP refund payments made outside of the MTF PM. As discussed in section 40.4.3.1 of this final guidance, for payments passed through the MTF PM, the MTF PM will timestamp the receipt of the claim-level payment elements. However, for payments made outside of the MTF PM, Primary Manufacturers will need to report the date and time that electronic payment was transmitted or the date that a paper check was mailed to a dispensing entity.

Additional claim-level payment elements may be necessary to provide information that would otherwise be available if the MFP refund payment was made through the MTF PM, such as claim-level payment elements related to the application of credits or debits to payments, or another reconciliation method agreed to between the Primary Manufacturer and dispensing entities. Additional details on specific claim-level payment elements that may be reported to the MTF DM when the Primary Manufacturer does not use the MTF PM will be provided in future guidance or technical instructions.

The claim-level payment elements must be submitted to the MTF DM within the 14-day prompt MFP payment window, including when the claim-level payment elements indicate that no MFP refund payment is made in response to the claim-level data elements received. If an MFP refund payment is transmitted in response to the claim-level data elements received, the Primary Manufacturer should submit claim-level payment elements after sending paper check or electronic payment of the MFP refund to the dispensing entity outside of the MTF PM. Failure by the Primary Manufacturer to transmit all claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window would be a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act (see section 100 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable). While the claim-level payment elements will serve as the record of a Primary Manufacturer's response to the claim-level data elements when a refund is transmitted outside of the MTF PM, the Primary Manufacturer also is required to maintain documentation for each claim received from the MTF of either: (1) the retrospective MFP refund payment amount, and details of transmission of payment; or (2) the explanation of why the Primary Manufacturer did not provide a retrospective MFP refund. The Primary Manufacturer must make this documentation available to CMS upon request.

As discussed in section 40.4.3 of this final guidance, CMS understands there are several reasons why a Primary Manufacturer may not pay an MFP refund or pay an MFP refund amount other than the SDRA for a given claim. To account for such scenarios, the Primary Manufacturer will report a mandatory claim-level payment element, "Method for Determining MFP Refund Amount," to be populated with one of several pre-identified justification codes indicating whether the MFP refund payment was made using the SDRA, a different amount, or the reason an MFP refund payment was not provided.[144] Examples of these justification codes, listed in

[144] Nothing in this section precludes a Primary Manufacturer and a dispensing entity from reaching agreements outside of the MTF to establish an adjusted refund amount based on the dispensing entity's acquisition costs.

Table 5 in section 40.4.3.1 of this final guidance, include codes indicating the drug was prospectively purchased at or below the MFP, the Primary Manufacturer and dispensing entity have a separately negotiated refund amount distinct from the SDRA, the Primary Manufacturer claims an exception under section 1193(d)(1) of the Act, or credits tracked outside of the MTF for refunds paid for subsequently adjusted claims were applied in lieu of payment. CMS believes that identifying standardized justifications for the report of claim-level payment elements will allow Primary Manufacturers to establish efficient processes to provide such reports to the MTF. CMS intends to work with interested parties to add justification codes, if necessary, to meet reporting needs.

Upon CMS' request, Primary Manufacturers must provide evidence of MFP refund payments made outside of the MTF PM, which could include any number of items including paper checks, ACH transfers, wholesaler chargebacks, e-vouchers, or other electronic means of paying the dispensing entity so long as the evidence clearly supports information furnished in the claim-level payment elements. The payment approach(es) used by the Primary Manufacturer must be included in the Primary Manufacturer's plan submitted to CMS regarding effectuation of the MFP as described in section 90.2.1 of this final guidance.

For Primary Manufacturers that make payments outside of the MTF PM, the MTF DM will receive the claim-level payment elements from the Primary Manufacturer but will not create and make available an ERA or remittance, as applicable, for the dispensing entity; in this case, it is the responsibility of the Primary Manufacturer to ensure that an ERA is created and transmitted to the dispensing entity for electronic transfer of funds. In instances where a Primary Manufacturer makes non-electronic payments outside of the MTF PM, the Primary Manufacturer must make available a remittance to the dispensing entity.

The MTF DM will maintain a record of the execution of MFP refund payments, as documented in the transmitted claim-level payment elements. Compliance with the 14-day prompt MFP payment window will be assessed using the "MFP Refund Transmission Date and Time." For electronic MFP refund payments made to dispensing entities outside of the MTF PM, this date must reflect the date that the Primary Manufacturer sent the payment to the dispensing entity. For paper checks sent outside of the MTF PM, this date must reflect the date that the paper check was mailed to the dispensing entity. In addition to monitoring for compliance with the 14-day prompt MFP payment window, this information will assist in the dispute and complaint resolution process between interested parties, described in section 90.2.2 of this final guidance. For informational purposes, the MTF DM will issue a receipt file to Primary Manufacturers that do not elect to participate in the MTF PM. This receipt file will provide a notice to the Primary Manufacturer that acknowledges receipt and processing of claim-level payment elements by the MTF DM.

40.4.4.3 Dispensing Entity Receipt of Payment Outside of the MTF PM
As discussed in section 40.4.3 of this final guidance, even if the Primary Manufacturer participates in the MTF PM, the Primary Manufacturer and dispensing entity may establish a mutually agreed-upon process for effectuating the MFP outside of the MTF PM. If the Primary Manufacturer does not participate in the MTF PM, then the Primary Manufacturer must establish its own methods of payment facilitation, which dispensing entities will be able to utilize to access the Primary Manufacturer's MFP refund payments. These MFP effectuation processes must be described in the Primary Manufacturer's MFP Effectuation Plan, as discussed in section 90.2.1 of this final guidance. The 14-day prompt MFP payment window applies regardless of whether the Primary Manufacturer elects to use the MTF PM or not to provide access to the MFP.

The Primary Manufacturer is responsible for issuing an ERA or remittance to dispensing entities for MFP refund payments made through the Primary Manufacturer's MFP effectuation processes. For electronic fund transfers, the Primary Manufacturer must ensure that the ERA created and made available to the dispensing entity uses the X12 835 standard adopted under HIPAA and can be utilized by dispensing entities to close accounts receivable. Primary Manufacturers should have access to bank account information and designated destination for ERA transmissions for dispensing entities through the MTF DM. The MTF DM will collect this information when dispensing entities enroll, and CMS plans to make this information available through the MTF DM to support the Primary Manufacturer's creation and transmission of an ERA or remittance, as applicable.

CMS encourages the dispensing entity to work with the Primary Manufacturer to resolve any concerns regarding the availability and amount of an MFP refund. Where a payment issue cannot be resolved, either the dispensing entity or the Primary Manufacturer can use the complaint process outlined in section 90.2.2 of this final guidance. Dispensing entities are encouraged to use the MTF complaint and dispute process, as described in section 90.2.2 of this final guidance, so that CMS is alerted to situations where the MFP may not have been made available. If a complaint is filed, CMS intends to take the steps outlined in section 90.2.2 of this final guidance and may issue a decision regarding whether the MFP was made available to the dispensing entity.

40.4.4.4 Primary Manufacturer and MTF PM MFP Refund Payment Adjustments due to Claim Amendments When Primary Manufacturer Makes Payment Outside of the MTF PM
For MFP refunds where payment was made outside of the MTF PM for a claim that is subsequently reversed or adjusted, the MTF will not maintain a credit/debit ledger system to address claim reversals, adjustments, and other changes in status that occur after an MFP refund payment has been made outside of the MTF PM. Primary Manufacturers may establish different methods for handling changes in payment amounts for payments made outside of the MTF PM, so long as such methods are consistent with the Primary Manufacturer's statutory obligation to make MFP available and adhere to GAAP standards and procedures. Accounting for claims reversals and adjustments must be detailed in a manufacturer's MFP Effectuation Plan, as discussed in 90.2.1 of this final guidance, and the Primary Manufacturer has an obligation to make these processes transparent to dispensing entities that receive MFP refunds outside of the MTF PM.

As noted in section 40.4.2.1 of this final guidance, the MTF DM will send all Primary Manufacturers claim-level data elements for all reversals and adjustments received for claims previously sent to that Primary Manufacturer. As discussed in section 40.4.2 of this final guidance, information about previously paid MFP refunds will be included in the claim-level data elements, if applicable. For MFP refund payments made outside of the MTF PM, Primary Manufacturers must submit claim-level payment elements as described in section 40.4.4.1 of this final guidance for these claims to provide the MTF DM with information on any changes to previously paid MFP refund amounts for purposes of program monitoring and oversight. CMS intends that the Primary Manufacturer will document adjustments through submission of their claim-level payment elements that include the final refund amount and a notation of adjustments. Credits, debits, forwarding balances, and other information should be captured in the Primary Manufacturer's accounting ledger. Collecting this information will assist in the dispute and complaint resolution process between interested parties, described in section 90.2.2 of this final guidance. CMS intends to conduct monitoring and oversight of these systems, including audits as appropriate. CMS may provide additional detail on reporting adjustments and reversals when the Primary Manufacturer makes payment outside of the MTF PM in future guidance or technical instructions.

40.4.5 Nonduplication with 340B Ceiling Price

In accordance with section 1193(d)(1) of the Act, the Primary Manufacturer of a selected drug is not required to provide access to the MFP for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act) is lower than the MFP for such selected drug.[145] Under section 1193(d)(2) of the Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.

A Primary Manufacturer that provides access to the MFP for a selected drug (whether via prospective discount or retrospective refund) is not required to provide a 340B ceiling price on that same selected drug claim if the MFP is lower than the 340B ceiling price. That is, these price concessions are not cumulative, but manufacturers must ensure that the appropriate price concession is honored, consistent with their obligations under section 1193 of the Act, and inclusive of their agreements under section 340B(a)(1) of the PHS Act. CMS expects that the acquisition cost for a selected drug will be no greater than the drug's MFP, including when those prescriptions are filled at 340B covered entities and their contract pharmacies. CMS understands that 340B covered entities and their contract pharmacies currently use various inventory management processes for drugs that are subject to an agreement under section 340B(a)(1) of the PHS Act, such as separate physical drug inventories or a virtual replenishment model.

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[145] Hereinafter, and solely for the purpose of this final guidance, a claim for a selected drug that is dispensed to an MFP-eligible individual who is eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act, and for which the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act, is referred to as a "340B-eligible claim." CMS does not determine nor verify 340B eligibility and expects manufacturers and covered entities to continue to be responsible for statutory obligations pursuant to section 340B of the PHS Act regarding proper identification of 340B-eligible patients and covered outpatient drugs dispensed to such patients.

To illustrate how the 340B nonduplication provision would apply in cases where the dispensing entity's acquisition cost is not already established as being equal to or less than the MFP, CMS first reiterates the prompt MFP payment requirement under section 40.4 of this final guidance that the Primary Manufacturer must transmit payment of an amount that provides access to the MFP within 14 days of the MTF sending claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual. Therefore, applying section 1193(d) of the Act, unless the claim for the selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the MFP for the selected drug or unless access to the MFP was provided prospectively, the Primary Manufacturer is required 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. Section 1193(a)(3) of the Act establishes that access to the MFP shall be provided by the manufacturer to dispensing entities, subject to section 1193(d) of the Act, which contains a limited exception to accommodate otherwise applicable 340B pricing obligations that applies only if certain express conditions are met.

In particular, section 1193(d)(1) of the Act applies 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 this final 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 further in section 90.2 of this final guidance. CMS also notes that a provider or prescriber ID alone (whether the Service Provider ID or the Prescriber ID, as included in Table 2 in section 40.4.2.1 of this final guidance) generally will not constitute sufficient evidence that a claim was 340B-eligible as not all individuals served by covered entities are necessarily eligible to receive a drug purchased at the 340B ceiling price.

Similar to the responses to draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS has received requests from numerous interested parties for CMS to assume responsibility for nonduplication of the 340B ceiling price and the MFP. CMS understands that these requests for CMS to undertake nonduplication would entail CMS, via the MTF, performing a widespread, independent collection of 340B-related transactional data from 340B covered entities or their third-party administrators (TPAs)—vendors that assist some 340B covered entities in identifying 340B claims—that would then be matched on a continuous, real-time basis against PDE records transmitted to the MTF to remove claims for which a discount may be required under 340B(a)(1) of the PHS Act.[146]

[146] The nonduplication functions described here, which reflect the requests of interested parties, would be primarily proactive in nature, and, for purposes of this discussion, are separate and distinct from any functions that may be performed in the context of the dispute or complaint process or in the enforcement context.

Considering numerous factors such as those outlined below, CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP. As described above, CMS intends to provide Primary Manufacturers with a process to identify applicable 340B-eligible claims through the reporting of claim-level payment elements to the MTF, as described in sections 40.4.3.1 and 40.4.4.1 of this final guidance. CMS will rely on such indications when determining the extent to which the obligation to provide access to the MFP has been discharged. CMS is continuing to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under section 1193(d)(1) of the Act into MTF processes in the future. For example, CMS continues to consider ways to incorporate asynchronous 340B data into MTF processes in the future.

If it is subsequently determined that a claim for a selected drug was a 340B-eligible claim but an MFP refund was provided for that claim, and the 340B ceiling price for the selected drug is determined to be lower than the MFP, then the Primary Manufacturer may use the credit/debit ledger system described in section 40.4.3.2 of this final guidance, if the Primary Manufacturer made payment through the MTF PM for the claim, to reconcile the duplicated discounts. As detailed in section 40.4.3.2 of this final guidance, CMS intends that dispensing entities and participating Primary Manufacturers will be able to view the status of available credits and MFP refunds through their MTF portal for payments made through the MTF PM. The MTF will provide functionality in the MTF DM for Primary Manufacturers to submit instructions for the MTF to apply a credit for the previously provided MFP refund in these scenarios such that Primary Manufacturers will have access to functionality to address duplicated discounts retroactively if needed. A Primary Manufacturer that makes payment outside the MTF PM for a claim will not have access to use the credit/debit ledger system operated by the MTF to apply a credit for that claim if it is subsequently determined to be 340B-eligible and the 340B ceiling price is lower than the MFP for the selected drug. A Primary Manufacturer that makes payment outside the MTF PM may develop its own process that may include a system to account for credits and debits to effectuate nonduplication between the MFP and 340B ceiling price. To the extent dispensing entities choose to voluntarily and proactively indicate on a submitted claim that the claim is 340B-eligible,[147] the MTF would pass along the 340B indication data as applicable to the Primary Manufacturer when the MTF shares the claim-level data elements with each Primary Manufacturer. A Primary Manufacturer could use this information to determine if the claim meets the limited exception under section 1193(d)(1) of the Act, or if the Primary Manufacturer is required to provide access to the MFP in accordance with section 1193(d)(2) of the Act.

CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is 340B-eligible. Nothing in this guidance modifies a Primary Manufacturer's statutory obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. Nothing in this guidance alters a Primary Manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the

[147] The NCPDP Telecommunications Standard includes an optional field that a covered entity can use to indicate that a claim is 340B-eligible. As noted in section 40.4.1 of this final guidance, beginning January 1, 2025, these optional fields have been added to the PDE record to indicate a 340B-eligible claim. See: https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf. See also: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.

340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11.

CMS understands that a majority of 340B claims are processed by a small number of 340B TPAs on behalf of 340B covered entities and dispensing entities. CMS also understands that 340B TPAs typically adjudicate claims to determine which claims are 340B eligible in a relatively short amount of time (often within as little as 24 hours). CMS strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price, wherever applicable. CMS anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders to ensure the process is not unduly burdensome for dispensing entities, 340B covered entities, and patients.

CMS acknowledges the intersection between its requirement under the Negotiation Program for manufacturers to provide access to the MFP and Health Resources and Services Administration's (HRSA's) requirements for manufacturers to offer the 340B ceiling price to 340B covered entities. As necessary, CMS will coordinate with HRSA to provide and share information to support compliance with each agency's respective program requirements.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

Pursuant to CMS' statutory obligation under sections 1191(a)(4), 1196, and 1197 of the Act, CMS established a robust program for monitoring compliance with the Negotiation Program. After entering into an Agreement with CMS and in accordance with section 1193(a)(5) of the Act, the Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program. For example, CMS may engage in auditing processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer under the requirements of section 1193(a)(4) of the Act. CMS also may audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. CMS will document all requests for information required to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. Written requests from CMS to the Primary Manufacturer will include a date by which the requested information shall be submitted to CMS. If the Primary Manufacturer fails to submit complete and accurate information to CMS by the deadline stated in a request for information, CMS will consider the Primary Manufacturer in violation of the Agreement and the Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act.

As feasible, CMS will provide Primary Manufacturers with information on certain CMS calculations during and after the negotiation period, including: (1) following the Primary Manufacturer's submission of data that complies with the submission of data described in section 50.1 of this final guidance, information on the agency's calculation of the ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug; and (2) following certain updates to CMS' computation of how the agency will

apply a single MFP across dosage forms and strengths of the selected drug (such as to account for the addition of new NDCs), information on such updates. CMS will allow a Primary Manufacturer that believes in good faith that CMS has made an error in the calculation of the ceiling or the computation of how CMS will apply a single MFP across dosage forms and strengths to submit a suggestion of error for CMS' consideration. Comments related to statutorily required criteria or the policies adopted in Negotiation Program guidance are outside the scope of the suggestion of error process. For example, comments on calculation methodology will be considered out of scope. As feasible, CMS will provide information on these calculations to the Primary Manufacturer within 45 days of the Primary Manufacturer's submission of data that complies with the submission of data described in section 50.1 of this final guidance (in other words, the statutory deadline of March 1, 2026).

A Primary Manufacturer will have 21 days to submit a suggestion of error. The suggestion of error must be submitted via email to IRARebateandNegotiation@cms.hhs.gov with the subject line "Suggestion of Error for [name of the selected drug]." This notification should include supporting information documenting why the Primary Manufacturer believes that CMS made a mathematical error in its calculations and corresponding steps that should be reviewed. A Primary Manufacturer may provide this information via a sample Excel file that CMS will provide to the Primary Manufacturer at the same time that CMS provides the calculation of the ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths to the Primary Manufacturer. CMS will review and respond within 21 days of receiving the suggestion of error from the Primary Manufacturer, if feasible. The suggestion of error process does not affect a Primary Manufacturer's obligation to comply with Negotiation Program requirements and will not alter or change any timelines or requirements of the Negotiation Program.

40.6 Termination of the Agreement for 2026, 2027, and 2028

In accordance with section 1193(b) of the Act, when the Primary Manufacturer enters into the Agreement described in section 40.1 of this final guidance, the Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer considered a selected drug under section 1192(c) of the Act as described in section 70 of this final guidance unless the Agreement is terminated sooner by the Primary Manufacturer under the conditions specified below. Accordingly, the Agreement will have an effective date as of the date the Agreement is signed by both parties (the "Effective Date"), and the term of the Agreement will be from the Effective Date of the Agreement to the earlier of the first year that begins at least nine months after the date on which CMS determines that the selected drug is no longer a selected drug under section 1192(c) of the Act or the Agreement is terminated by either party in accordance with this section (the "Termination Date").

In accordance with section 1193(a)(5) of the Act, a Primary Manufacturer may terminate its 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 Agreement with respect to a selected drug must submit to CMS a notice of request to terminate. As noted in section 40.1 of this final guidance, 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. 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 and the Department of the Treasury regulations referenced in section 90.3 of this final guidance. 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 manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of its drugs are covered by an agreement under section 1860D-14A or 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. A Primary Manufacturer with an 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 CMP liability by terminating its 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.

Thus, in accordance with section 1193(a)(5) of the Act, CMS has determined that the Primary Manufacturer's notice of termination of the Agreement (herein "Request to Terminate") must incorporate both: (1) a request for termination of the Primary Manufacturer's applicable 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 (a) shall not seek to enter into any subsequent agreement with any such program and (b) 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).[148] A Primary Manufacturer later seeking to re-enter any applicable agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program would be deemed to have provided an invalid attestation that was a condition of termination, and the Agreement would once again become operative as of the date of re-entry into the applicable agreements or coverage for any of its drugs under the Manufacturer Discount Program. If a Primary Manufacturer terminated its Agreement prior to completing the negotiation process and agreeing to an MFP, such process will be initiated or resumed in accordance with the negotiation process described in section 60 of this final guidance. In addition, the timing of the Primary Manufacturer's decision to resume participation in the Negotiation Program may implicate the renegotiation process described in section 130 of this final guidance.

If the conditions for termination of the Agreement for the Negotiation Program described above are met, CMS will terminate such Agreement effective on the first date on which the notices of termination for all applicable agreements have been received and none of the drugs of the

[148] See also section 80.1.3.1 of the Manufacturer Discount Program Final Guidance, which describes termination of applicable agreements in the context of Medicare Part D.

Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program. As is noted above, 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. If a Primary Manufacturer determines after executing its Agreement that it is unwilling to continue its participation in the Negotiation Program and provides a Request to Terminate that complies with the requirements in this section 40.6, the Primary Manufacturer's request will constitute good cause to terminate the Primary Manufacturer's agreement(s) under the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14C(b)(4)(B)(i) of the Act to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14C of the Act and thus facilitate an expedited Termination Date. Consistent with section 1860D-14C(b)(4)(B)(i) of the Act, and as described in section 40.1 of this final guidance and section 80.1.3 of the Manufacturer Discount Program Final Guidance,[149] a termination of a Manufacturer Discount Program agreement by CMS will not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination. As described in section 60.4 of this final guidance, CMS revised certain deadlines for the negotiation process for initial price applicability year 2028, 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.

Moreover, consistent with the process described in section 40.1 of this final guidance, if a Primary Manufacturer has determined it is unwilling to continue its participation in the Negotiation Program and provides a Request to Terminate that complies with the requirements in this section 40.6, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning the termination of the Primary Manufacturer's applicable agreements under the Manufacturer Discount Program, in accordance with section 1860D-14C(b)(4)(B)(i) of the Act. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers. CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision to terminate its participation in the Negotiation Program. Therefore, 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 the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its Request to Terminate.

If CMS determines the Primary Manufacturer's Request to Terminate complies with the requirements in this section 40.6, the Primary Manufacturer's request also will constitute good cause for CMS to terminate the Primary Manufacturer's applicable agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and section VII(b) of the NDRA. The Primary Manufacturer's applicable agreements include all the NDRAs of the Primary Manufacturer. Consistent with section 1927(b)(4)(B)(i) of the Act and section VII(b) of 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. CMS shall, upon request from the Primary Manufacturer, provide a hearing concerning the termination of the

[149] See: https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf.

Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program, in accordance with section 1927(b)(4)(B)(i) of the Act. Consistent with the procedures described above in the context of the Manufacturer Discount Program, such a hearing will be held solely on the papers and if the manufacturer has asked to rescind its Request to Terminate prior to the effective date of the termination, CMS will automatically grant such request.

For clarity, if the request to rescind termination of the applicable 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.

Notwithstanding any termination of the Agreement, the MFP shall continue to apply for any selected drugs that were dispensed prior to the Termination Date. Also, notwithstanding the termination of the Agreement, any confidentiality, record retention, and/or data requirements and any requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities shall continue to apply.

40.7 Other Provisions in the Agreement

Additional terms in the Agreement set forth general provisions in accordance with requirements determined by CMS to be necessary for purposes of administering or monitoring compliance with the Negotiation Program. For example, any notice required to be given by the Primary Manufacturer or CMS must be sent in writing via email to CMS- and the Primary Manufacturer-designated email addresses. CMS retains the authority to amend the Agreement to reflect changes in law, regulation, or guidance, and, when possible, CMS will give the Primary Manufacturer at least 60-day notice of any change to the Agreement.

In accordance with section 1193(a)(5) of the Act, if, after entering in an Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs / BLAs of the selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Agreement, including the requirement to provide access to the MFP, associated with the transferred NDA(s) / BLA(s) unless and until the Primary Manufacturer transfers all the NDAs / BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer. 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 Agreement for the Negotiation Program. 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. The transferring Primary Manufacturer shall provide CMS at least 30 calendar days written notice before the effective date of any such transfer and, if applicable, any novation.

If the Primary Manufacturer of a selected drug transfers all NDAs / 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, CMS recognizes 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 as described in section

40.6 of this final guidance for a Primary Manufacturer seeking to invoke the statutory suspension of the excise tax. CMS recognizes that whether this transfer of ownership would have these impacts may depend on whether the transfer of the NDA(s) / BLA(s) was made to an entity that is not a related party and complied with relevant principles of tax law.

If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.

50. Negotiation Factors

In accordance with sections 1193(a)(4) and 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug that has chosen to sign the Agreement must submit, in a form and manner specified by CMS, information on the non-FAMP for the selected drug (described in section 50.1.1 of this final guidance). The Primary Manufacturer must also submit information on certain factors (described in section 1194(e)(1) of the Act and described further in section 50.1 of this final guidance). The Primary Manufacturer will be responsible for aggregating and reporting information from any applicable Secondary Manufacturer(s). In addition, the statute prescribes that CMS also consider available evidence about therapeutic alternatives to the selected drug(s) (described in section 1194(e)(2) of the Act and described further in section 50.2 of this final guidance).

While the statute requires that CMS consider manufacturer-specific data for the factors described at section 1194(e)(1) of the Act, the statute does not specify what sources CMS must use for the factors described at section 1194(e)(2) of the Act regarding therapeutic alternatives to a selected drug. CMS will consider evidence about therapeutic alternatives relevant to the factors described in section 1194(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS would be best positioned to identify all available, relevant evidence for the factors described at section 1194(e)(2) of the Act.

CMS published the Drug Price Negotiation ICR in the Federal Register for a 60-day public comment period on June 30, 2025 and intends to publish a revised version of the ICR for a 30-day comment period in late Fall 2025. The Drug Price Negotiation ICR for initial price applicability year 2028 will describe how CMS intends to collect the data outlined in sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act, and will include instructions on how Primary Manufacturers and members of the public may submit relevant data. The ICR incorporates lessons learned pertaining to the collection process, question format, and content received from respondents for initial price applicability years 2026 and 2027.

The definitions that CMS is adopting for the purposes of describing the data to be collected for use in the Negotiation Program under sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act are specified in Appendix A of this final guidance.

In accordance with sections 1193(a)(4)(B) and 1194(b)(2)(A) of the Act, the data described in sections 50.1 and 50.2 of this final guidance for drugs selected for initial price applicability year

2028 must be submitted to CMS by March 1, 2026. CMS' intention to require public submission on the same date as manufacturer submission (i.e., March 1, 2026) serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer, pursuant to general program administration authority.

CMS will also obtain new information on the factors described at sections 1194(e)(1) and 1194(e)(2) of the Act for purposes of renegotiation (as described in section 1194(f) of the Act). These requirements are described further in section 130.3 of this final guidance.

50.1 Manufacturer-Specific Data

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 its offers, as described in section 60 of this final guidance. These factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Submission of these data by the Primary Manufacturer is required if an Agreement is signed; details related to the submission process are described in section 40.2 of this final guidance.

Section 1194(f)(4)(B) of the Act directs CMS to establish a renegotiation process that is, to the extent practicable, consistent with the negotiation process under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. Consistent with this directive, as described in section 130.3.2 of this final guidance, once a renegotiation-eligible drug is selected for renegotiation, CMS will collect new information for all section 1194(e)(1) data elements from all Primary Manufacturers with a drug selected for renegotiation.

The section 1194(e)(1) data elements include the following and are required to be reported by the Primary Manufacturer to CMS by March 1, 2026:

1. Research and development (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, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
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 for the Primary Manufacturer and any Secondary Manufacturer(s).

The Primary Manufacturer should submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to section 40.2 of this final guidance (e.g., NDC-11s distributed by a private label distributor and NDC-11s listed as a sample package, an inner package, an outer package, and discontinued). As noted above, CMS requires the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-

FAMP, current unit costs of production and distribution, and certain data pertaining to market data and revenue and sales volume data for the selected drug.

See Appendix A of this final guidance for a list of definitions that apply for purposes of describing these data to be collected for use in the Negotiation Program, including for renegotiation.

Additionally, the Primary Manufacturer has an ongoing obligation to timely report certain updates to data submissions required of Primary Manufacturers under sections 1193(a)(4)(A) and 1194(e)(1) of the Act and previously submitted to CMS through the initial response to the Drug Price Negotiation ICR Form. Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under sections 1193(a)(4)(A) and 1194(e)(1) to CMS if the data was restated due to requirements of the government entity that initially receives and oversees processing of such data. For example, under the Medicaid program, manufacturers must report revisions to best price under 42 C.F.R. § 447.510. Timely notify CMS via the IRA Mailbox at IRARebateandNegotiation@cms.hhs.gov with the subject line "Updates to 1194(e)(1) data submission for [name of selected drug]" if updates are applicable to the selected drug. CMS will provide a method and process for submission of these updates via the CMS HPMS at such time. 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 (see section 130.3.1 of this final guidance) and the required submission of section 1194(e)(1) data to CMS for renegotiation of drugs selected for renegotiation (see section 130.3.2 of this final guidance), which cover different reporting periods. CMS may also consider the Primary Manufacturer's original data submission, 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.

50.1.1 Non-FAMP Data

The Primary Manufacturer must submit data on non-FAMP for the selected drug for the Primary Manufacturer and any Secondary Manufacturer(s), as required under section 1193(a)(4)(A) of the Act. CMS will collect these data through the Drug Price Negotiation ICR described above. Specifically, under section 1194(c)(1)(C)(ii) of the Act, for initial price applicability year 2028, the Primary Manufacturer must submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar years 2021, as well as calendar year 2025 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2026). In the case that there is not an average non-FAMP price available for such drug for 2021, the Primary Manufacturer must submit 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 market entry of such drug. For purposes of determining the applicable year, CMS intends to consider the average non-FAMP price to be available for a selected drug for calendar year 2021 if the Primary Manufacturer reports at least one quarter of non-FAMP data for at least one NDC-11 of the selected drug in calendar year 2021.

As described in Appendix A, when for a given NDC-11 of a selected drug 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 calendar year 2025, 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. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS. The use of these data to calculate the ceiling for the MFP is further described in section 60.2 of this final guidance. Details on how CMS defines the parameters of the non-FAMP data collection are included in Appendix A of this final guidance and will be included in the Drug Price Negotiation ICR.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

As noted above, section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

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, hereinafter the "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the 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 additionally 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. Information submitted by members of the public, including manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties, or other information found by CMS that treats extending the life of individuals in these populations as of lower value will not be used in the Negotiation Program.[150] CMS will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the measure used is permitted in accordance with section 1194(e)(2) of the Act as well as section 1182(e) of Title XI of the Act and other applicable law, including section 504 of the Rehabilitation Act. 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 the law and does not treat 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

[150] Some uses of quality-adjusted life-years (QALYs) treat 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. CMS will not use any QALYs in the Negotiation Program.

terminally ill. In instances where some, but not all, content in a study is excluded (e.g., Quality-Adjusted Life Years (QALYs)), CMS may still consider content that is relevant and allowable (e.g., clinical effectiveness, risks, harms) under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act.

CMS removed the requirement for respondents to the Drug Price Negotiation ICR for initial price applicability year 2028 to indicate whether their submission contains information from studies that use measures or methods that treat 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 and the request that respondents provide a short description of any cost-effectiveness measures included in the research they are submitting, and how they believe the data avoids treating 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. Previous submissions to the Negotiation Data Elements and Drug Price Negotiation Process ICR from initial price applicability years 2026 and 2027 indicated that not all respondents are familiar with cost-effectiveness measures and, therefore, may not be able to provide relevant information to fulfill this requirement. Nonetheless, CMS reviews, and will continue to review, measures included in studies submitted by respondents through the Drug Price Negotiation ICR. CMS determines, and will continue to determine, if it is appropriate under section 1194(e)(2) of the Act for CMS to consider the information submitted.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties, may submit information on selected drugs and their therapeutic alternatives (specifically pharmaceutical therapeutic alternatives, as described in detail in section 60.3.1 of this final guidance), including information on whether the selected drug represents a therapeutic advance over its therapeutic alternative(s), prescribing information for the selected drug and its therapeutic alternative(s), comparative effectiveness data for the selected drug and its therapeutic alternative(s), information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, information about patient experience, and/or information on whether the selected drug addresses unmet medical need, as described in section 1194(e)(2) of the Act. Outcomes such as changes to productivity, independence, and quality of life will also be considered when these outcomes correspond with a direct impact on the individuals taking the selected drug or therapeutic alternative and are appropriately measurable and quantifiable.

CMS additionally will review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this final guidance) when considering available evidence about alternative treatments to the selected drug. When reviewing the literature from the public and manufacturer submissions as well as literature from CMS' review, CMS intends 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. CMS will prioritize research, including both observational

research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., 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.

CMS will consider research and real-world evidence relating to Medicare populations, including individuals with disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS intends 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.

All information on the factors described in section 1194(e)(2) of the Act related to drugs selected for initial price applicability year 2028 must be submitted to CMS by March 1, 2026.

See Appendix A of this final guidance for a list of definitions that apply for the purposes of describing these data to be collected for use in the Negotiation Program.

Pursuant to section 1195(a)(2) of the Act and as discussed in section 60.6.1 of this final guidance, CMS is required to publish the explanation of the MFP by March 1, 2027 for initial price applicability year 2028 selected drugs. Within the explanation of the MFP, CMS may also make public high-level comments about the section 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, for each drug, CMS will make available on the CMS website redacted versions of section 1194(e)(2) data submitted by the public that are determined to be non-proprietary and will not disclose any PHI, PII, or information that is protected from disclosure under other applicable law.

60. Negotiation Process

In accordance with section 1194(b)(1) of the Act, CMS will develop and use a consistent methodology and process for negotiation with the aim of achieving agreement on "the lowest maximum fair price for each selected drug." This section 60 describes the negotiation process, including engagement with Primary Manufacturers and interested parties, the development of the written initial offer, the process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug, the process and requirements for accepting an offer or providing a statutory written counteroffer, optional negotiation meetings between CMS and the Primary Manufacturer, additional price exchange opportunities, the conclusion of negotiation, the publication of the MFP, and explanation of the MFP. The policies and procedures set forth in sections 60.1, 60.3, 60.4, 60.5, and 60.6 of this final guidance will also apply for purposes of renegotiation such as: (1) for drugs selected for renegotiation, the renegotiation process will establish a single price based on 30-day equivalent supply, as described below for the negotiation process in section 60.1 of this final guidance; (2) the methodology for developing an initial offer

as described in section 60.3 of this final guidance; (3) drugs selected for renegotiation will go through the same procedures, structure, and timing as selected drugs for negotiation as described in section 60.4 of this final guidance; (4) a single MFP will apply across dosage forms and strengths of the renegotiated selected drug, for drugs payable under Part B and/or covered under Part D, as applicable as described in section 60.5 of this final guidance; and (5) publication and explanation of the MFP as described in section 60.6 and 60.6.1 respectively of this final guidance. Determining the ceiling for renegotiation is described in section 130.4.1 of this final guidance.

60.1 Establishment of a Single MFP for Negotiation and Renegotiation Purposes
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 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. CMS interprets this language to refer to negotiation of a single price for a selected drug with respect to its price applicability period. Accordingly, CMS will identify a single price for use at each step in the negotiation process described in this section 60, meaning each offer and counteroffer, described in section 60.4 of this final guidance, will include a single price, even for a selected drug with multiple dosage forms and strengths. Once the MFP has been agreed upon, section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply the MFP across different dosage forms and strengths of a selected drug.

Whereas for purposes of negotiation and renegotiation, the focus is on establishing the MFP, for purposes of MFP implementation, the Medicare payment will use the MFP, as applicable, within established Medicare payment methodologies. For example, in accordance with section 1847A(b)(1)(B) of the Act, Medicare payments under Part B for a selected drug shall be 106 percent of the MFP. In another example, in accordance with section 1860D-2(d)(1) of the Act, the negotiated prices used for payment under Part D for a selected drug shall be no greater than the MFP plus any dispensing fees.

For the purposes of determining a single price included in an initial offer (including evaluating clinical benefit compared to the therapeutic alternative(s), as described in section 60.3 of this final guidance) and conducting the negotiation, CMS intends 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 and/or covered under Part D, as applicable), weighted across dosage forms and strengths. This approach of negotiating a single price across all dosage forms and strengths aligns with the statutory requirement to negotiate an MFP for a selected drug. CMS believes this will also allow for a more direct comparison with the therapeutic alternative(s), which might have different dosage forms, strengths, and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) than the selected drug.

Section 60.5 of this final guidance describes the methodology CMS will use to translate the MFP once finalized (which, per above, will be an average price per 30-day equivalent supply for the selected drug across all formulations of the drug) back into per unit (e.g., tablet) prices at the dosage form and strength level, per package (e.g., bottle), and per HCPCS code dosage, for the

purposes of publishing per-unit, per-package, and per-HCPCS code dosage MFPs for the different dosage forms and strengths of the selected drug at the NDC-9, NDC-11, and HCPCS code levels, as contemplated under section 1196(a)(2) of the Act. Section 60.5.1 of this final guidance describes the process by which CMS will apply the MFP to new NDAs / BLAs, NDCs, or HCPCS codes, including those added during the negotiation period or after any agreement upon MFP is reached, and to NDCs and HCPCS codes with insufficient PDE, Part B data, or WAC data in calendar year 2025 to apply the MFP across those dosage forms and strengths. In addition to the description of that methodology included in this final guidance, as feasible, CMS will share the inputs behind that methodology specific to the selected drug with the Primary Manufacturer of the selected drug during the negotiation period such that the Primary Manufacturer will have visibility into the implied unit prices, package prices, and HCPCS code dosage prices based on the MFP for the different dosage forms and strengths of the selected drug throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price would be clearly translatable to per unit, per package, and per HCPCS dosage code prices at the dosage form and strength level).

60.2 Limitations on Offer Amount

In accordance with section 1194(b)(2)(F)(i) of the Act, in negotiating the MFP of selected drugs with respect to initial price applicability year 2028, 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. This section 60.2 of this final guidance provides details on the determination of the ceiling for the MFP and comparison of the ceiling to the MFP.

60.2.1 Determination of the Ceiling for the MFP

In accordance with section 1194(c) of the Act, for initial price applicability year 2028, the ceiling for the MFP for a selected drug shall not exceed the lower of the following:

- As described in section 60.2.2 of this final guidance and section 1194(c)(1)(B) of the Act, an amount equal to one of the following, as applicable to the selected drug:
    - 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 described in section 60.2.2.1 of this final guidance; or
    - 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, as described in section 60.2.2.2 of this final guidance; or
    - 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 weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount (hereinafter the "combined Part B and Part D amount"), as described in section 60.2.2.3 of this final guidance. CMS interprets the language in section 1194(c)(1)(B) of the Act to mean that it should calculate a single ceiling incorporating both of these amounts for selected drugs payable under Part B and covered under Part D; or
    - For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act (for example, selected drugs which are paid on the

basis of 95 percent of Average Wholesale Price (AWP)), but is not covered under Part D, an amount based on the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance; or
    - For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and covered under Part D, an amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance or the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.
- As described in section 60.2.3 of this final guidance and section 1194(c)(1)(C) of the Act, an amount equal to the applicable percent, as applicable to the selected drug, of the lower of:
    - The average non-FAMP as defined in section 1194(c)(6) of the Act for such 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 2025;[151] or
    - The average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for the calendar year prior to the selected drug publication date, February 1, 2026, which for initial price applicability year 2028 is 2025.

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean that it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan-specific enrollment weighted amounts under Part D, the payment amount under section 1847A(b)(4) under Part B, the combined Part B and Part D amount, and the applicable percent of the average non-FAMP in order to determine which one is lower and will serve as the ceiling for the MFP. To determine which of these will be used to calculate the ceiling for the MFP, CMS will aggregate the amounts determined for each NDC-11 for the selected drug to calculate a single amount—separately for each methodology—across dosage forms, strengths, and package sizes of the selected drug. These amounts can then be directly compared, and the ceiling for the single MFP of the selected drug (including all dosage forms and strengths) will be the lower amount.

CMS will use information submitted by manufacturers to the CMS HPMS pursuant to section 40.2 of this final guidance to determine which NDC-11s of the selected drug will be included in the ceiling calculations described in sections 60.2.2 and 60.2.3 of this final guidance, based on the criteria described below.

- Sum of the plan-specific enrollment weighted amounts for the most recent year for which data is available (calendar year 2024 for initial price applicability year 2028): (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) CMS observes any PDE days' supply, PDE quantity dispensed, and PDE gross expenditures in calendar year 2024; and (4) CMS observes any associated Direct and Indirect Remuneration (DIR) amounts for the NDC-11 for calendar year 2024.

[151] Data retrieved from https://www.bls.gov/cpi/data.htm.

- Payment amount under section 1847A(b)(4) for the most recent year for which data is available (calendar year 2025 for initial price applicability year 2028): (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) the NDC-11 is assigned to a HCPCS code; and (4) CMS observes any Part B data for the HCPCS code to which the NDC-11 is assigned in calendar year 2025.
- Average non-FAMP 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): (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) CMS received non-FAMP data for the NDC-11 for at least one calendar quarter in 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); and (4) 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 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).
- Average non-FAMP for calendar year 2025: (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) CMS received non-FAMP data for the NDC-11 for at least one calendar quarter in calendar year 2025; and (4) 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 2025.

For the purposes of calculating the sum of the plan-specific enrollment weighted amounts and average non-FAMP amounts, PDE data will be included in the ceiling calculation for the included NDC-11s of the selected drug when the PDE record is associated with a prescription filled between January 1 and December 31 of the calendar year of interest for the calculation and meets the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance.[152] An additional requirement specific to the sum of the plan-specific enrollment weighted amount calculation for calendar year 2024 is that the Part D plan that submitted the PDE record also included the NDC-11 associated with the PDE record in their calendar year 2024 DIR data (discussed further in section 60.2.2 of this final guidance).[153]

For the purposes of calculating the payment amount under section 1847A(b)(4) of the Act, FFS Part B claims data will be included in the ceiling calculation for HCPCS codes to which the NDC-11s of the selected drug are assigned when the claim line is associated with a service date

[152] The year used for average non-FAMP for calendar year (CY) is CY 2021, CY 2024 is used for sum of the plan-specific enrollment weighted amounts, and CY 2025 is used for average non-FAMP for CY 2025 as stated in the bulleted criteria above in this section.

[153] For example, if a Part D plan submitted five PDE records associated with a particular NDC-11, but the Part D plan did not include that NDC-11 in their Detailed DIR data submitted to CMS then the five PDE records from this Part D plan associated with that NDC-11 would be excluded from the sum of the plan-specific enrollment weighted amounts calculations. PDE records associated with that NDC-11 from other Part D plans would be included in the sum of the plan-specific enrollment weighted amounts calculations if they met the criteria described in this paragraph.

between January 1, 2025, and December 31, 2025, and meets the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance.

For the purposes of calculating the payment amount under section 1847A(b)(4) of the Act, MA encounter data for Part B items and services will be included in the ceiling calculation for HCPCS codes to which the NDC-11s of the selected drug are assigned when the MA encounter data record for Part B items and services has an encounter data record line that is associated with a service date between January 1, 2025, and December 31, 2025, and meets the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance.

60.2.1.1 Determination of the 30-Day Equivalent Supply for a Selected Drug

CMS will calculate a single ceiling per 30-day equivalent supply across all dosage forms and strengths of the selected drug. 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 (e.g., mg versus mL) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ.

To calculate the 30-day equivalent supply for each PDE record associated with a selected drug that is a drug covered under Part D, CMS will use the methodology as described at 42 C.F.R. § 423.104(d)(2)(iv)(A)(2). This methodology relies on the "days' supply" field in PDE records.

To calculate the 30-day equivalent supply for Part B data associated with selected drugs that are payable under Part B, CMS must use an alternative methodology because Part B data does not contain a "days' supply" field. CMS will conduct the following steps to determine the 30-day equivalent supply for Part B data:

1. For a given Part B claim or record for the selected drug's HCPCS code in calendar year 2025, CMS will identify any subsequent Part B claim or record, 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 as the selected drug.
2. CMS will calculate a "days between service" amount by counting the days between the first Part B claim or record's date of service and the immediately subsequent Part B claim or record's, or PDE record's, date of service. For example, if the first Part B claim or record's date of service is January 12, 2025 and the immediately subsequent Part B claim or record with the same active moiety / active ingredient is another Part B claim or record with a date of service of March 12, 2025, the "days between service amount" would be calculated as 59 days. This would be the same calculation if the subsequent claim was a PDE record.
    a. If the beneficiary does not have subsequent Part B claim or record or PDE record with the same active moiety / active ingredient (for example, if the Part B claim or record in question is the last Part B claim or record or PDE record associated with the active moiety / active ingredient that the beneficiary received), CMS intends to assign a "days between service" amount equal to the median "days between service" amount for all other Part B claims or records or PDE records for that selected drug associated with that beneficiary during the applicable claims period. CMS chose median as opposed to other measures because median is a common measure of central tendency that is less influenced by outlier values. If there are

no other Part B claims or records or PDE records for that selected drug associated with that beneficiary during the applicable claims period, CMS will not assign a "days between service" amount, and the claim will not be included in the calculations.

b. Continuing the example above, if the beneficiary's third Part B claim or record or PDE record was August 1, 2025, the number of "days between service" amount, for days between March 12, 2025 and August 1, 2025, would be calculated as 142. If the beneficiary only had one Part B claim or record or PDE record after August, it would be assigned the median of 59 and 142, which is 100.5.

3. CMS will use the "days between service" amount calculated for each Part B claim or record or PDE record to calculate the 30-day equivalent supply. For each Part B claim or record or PDE record, the number of 30-day equivalent supplies is equal to the 'days between service' divided by 30.

Because 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, CMS will allocate a portion of the HCPCS code's 30-day equivalent supply to each NDC within the HCPCS code for calculations that require 30-day equivalent supply at the NDC level.

To determine the total Part B 30-day equivalent supply at the NDC-level, CMS will conduct the following steps:

1. 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 applicable quarter, 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.
2. For all NDC-11s assigned to the HCPCS code, sum the total billing units sold for such NDC-11s across all calendar quarters to calculate an annual amount.
3. For each NDC-11 associated with the selected drug, divide the total billing units sold for that NDC-11 by the total billing units sold for all applicable NDC-11s of the same HCPCS code.
4. For each NDC-11 associated with the selected drug, multiply the 30-day equivalent supply for the HCPCS code (as described above) by the quotient calculated in step 3 to yield the 30-day equivalent supply for the NDC-11.
    a. If the calculation for which CMS is using 30-day equivalent supply requires the 30-day equivalent supply at the NDC-9 level, sum the amount calculated in step 4 for all NDC-11s within the NDC-9 to calculate the total Part B 30-day equivalent supply attributed to the NDC-9.

60.2.2 Determination of the Sum of the Plan-Specific Enrollment Weighted Amounts, the Payment Amount Under Section 1847A(b)(4) of the Act, and the Combined Part B and Part D Amount

If a selected drug is covered under Part D but is not payable under Part B, as set forth in the preceding section, CMS will calculate the sum of the plan-specific enrollment weighted amounts as described in section 60.2.2.1 of this final guidance. If a selected drug is payable under Part B and paid under section 1847A(b)(4) of the Act, but is not covered under Part D, as set forth in the

preceding section, CMS will calculate the payment amount under Section 1847A(b)(4) of the Act as described in section 60.2.2.2 of this final guidance. If a selected drug is payable under Part B and paid under section 1847A(b)(4) of the Act and covered under Part D, as set forth in the preceding section, CMS will calculate a single amount referred to as the combined Part B and Part D amount as described in section 60.2.2.3 of this final guidance.

60.2.2.1 The Sum of the Plan-Specific Enrollment Weighted Amounts

In accordance with section 1194(c)(1)(B)(i) of the Act, CMS will calculate for a selected drug that is covered under Part D an amount equal to the sum of the plan-specific enrollment weighted amounts determined using the methodology described in section 1194(c)(2) of the Act. Plan sponsors report Part D PDE data to CMS at the NDC-11 level. Sponsors also report DIR data to CMS at the NDC-11 level in the annual Detailed DIR Report. As directed by statute, CMS will use these reported data for plan year 2024, which is the most recent year for which data will be available, for the purpose of determining the sum of the plan-specific enrollment weighted amounts for a selected drug that is covered under Part D for initial price applicability year 2028.

CMS will include all Part D plans[154] found in the PDE data that meet the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance. Because CMS will have no PDE data for Part D plans in the following circumstances, such Part D plans will, by definition, be excluded from the calculation of the sum of the plan-specific enrollment weighted amounts: (1) plans that have no utilization for the selected drug; and (2) plans that have no enrollment for 2024.[155]

CMS will calculate the sum of the plan-specific enrollment weighted amounts in two stages. First, CMS will calculate the sum of the plan-specific enrollment weighted amounts for each NDC-9 associated with NDC-11s identified based on the criteria described in section 60.2.1 of this final guidance. Second, CMS will calculate the sum of the plan-specific enrollment weighted amounts across these NDC-9s. The amounts calculated at each stage are for a 30-day equivalent supply (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology).

To determine the sum of the plan-specific enrollment weighted amounts for each NDC-9 and across all NDC-9s of the selected drug associated with the NDC-11s, CMS will conduct the following steps.

Steps 1 through 8 will result in the sum of the plan-specific enrollment weighted amounts for each NDC-9 of the selected drug associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this final guidance:

1. For each Part D plan, CMS will identify the PDE data for the selected drug for 2024 using the criteria described in section 60.2.1 of this final guidance.

[154] CMS intends to identify Part D plans based on the combination of the Part D contract identifier and the plan benefit package identifier.

[155] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

2. For each Part D plan and each NDC-9, CMS will separately sum the negotiated price amounts (as defined in 42 C.F.R. § 423.100), the estimated remuneration at point-of-sale amounts (ERPOSA),[156] and units dispensed.
3. For each Part D plan and each NDC-9, CMS will sum the total DIR amounts found in the 2024 Detailed DIR Report and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale.
4. For each Part D plan and each NDC-9, CMS will subtract the total DIR minus ERPOSA amount calculated in step 3 from the total negotiated price amounts calculated in step 2 and then divide by the total units dispensed also determined in step 2. This calculation results in the NDC-9 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.
5. Separately, CMS will identify the total number of individuals enrolled in all Part D plans in December 2024 and the total number of individuals enrolled in each Part D plan in that same month, for each NDC-9 of the selected drug.[157] The Part D plans included in the calculations of this step for a given NDC-9 will be restricted to Part D plans with at least one PDE record for that NDC-9 identified in step 1.
6. For each Part D plan and each NDC-9, CMS will divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2024 as identified in step 5 by the total number of individuals enrolled in all Part D plans also as identified in step 5, and multiply 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, calculated in step 4, to arrive at the plan-specific enrollment weighted amount.
7. For each NDC-9, CMS will then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan-specific enrollment weighted amounts.
8. For each NDC-9, CMS will then multiply the sum of the plan-specific enrollment weighted amounts calculated in step 7, which are a per unit price, by the NDC-9 average number of units per 30-day equivalent supply calculated from PDE data for 2024 (i.e., quotient of the total quantity dispensed and the total 30-day equivalent supply) to yield the price of a 30-day equivalent supply.

Steps 9 through 10 result in the sum of the plan-specific enrollment weighted amounts across all NDC-9s of the selected drug:

9. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s of the selected drug, both calculated from 2024 PDE data, and multiply this quotient by the sum of the plan-specific enrollment weighted amounts for a 30-day equivalent supply as calculated in step 8.
10. CMS will then sum amounts calculated in step 9 across all NDC-9s 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.

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[156] ERPOSA is 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 (POS). For further information please see: https://www.cms.gov/files/document/erposamemo508g.pdf or refer to 87 Fed. Reg. 27704 (May 9, 2022).

[157] CMS 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 CMS chose December as the most stable month to identify enrollment. The choice of one month to identify enrollment also allows the weights calculated in step 6 to sum to one.

60.2.2.2 Payment Amount Under Section 1847A(b)(4) of the Act

In accordance with section 1194(c)(1)(B)(ii) of the Act, CMS will calculate for a selected drug payable under Part B 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. The payment amount ceiling calculated and described below will be considered only for selected drugs that are payable under Part B and paid according to section 1847A(b)(4). Section 60.2.2.3 of this final guidance will describe the determination of payment amount for selected drugs payable under Part B and covered under Part D.

CMS interprets the statute to mean that the payment amount under section 1847A(b)(4) of the Act refers to the payment amount specified in section 1847A(b)(4) of the Act which is, for single-source drugs and biological products, the lesser of the annual ASP or WAC. The amount described under section 1847A(b)(4) of the Act is not adjusted to account for sequestration. Therefore, CMS does 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.[158] As directed by statute, CMS will use the quarterly reported ASP and WAC data for calendar year 2025, for the purpose of determining the payment amount under section 1847A(b)(4) of the Act for a selected drug for initial price applicability year 2028.

For single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP), but are not covered under Part D (meaning CMS is unable to calculate the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount), CMS would default to the ceiling amount determined under section 1194(c)(1)(C)(ii) of the Act. That is, for selected drugs payable under Part B but not paid based on section 1847A(b)(4) of the Act, CMS would calculate the ceiling based on the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance.

Before calculating the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply across all dosage forms and strengths of a selected drug, CMS will first (1) calculate the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which NDC-11s of the selected drug are assigned, which CMS will then assign as the payment amount under section 1847A(b)(4) of the Act for each NDC-11 of the selected drug within such HCPCS code; and (2) allocate HCPCS code-level utilization from Part B data across each NDC-11 assigned to such HCPCS code, so that CMS 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.

[158] A sequestration payment adjustment, when applicable, is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, Merit-based Incentive Payment (MIPS) adjustments, and any applicable Medicare Secondary Payment adjustments.

Calculating the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which NDC-11s of the selected drug are assigned

CMS will calculate the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which an NDC-11 of the selected drug is assigned using data from manufacturers of all NDC-11s that (1) are assigned to the HCPCS code; and (2) are part of the selected drug. CMS will separately calculate annual ASP and WAC amounts and then compare the amounts to determine the lower value for use as the payment amount under section 1847A(b)(4) of the Act, based on ASP and WAC data as reported in sections 1927(b)(3) and 1847A(f) of the Act.

CMS will convert the quarterly ASP and WAC reported by manufacturers for each NDC for a selected drug that is associated with a HCPCS code to an annual calendar year 2025 ASP or WAC amount for each HCPCS code by taking an average of the reported ASP or WAC amounts for the HCPCS code across all four quarters of calendar year 2025, weighted by the total number of billing units in the Part B data within that HCPCS code each quarter. If the total units reported for all NDC-11 sales within the HCPCS code are negative, zero, or missing for a given quarter,[159] CMS will assign that quarter the total units of the lowest positive total units from the other quarters in calendar year 2025 for that HCPCS code.

For each of the ASP and WAC calculations separately, if the reported price is negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code in a given quarter, CMS will exclude that quarter from the calculation. 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, CMS will use the WAC reported by Primary Manufacturers to CMS under section 1194(e)(1) as described in section 50.1 and Appendix A of this final guidance.

After calculating an annual ASP and an annual WAC, CMS will determine the lesser of the two to yield the payment amount under section 1847A(b)(4) of the Act for that HCPCS code. This amount will apply to all applicable NDC-11s assigned to that HCPCS code.

If both ASP and WAC are negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code for all four quarters of calendar year 2025, CMS will calculate the payment amount under section 1847A(b)(4) of the Act by taking the average of the published payment limits in the ASP pricing file (or in the OPPS Addendum B file, if it is not available in the public pricing file) for the HCPCS code across all four quarters, weighted by reported ASP units following the methodology for weighting by reported ASP units described above (including the adjustments made when units are negative, zero, or missing for at least one quarter). CMS believes 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 (e.g., negative, zero, or missing ASP and/or WAC).

Allocating HCPCS code-level utilization from Part B data for Part B services across each NDC-11 assigned to that HCPCS code

Because Part B data are recorded at the HCPCS code level and CMS uses NDC-level utilization weighting to calculate amounts for the ceiling, CMS will allocate HCPCS code-level utilization

[159] For more information on ASP, see: https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.

from Part B data to NDC-9-level utilization using the proportion of ASP units reported by manufacturers to CMS for each NDC-11 that is associated with the NDC-9 and is assigned to the HCPCS code. CMS will also convert Part B data unit types to be equivalent to PDE unit types to facilitate the calculation of a single amount, the combined Part B and Part D amount, that incorporates both the sum of the plan-specific enrollment weighted amounts and the payment amount under Section 1847A(b)(4) of the Act as described in section 60.2.2.3 of this final guidance. If there is no equivalent unit type in PDE, CMS will not convert the Part B unit type to a PDE unit type. CMS believes that this circumstance typically occurs in situations where the drug is not covered under Part D (e.g., radiopharmaceuticals that use HCPCS units expressed in millicuries)—meaning CMS would not need to calculate a combined Part B and Part D amount. However, in the event that the drug is also covered under Part D, CMS would separately calculate the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act and take the average of the two total amounts (expressed in terms of a 30-day equivalent supply), weighted by the total 30-day equivalent supply of each, to yield the combined Part B and Part D amount.

CMS will convert Part B data billing units to be equivalent to NCPDP units that are used in PDE records, and determine the respective share of the combined utilization from Part B data for an NDC-9 within a HCPCS code ("converted Part B units attributed to the NDC-9") using the following steps:

1. For each HCPCS code, calculate the total Part B units by multiplying the total billing units in Part B data for the HCPCS code by the standard billing unit for the HCPCS code.
2. 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), calculate the total number of billing units for the NDC-11 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.
3. For each NDC-9, divide the sum of billing units, as calculated in step 2, for all NDC-11s that belong to the selected drug and are associated with that NDC-9 by the total billing units for all NDC-11s of the same HCPCS code.
4. For each NDC-9, multiply the total Part B units from Part B data for the HCPCS code as calculated in step 1 by the quotient calculated in step 3 to determine the total Part B units for each NDC-9.
5. For each NDC-9, multiply the total Part B units from Part B data for that NDC-9 by the billing unit to NCPDP unit 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 B units for that NDC-9.

Calculating the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug

CMS will calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug in two stages. First, CMS will calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of each NDC-9 associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this

final guidance. Second, CMS will calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply across all NDC-9s for a selected drug.

To determine the payment amount under section 1847A(b)(4) of the Act for each NDC-9 and across all NDC-9s of the selected drug associated with the NDC-11s, CMS will conduct the following steps.

Steps 1 through 6 will result in the payment amount under section 1847A(b)(4) of the Act for each NDC-9 of the selected drug associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this final guidance:

1. For each selected drug, CMS will identify the NDC-11s and the unique HCPCS code(s) associated with the selected drug using the criteria described in section 60.2.1 of this final guidance. CMS intends to identify the annual calendar year 2025 payment amount under section 1847A(b)(4) of the Act for each HCPCS code and assign it to each NDC-9 within that HCPCS code as described earlier in section 60.2.2.2 of this final guidance.
2. For each NDC-9, CMS will sum the converted Part B units from Part B data attributed to the NDC-9 (calculated as described immediately preceding these steps in section 60.2.2.2 of this final guidance) across all four quarters of calendar year 2025 to calculate the annual Part B units of that NDC-9.
3. For each NDC-9, CMS will calculate the total Part B 30-day equivalent supply in Part B data attributed to that NDC-9 in calendar year 2025 as described in section 60.2.1.1 of this final guidance.
4. For each NDC-9, CMS will calculate the quotient of the annual Part B units in Part B data of the NDC-9 calculated in step 2 and the total Part B 30-day equivalent supply in Part B data calculated in step 3 (the average number of units per 30-day equivalent supply).
5. For each NDC-9, CMS will then multiply the payment amount under section 1847A(b)(4) of the Act in step 1 by the average number of units per 30-day supply calculated in step 4 to yield the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9.

Steps 6 through 7 will result in the annual calendar year 2025 payment amount under section 1847A(b)(4) of the Act across all NDC-9s of the selected drug:

6. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9, calculated in step 3, by the total 30-day equivalent supply across all NDC-9s of the selected drug and multiply this quotient by the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9 as calculated in step 5.
7. CMS will then sum the amounts calculated in step 6 across all NDC-9s 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.

60.2.2.3 Determination of Combined Part B and Part D Amount for Selected Drugs Payable Under Part B and Covered Under Part D

CMS interprets the language in section 1194(c)(1)(B) of the Act to mean it should calculate a single amount across the payment amount under section 1847A(b)(4) of the Act and the sum of

the plan-specific enrollment weighted amounts for all dosage forms and strengths of a selected drug that is payable under Part B and covered under Part D. Section 1194(c)(1)(B) of the Act provides for the calculation of "an amount," in the singular, for each selected drug. It then specifies the payment amount under section 1847A(b)(4) of the Act as the amount to be used for selected drugs for which payment may be made under Part B and the sum of the plan-specific enrollment weighted amounts as the amount to be used for selected drugs covered under Part D. It does not specify that CMS should select only one when calculating the amount for a drug that fits into both categories. For such selected drugs, section 1194(c)(1)(B) of the Act's direction to calculate a single amount for each selected drug therefore means that CMS should calculate a single 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. To calculate the subparagraph (B) amount for such a selected drug, CMS will calculate a weighted average of the payment amount under section 1847A(b)(4) of the Act as outlined in section 60.2.2.2 and the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.

For single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP), and covered under Part D, CMS will calculate the ceiling amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.3 of this final guidance and the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.

CMS will calculate a single payment amount per 30-day equivalent supply across the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act in several stages. First, CMS will separately calculate the sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for each NDC-9, as described in sections 60.2.2.1 and 60.2.2.2 of this final guidance, respectively. Second, CMS will calculate a weighted average of the sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act per 30-day equivalent supply for these NDC-9s, using the respective utilization for the NDC-9 in Part D and Part B as described in the following steps.

Steps 1 through 3 will result in the sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply for each NDC-9 of the selected drug associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this final guidance:

1. For all NDC-9s associated with NDC-11s of the selected drug that meet the criteria described in section 60.2.1 of this final guidance, CMS will separately calculate the sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply. If an NDC-9 is only present in PDE data, CMS will calculate only the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply for that NDC-9. If an NDC-9 is only associated with a Part B HCPCS code that is present in Part B data, CMS will calculate only the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9. If an NDC-9 is both present in PDE data and is associated with a Part B HCPCS code that is present in Part B data, CMS intends to calculate 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-9; however, in the utilization weighting described below, CMS will treat the NDC-9 as having two distinct versions and keep those versions separate in the utilization weighting to allow the Part D formulations and Part B formulations to contribute separately to the single amount. CMS believes this step is necessary to account for differences in the pricing data between Part D and Part B.

2. For each NDC-9 identified in step 1 present in PDE data, CMS will calculate the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply as described in steps 1 through 8 under section 60.2.2.1 of this final guidance and the total 30-day equivalent supply.
3. For each NDC-9 identified in step 1 associated with a HCPCS present in Part B data, CMS will calculate the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply as described in steps 1 through 5 under section 60.2.2.2 of this final guidance and the total 30-day equivalent supply.

Steps 4 through 5 will result in the combined sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act across all NDC-9s of the selected drug:

4. For each NDC-9 identified in steps 2 and 3, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s (both those present in PDE data and those associated with HCPCS present in Part B data) of the selected drug, and multiply 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-9. As stated above, if an NDC-9 is present in both PDE data and associated with a HCPCS code present in Part B data, CMS will treat each version as a distinct NDC-9 in this step of the calculation.
5. CMS will then sum the amounts calculated in step 4 across all NDC-9s of the selected drug (including both the Part B version and the Part D version of NDC-9s 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.

60.2.3 Determination of the Average Non-Federal Average Manufacturer Price

In accordance with section 1194(c)(1)(C)(ii) of the Act, when comparing against the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable, to determine the ceiling for each selected drug for initial price applicability year 2028, CMS will use the lower of:

1. The calculated amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021,[160] increased by the percentage increase

[160] If there is not a non-FAMP (or an average non-FAMP can't be calculated) for such drug for calendar year 2021, CMS intends to use the data for the first full year following the market entry for such drug. This applies for all references of calendar year 2021 when cited for non-FAMP, average non-FAMP, and PDE in section 60.2.3 of this final guidance.

in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September 2025;[161] or
2. The calculated amount equal to the applicable percent of the average non-FAMP price for the selected drug for calendar year 2025.

First, CMS will use the non-FAMP price and unit volume data for each NDC-11 that meets the criteria to be included in the 2021 average non-FAMP calculation as described in section 60.2.1 of this final guidance. CMS will use the data that is submitted by the Primary Manufacturer pursuant to section 1193(a)(4)(A) of the Act (as described in section 50.1 of this final guidance) for each quarter of calendar year 2021 to calculate an annual average non-FAMP per-unit for calendar year 2021.

CMS will then use 2021 PDE quantity dispensed and days' supply data submitted to CMS at the NDC-11 level by Part D plan sponsors, and/or total Part B billing units from Part B data and 30-day equivalent supply data at the HCPCS code level, as applicable, for calendar year 2025 for the following:

1. To calculate an annual average non-FAMP per unit for each NDC-9 of the selected drug.
2. To calculate the annual average non-FAMP per 30-day equivalent supply for each NDC-9 of the selected drug.
3. To calculate the annual average non-FAMP per 30-day equivalent supply for the selected drug.

Second, CMS will follow the same methodology that is described above for calendar year 2021 to calculate the average non-FAMP for calendar year 2025. The methodology will use the manufacturer-reported non-FAMP for 2025 and calendar year 2025 PDE quantity dispensed and days' supply and/or total Part B billing units from Part B data and 30-day equivalent supply data, as applicable, in the calculation for NDC-11s that meet the criteria to be included in the 2025 average non-FAMP calculation as described in section 60.2.1 of this final guidance. As described in section 60.2.1 of this final guidance, for initial price applicability 2028, the set of NDCs used to calculate the annual average non-FAMP calculation for calendar year 2021 may differ from the set of NDCs used to calculate the annual average non-FAMP calculation for calendar year 2025.

In order to directly compare the amount calculated based on the applicable percent of average non-FAMP and the amount calculated based on the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable, (as described in section 60.2.2 of this final guidance), CMS will base the average non-FAMP calculations on a 30-day equivalent supply.

CMS will calculate the applicable percent of the average non-FAMP for calendar year 2021 and 2025 in two stages to determine which is lower. First, for each calendar year, CMS will calculate the applicable percent of the average non-FAMP for each NDC-9 of the selected drug. Second, for each calendar year, CMS will calculate the applicable percent of the average non-FAMP across NDC-9s of the selected drug. The amounts calculated in each stage are for a 30-day equivalent supply as described in section 60.2.1 of this final guidance.

[161] Data retrieved from https://www.bls.gov/cpi/data.htm.

To determine the applicable percent of the average non-FAMP for each NDC-9 and across all NDC-9s of the selected drug, CMS will conduct the following steps separately for calendar year 2021 and calendar year 2025.

Steps 1 through 9 will result in the average non-FAMP, adjusted for inflation if applicable, and with the applicable percent applied, for each NDC-9 of the selected drug associated with the NDC-11s identified in section 60.2.1 of this final guidance:

1. To calculate an average non-FAMP that is comparable to the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable, described in section 60.2.2 of this final guidance, CMS will determine the total number of NCPDP units per NDC-11 package, so that the payment amounts (average non-FAMP and the sum of the plan-specific enrollment weighted amounts, payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount) represent the same quantity of the selected drug.[162]
2. For each NDC-11 and for each quarter during the calendar year, CMS will calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of NCPDP units per package.
    - Note: For the calendar year 2021 calculation, if the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 50.1.1 of this final guidance), CMS will use the non-FAMP for the quarters of the first full calendar year following the market entry for such drug.
3. For each NDC-11 and for each quarter during the calendar year, CMS will divide 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 step 2.
    - Note: For the calendar year 2021 calculation, if the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 50.1.1 of this final guidance), CMS will use the non-FAMP and total unit volumes for the quarters of the first full calendar year following the market entry for such drug.
4. For each NDC-11, CMS will sum the amounts calculated in step 3 across quarters to calculate the average non-FAMP per unit for that NDC-11 for the calendar year. CMS believes steps 3 and 4 are necessary to account for non-FAMP unit volume fluctuations that may occur across quarters.
5. For each NDC-11, CMS will divide the total units for that NDC-11 by the total units for all applicable NDC-11s of the same NDC-9 and multiply this quotient by the average non-FAMP per unit for the calendar year calculated in step 4, applying the methodology below, as applicable:

[162] National Council for Prescription Drug (NCPDP) defined values are each, milliliter, and grams. See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

5a. NDC-11s that are present only in PDE data: Total units are defined as the total quantity dispensed for an NDC-11 as determined using the applicable 2021 or 2025 PDE data identified in section 60.2.1 of this final guidance.

5b. NDC-11s that are only associated with HCPCS codes present in Part B data: Total units are defined as the total Part B units for an NDC-11 as determined using the unit allocation and standardization methodology described for calculating converted Part B units attributed to the NDC-9 in section 60.2.2.2 of this final guidance, adjusted to the NDC-11 level by removing step 3, changing all references to "NDC-9" in steps 4 and 5 to "NDC-11", and changing the reference to "step 3" in step four to "step 2."

5c. NDC-11s that are both present in PDE data and associated with HCPCS codes present in Part B data: Total units are defined as the sum of the total quantity dispensed for the NDC-11 and the total Part B units for an NDC-11 as determined using the unit allocation and standardization methodology described in section 60.2.2.2 of this final guidance.

6. For each NDC-9, CMS will sum the amounts calculated in step 5 to calculate the average non-FAMP per unit for that NDC-9 for the calendar year. CMS believes steps 5 and 6 are necessary to account for fluctuations in quantity dispensed that may occur across NDC-11s of an NDC-9 in the Medicare Part D population.
7. For the calendar year 2021 calculation only: for each NDC-9, CMS will then increase the average non-FAMP per unit for calendar year 2021 calculated in step 6 by the percentage increase in CPI-U (all items; United States city average) from September 2021 to September 2025 as specified in section 1194(c)(1)(C)(ii) of the Act. CMS would not apply a CPI-U (all items; United States city average) adjustment to the average non-FAMP per unit for calendar year 2025.
    - Note: For initial price applicability year 2028, if the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 60.1.1 of this final guidance), then the non-FAMP is based on data from the first full calendar year following the market entry of such drug. In such cases, CMS will increase the average non-FAMP per unit for the first full calendar year following the market entry of such drug by the percentage increase in CPI-U from December of such year to September 2025.
8. For each NDC-9, after CMS has calculated the average non-FAMP per unit for the calendar year (step 6 for the calendar year 2025 calculation or step 7 for the calendar year 2021 calculation adjusted), adjusted for inflation if applicable, CMS will then apply the applicable percent specified in section 1194(c)(3) of the Act for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1 of this final guidance). Applying the applicable percent here, in step 8, results in the same step 11 amount as would result if CMS were to apply the applicable percent to the average non-FAMP per 30-day equivalent supply for the selected drug in step 11. The definition of each monopoly type and the applicable percent are described below, in Table 7, for initial price applicability year 2028. CMS notes that the "extended-monopoly" type is not discussed below because the definition of extended-monopoly drug under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030. CMS interprets this to mean that no selected drug will be considered

an extended-monopoly drug for purposes of calculating the ceiling prior to initial price applicability year 2030.

Table 7: Monopoly Types and Applicable Percent for Initial Price Applicability Year 2028

Monopoly Type	Definition	Applicable Percent	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[163]	For initial price applicability year 2028, a selected drug that is not a long-monopoly drug or a selected drug that is a vaccine licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	75%	The first approval date, under section 505(c) of the FD&C Act, associated with the initial FDA application number for the active moiety (or fixed combination drug) must be after January 1, 2012, and before February 1, 2019. The earliest licensure date, under section 351(a) of the PHS Act, associated with the initial FDA application number for the active ingredient (or fixed combination drug) must be after January 1, 2012, and before February 1, 2015 for drugs, or before February 1, 2015 for vaccines.
Long-monopoly drug (section 1194(c)(5)(A) of the Act)	With respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term 'long-monopoly drug' does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	40%	The first approval date under section 505(c) of the FD&C Act or the earliest licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or fixed combination drug) must be on or before January 1, 2012.

9. For each NDC-9, CMS will then multiply the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied

[163] Because the definition of extended-monopoly drug at section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with CMS with respect to an initial price applicability year before 2030, for initial price applicability year 2028, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

as calculated in step 8 by the quotient of total units divided by the total 30-day equivalent supply (i.e., this quotient represents the average units per 30-day supply equivalent for that NDC-9) as described in step 5 and section 60.2.1 of this final guidance for when a selected drug is covered under either Part D, Part B, or both, respectively, to determine the average non-FAMP for a 30-day equivalent supply. As described above in section 60.2.1 of this final guidance, CMS believes calculating the average non-FAMP for a 30-day equivalent supply is necessary to account for different units and treatment regimens across dosage forms and strengths.

Steps 10 and 11 will calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with applicable percent applied, across all NDC-9s of the selected drug:

10. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s of the selected drug, both calculated based on the methodology outlined in section 60.2.1 of this final guidance, and multiply this quotient by the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation if applicable, and with the applicable percent applied, calculated in step 9.
11. CMS will then sum amounts calculated in step 10 across all NDC-9s of the selected drug to calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied, for the selected drug.

CMS will then compare the applicable percent of the calendar year 2021 average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, with the applicable percent of the calendar year 2025 average non-FAMP per 30-day equivalent supply for the calendar year and determine which is lower.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS will compare the lower amount of the applicable percent of the average non-FAMP as determined in section 60.2.3 of this final guidance to the amount calculated in section 60.2.2 of this final guidance (sum of the plan-specific enrollment weighted amounts, the payment amount under section1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable) to determine the lower amount, which will be the ceiling for the selected drug. Once CMS has determined the ceiling for the selected drug, CMS will ensure that the MFP per 30-day equivalent supply, as negotiated through the process described in sections 60.3 and 60.4 of this final guidance, is no greater than the ceiling.

60.3 Methodology for Developing an Initial Offer

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. The statute requires CMS to provide the manufacturer of a selected drug with an 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, CMS has the discretion to determine how and to what degree each factor should be considered.

As discussed in greater detail below, consistent with section 1194(e) of the Act, for the purpose of determining an initial offer, CMS will: (1) identify the therapeutic alternative(s), if any, for the selected drug, as described in section 60.3.1 of this final guidance; (2) use the lowest of the following prices of a therapeutic alternative(s) covered under Part D to determine the starting point for developing the initial offer (described in section 60.3.2 of this final guidance): Part D total gross covered drug cost (TGCDC) net of DIR and CGDP and/or Manufacturer Discount Program payments (hereinafter the "Net Part D Plan Payment and Beneficiary Liability"[164]), WAC, or the MFP; for a therapeutic alternative(s) payable under Part B, use the lower of ASP or WAC; and for a therapeutic alternative(s) that is both covered under Part D and payable under Part B, use an approach that combines the two lowest relevant prices to determine a starting point similar to the methodology described in section 60.2.2.3 of this final guidance; (3) 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, including but not limited to comparative effectiveness of the selected drug and therapeutic alternatives, including the selected drug's impact on specific populations, the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need, the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s), and the prescribing information approved by the FDA for the selected drug and its therapeutic alternative(s), as described in section 60.3.3 of this final guidance (resulting in the "preliminary price"); and (4) further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act (described in section 60.3.4 of this final guidance) to determine the initial offer price.

Pursuant to section 1194(b)(2)(F) of the Act, CMS will not make any offers or accept any counteroffers for the MFP that are above the statutorily defined ceiling.

60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication

For initial price applicability year 2028, for the purpose of identifying indications[165] for the selected drug, CMS will identify the FDA-approved indication(s) of the selected drug covered under Part D or payable under Part B using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS 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 and/or accepted standards of medical practice. In initial price applicability year 2028, CMS will exclude from its analysis any FDA-approved indication(s) used solely in a setting in which the selected drug is not billed under Part B or Part D since the MFP resulting from a

[164] The CGDP ended on December 31, 2024 and the Medicare Part D Manufacturer Discount Program took effect January 1, 2025. As such, the Net Part D Plan Payment and Beneficiary Liability will be determined using PDE records to remove Manufacturer Discount Program payments rather than CGDP payments, as applicable and as available.

[165] For purposes of this section of this final guidance and the Drug Price Negotiation ICR, CMS distinguishes between the use of the word "indication" and the term "FDA-approved indication" such that "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s) and "indication" refers to the condition or disease state for which the selected drug is used. CMS intends to use "indication" for purposes of this final guidance.

negotiation may only be applied for drugs payable under Medicare Part B and drugs covered under Medicare Part D.

For each indication of the selected drug that is not excluded, CMS will follow the steps outlined below to identify a pharmaceutical therapeutic alternative(s), if any, for purposes of developing the initial offer. CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, consistent with past guidance, CMS will only consider therapeutic alternatives that are drugs or biological products covered under Part D or Part B for initial price applicability year 2028. CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials. For purposes of this final guidance, the term "therapeutic alternative" may refer to one or more therapeutic alternative(s) or a subset of therapeutic alternatives that are clinically comparable.

To identify potential therapeutic alternatives for the indications of a selected drug, CMS intends 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 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, CMS intends to consider generic drugs and biosimilars when identifying a potential therapeutic alternative(s) to a selected drug. CMS may consider off-label use when identifying indications for therapeutic alternatives if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication covered under Part D or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

CMS will begin by identifying 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 then also consider potential therapeutic alternatives in different pharmacologic classes based on CMS' review of the sources noted above. Where appropriate, only certain formulations or dosage forms and strengths will be identified as the therapeutic alternative to the selected drug. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug for the purpose of developing the initial offer. For example, for a potential therapeutic alternative, CMS 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. CMS may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same indication. CMS may also consult with clinicians, patients or patient organizations, and/or researchers, to ensure that appropriate therapeutic alternatives are identified. CMS may also consider peer-reviewed or other clinical evidence and information submitted by the Primary Manufacturer and the public to inform the selection of a therapeutic alternative(s). CMS will prioritize clinical appropriateness in the selection of therapeutic alternatives.

60.3.2 Developing a Starting Point for the Initial Offer

CMS 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) and/or the ASP/WAC(s) of therapeutic alternative(s), if any, to the selected drug, the unit cost of production and distribution for the selected drug, the ceiling for the selected drug (as described in section 60.2 of this final guidance), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule[166] (FSS) price), or 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. Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling.

After considering these options and in accordance with section 1194(e)(2)(A) of the Act, which directs CMS to consider the cost of therapeutic alternative(s), for initial price applicability year 2026, CMS used the Part D net price(s) ("net price(s)") and/or ASP(s) of the therapeutic alternative(s) (or a subset of clinically comparable therapeutic alternatives) for the selected drug, as applicable, as the starting point for developing the initial offer unless the net price(s) or ASP(s) was greater than the statutory ceiling and then considered adjustments based on section 1194(e)(2) data and manufacturer-submitted data per section 1194(e)(1) of the Act. For initial price applicability year 2026, CMS identified the price of each therapeutic alternative that is covered under Part D net of all price concessions received by any Part D plan or pharmacy benefit manager on behalf of the Part D plan by using PDE data and detailed DIR report data.

For initial price applicability year 2027, CMS identified the price of therapeutic alternative(s) to determine the starting point for developing the initial offer using the same approach that the agency used for initial price applicability year 2026 (described above) but also considered the CGDP and Manufacturer Discount Program payments, as applicable and available, for a therapeutic alternative(s) covered under Part D as well as the MFP in situations where a therapeutic alternative for a selected drug for initial price applicability year 2027 was itself a selected drug from initial price applicability year 2026 and has an MFP. Reducing the TGCDC by both DIR and CGDP or Manufacturer Discount Program payments permits an appropriate accounting of the price paid by the plan and beneficiary.

Building on experience from the first two cycles of negotiations, for selected drugs in initial price applicability year 2028, when assessing a therapeutic alternative(s) covered under Part D to determine the starting point for the initial offer, CMS will use the lower of: (1) the Net Part D Plan Payment and Beneficiary Liability, which reflects TGCDC net of DIR and CGDP or Manufacturer Discount Program payments, as applicable; (2) the MFP for selected drugs negotiated for a prior initial price applicability year, if applicable; or (3) WAC. When determining the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative, CMS will exclude PDE records for which a compound code indicates the PDE record is for a compounded drug. For initial price applicability year 2028, when assessing a therapeutic

[166] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government.

alternative(s) payable under Part B to determine a starting point for the initial offer, CMS will use the lesser of ASP or WAC, in order to better align with the payment amount under section 1847A(b)(4) of the Act in circumstances where the WAC of a therapeutic alternative is lower than its ASP.

In taking this approach, CMS acknowledges 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 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), CMS will be able to focus the adjustments made to the preliminary price on section 1194(e)(2) factors by adjusting this starting point relative to whether the selected drug offers more, less, or similar benefit compared to 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.

To inform a starting point for the initial offer, CMS may use an alternative methodology to calculate the 30-day equivalent supply as appropriate for the therapeutic alternatives to ensure comparability with the selected drug. For example, if a therapeutic alternative has an indication for which it is typically prescribed for a period meaningfully shorter than 30 days (e.g., for a two-week period, meaning that one fill would be defined as a 30-day equivalent supply despite lasting only two weeks), and the selected drug does not have a similar prescribing pattern, CMS 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 of the selected drug.

If there is one therapeutic alternative for the selected drug, CMS will use the lowest of the following prices of a therapeutic alternative covered under Part D to determine the starting point for developing the initial offer: 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); and for a therapeutic alternative payable under Part B, use the lower of ASP or WAC. If the therapeutic alternative is payable under Part B and covered under Part D, then CMS will use an approach to combine the two relevant prices to determine a starting point 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 section 60.2.2.3 of this final guidance.

If there are multiple therapeutic alternatives, CMS will consider the range based on the prices of the therapeutic alternatives (e.g., the lower of Net Part D Plan Payment and Beneficiary Liability, MFP(s) for a selected drug negotiated for a prior initial price applicability year, or WAC for a drug covered under Part D, and/or the lower of ASP or WAC for a drug payable under Part B and/or the combined amount for a drug covered under Part D and payable under Part B),

including the prices of generic and biosimilar therapeutic alternatives, as well as the utilization of each therapeutic alternative, to determine the starting point within that range. As part of its determination of a starting point within such a range, CMS will consider therapeutic alternative prices within each indication (when available and if different from therapeutic alternative prices across indications), or will consider the lower of the ceiling, "Big Four Agency"[167] price ("Big Four price"), or the FSS price for an indication for which CMS has not identified any therapeutic alternatives, and will consider weighing such prices by the utilization of therapeutic alternatives within and across multiple indications or other patterns of use for the therapeutic alternatives or the selected drug.

If the selected drug has no therapeutic alternative, if the prices of all therapeutic alternatives identified are above the statutory ceiling for the MFP (as described in section 60.2 of this final guidance), or if there is a single therapeutic alternative for the selected drug and its price is above the statutory ceiling for the MFP, then CMS will determine the starting point for the initial offer based on the FSS or Big Four price, whichever is lower. If the FSS and Big Four prices are above the statutory ceiling, then CMS will use the statutory ceiling as the starting point for the initial offer. In all cases, the starting point will not exceed the statutory ceiling and will be subject to adjustments as described further below.

60.3.3 Adjusting the Starting Point Based on Section 1194(e)(2) Factors

To evaluate the section 1194(e)(2) factors, including the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), CMS will broadly evaluate the body of available evidence, including information received from the public and manufacturers as described in section 50.2 of this final guidance, and evidence identified through a CMS-led literature review. CMS may also analyze 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) and may consult with clinicians, patients or patient organizations, researchers, and/or FDA. As described in section 60.4.1 of this final guidance, CMS will provide additional engagement opportunities for interested parties—specifically, meetings with the Primary Manufacturer and patient-focused events—after the March 1, 2026, deadline for submission of section 1194(e)(2) data (further described in section 60.4.1 of this final guidance).

This approach provides 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 whitepapers, clinician expertise, real-world evidence, and patient experience. This approach also provides CMS flexibility to consider a variety of aspects in its 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.

Once the starting point for the initial offer has been established and evidence on section 1194(e)(2) factors has been considered, CMS will adjust the starting point for the initial offer based on the review of section 1194(e)(2) factors. CMS will not, per section 1194(e)(2) of the

[167] The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard. See generally 38 U.S.C. § 8126; https://www.cbo.gov/publication/57007.

Act, use evidence from comparative 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, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. CMS considered employing both a qualitative approach (e.g., 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 past guidance, CMS will 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.

60.3.3.1 Analysis for Indications of Selected Drugs with Therapeutic Alternative(s)
To consider comparative effectiveness of a selected drug and its therapeutic alternative(s), CMS will identify outcomes to evaluate for each identified indication of the selected drug. CMS will consider the identified outcomes of interest, including patient-centered outcomes,[168] and patient experience data, when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s) for those indications. When reviewing such information, as noted above, CMS will 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 will not, per section 1182(e) of the Act, use QALYs. Outcomes of interest to CMS may include direct clinical outcomes (e.g., cure, mortality) and/or validated or reasonably likely surrogate endpoints (e.g., serum hemoglobin A1c). In determining outcomes of interest, CMS will consider patient-reported outcomes and outcomes of importance to patients, if available. CMS may also consider additional outcomes and contextual factors, such as health-related quality of life or patient/caregiver preferences regarding treatment, to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternatives. CMS may 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. Relevant outcomes will be identified using the CMS-led literature review and information submitted by manufacturers and the public, including patients and caregivers, through the Drug Price Negotiation ICR described in section 50 of this final guidance, as well as in the patient-focused events described in section 60.4.1 of this final guidance.

In all cases, CMS will consider applicable evidence and other input collectively, within the context of the course of care for each indication of the selected drug and in accordance with section 50 of this final guidance. As noted previously, this approach provides flexibility to consider a variety of aspects in its 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 indication.

[168] A patient-centered outcome is defined as: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves. See: https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary.

CMS will 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, as required by section 1194(e)(2)(C) of the Act. To do so, CMS intends to seek to identify studies focused on the indications for which each selected drug is used and the impact of the selected drug and its therapeutic alternative(s) on such specific populations. Further, for each indication in which CMS has identified a therapeutic alternative, CMS will consider the extent to which the selected drug and its therapeutic alternatives address unmet medical needs. CMS will 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 each indication of the selected drug for which CMS has identified a therapeutic alternative, CMS will consider the selected drug, therapeutic alternatives to the selected drug, and any existing treatment options to determine the extent to which the selected drug and its therapeutic alternatives address an unmet medical need at the indication level as of the time the section 1194(e)(2) data is submitted. CMS will consider the nonbinding recommendations in the FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics,"[169] 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 an indication.

For each indication in which CMS has identified a therapeutic alternative, CMS will examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression) and will consider the costs of the selected drug and its therapeutic alternative(s). CMS may 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 indication in which CMS has identified a therapeutic alternative, when determining the extent to which a selected drug represents a therapeutic advance. CMS understands that a selected drug can be first in class,[170] however, other drugs may have become available since the selected drug's initial approval and therefore CMS will consider the extent to which a selected drug represents a therapeutic advance for an indication at the time the section 1194(e)(2) data is submitted. In accordance with section 1194(e)(2)(A) of the Act, CMS intends to review the analyses detailed above for each identified indication 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).

60.3.3.2 Analysis for Indications of Selected Drugs Without Therapeutic Alternatives[171]
CMS will consider the totality of available information relevant to the section 1194(e)(2) factors as detailed above, including information received from Primary Manufacturers and the public as

[169] 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.
[170] For purposes of this discussion in section 60.3.3.1, 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.
[171] CMS has renamed this section and made some minor clarifications throughout to explain that this section of guidance applies in cases where an indication for a selected drug does not have a therapeutic alternative. This change provides further transparency to stakeholders as some commenters requested.

described in section 50.2 of this final guidance, and evidence identified through a CMS-led literature review, for each indication of a selected drug without an identified therapeutic alternative.

CMS will consider the selected drug and any existing treatment options to determine the extent to which the selected drug addresses an unmet medical need at the indication level as of the time the section 1194(e)(2) data is submitted. CMS defines unmet medical need as a circumstance in which the relevant disease or condition is one for which no treatment options exist, or existing treatments do not adequately address the disease or condition. As noted previously, CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics," as well as any updates that may be issued by FDA in the future, when considering the extent to which a drug addresses an unmet medical need for the purpose of the Negotiation Program.

CMS will examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance. CMS may consider the extent to which a selected drug represents a therapeutic advance by examining the magnitude of differences in outcomes of interest conferred by the selected drug for an indication in which CMS has not identified a therapeutic alternative.

60.3.3.3 Preliminary Price

As previously noted, CMS will 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, the applicable starting point will be adjusted (i.e., apply an upward or downward adjustment, or no adjustment) based on the totality of the relevant information and evidence submitted and gathered through CMS' analysis based on section 1194(e)(2) factors. CMS may adjust the starting point based on how the section 1194(e)(2) factors apply with respect to individual indication(s) in cases where there are notable differences relative to the therapeutic alternative(s).

After the starting point has been adjusted, as appropriate, based on section 1194(e)(2) factors, evaluated using data submitted by manufacturers and the public through the Drug Price Negotiation ICR and gathered through CMS-led analyses and literature review, the resulting price is referred to as "the preliminary price."

As described in section 60.3.4 of this final guidance, the preliminary price will be adjusted, as appropriate, based on data submitted by the Primary Manufacturer in accordance with section 1194(e)(1) of the Act.

60.3.4 Adjusting the Preliminary Price Based on Consideration of Section 1194(e)(1) Factors[172]

CMS must also consider the factors listed in section 1194(e)(1) of the Act and described in section 50.1 of this final guidance, which will be reported by each Primary Manufacturer. The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or

[172] CMS notes that the title of this subsection has been revised to reference "section 1194(e)(1) factors" in place of "manufacturer-specific data" to align more closely with the title of section 60.3.3 of this final guidance. This revision does not indicate a change in approach or factors considered for adjusting the preliminary price.

downward as needed to account for these manufacturer-specific data elements. The section 1194(e)(1) factors are: (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.

CMS will consider the five factors outlined in section 1194(e)(1) of the Act in totality and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price. CMS provides illustrative examples for the manufacturer-specific data elements below. However, the overall adjustment, inclusive of all five elements taken together, may differ from the example adjustment for any single element viewed in isolation.

In considering factor (1) above on R&D costs, CMS will consider the extent to which the Primary Manufacturer has recouped its R&D costs. CMS will 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, CMS may consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its R&D costs, CMS may consider adjusting the preliminary price downward or apply no adjustment. CMS 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 the Drug Price Negotiation ICR and in Appendix A of this final guidance to adjust the preliminary price.

In considering factor (2) on current unit costs of production and distribution, CMS will consider the relationship between the preliminary price and the unit costs of production and distribution. For example, CMS 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, CMS may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug to determine if an adjustment is appropriate.

In considering factor (3) on prior Federal financial support, CMS will consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

In considering factor (4) on patent applications, exclusivities, and applications and approvals for the selected drug, CMS will review the patents and exclusivities reported as it develops its initial offer. CMS believes that this information will support CMS' consideration of the section 1194(e)(1) and 1194(e)(2) factors described in section 50 of this final guidance. For instance, patents and exclusivities may inform CMS' 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 CMS' consideration of the extent to which the selected drug addresses an unmet medical need for that disease or condition.

Finally, in considering factor (5) on market data and revenue and sales volume data for the U.S., CMS will consider how the data compare to the preliminary price. For example, if the average commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward. If the average commercial net price is greater than the preliminary price, CMS may consider adjusting the preliminary price upward. CMS intends to include a requirement for the Primary Manufacturer to report the ASP and ASP units for the last two sales quarters in calendar year 2025 in the 30-day revisions to Drug Price Negotiation ICR for initial price applicability year 2028 to ensure that CMS has the most recent ASP to inform the consideration of the factor at section 1194(e)(1)(E) of the Act, as applicable. Defined terms related to these data elements are included in Appendix A.

Appendix A of this final guidance includes a list of definitions that apply for the purposes of describing the data to be collected with respect to the data elements listed in section 1194(e)(1) of the Act.

After any adjustments to the preliminary price are made under this section 60.3.4 of this final guidance, the result is the initial offer.

60.4 Negotiation Process

In accordance with section 1191(b)(4)(A) of the Act, and as described in section 40.1 of this final guidance, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into an Agreement, or, for initial price applicability year 2028, February 28, 2026. CMS will implement the negotiation process consistent with the requirements of the statute, with the aim of achieving "the lowest maximum fair price for each selected drug" consistent with section 1194(b)(1) of the Act.

The negotiation process may include the following steps, as discussed in detail in the subsections of this section:

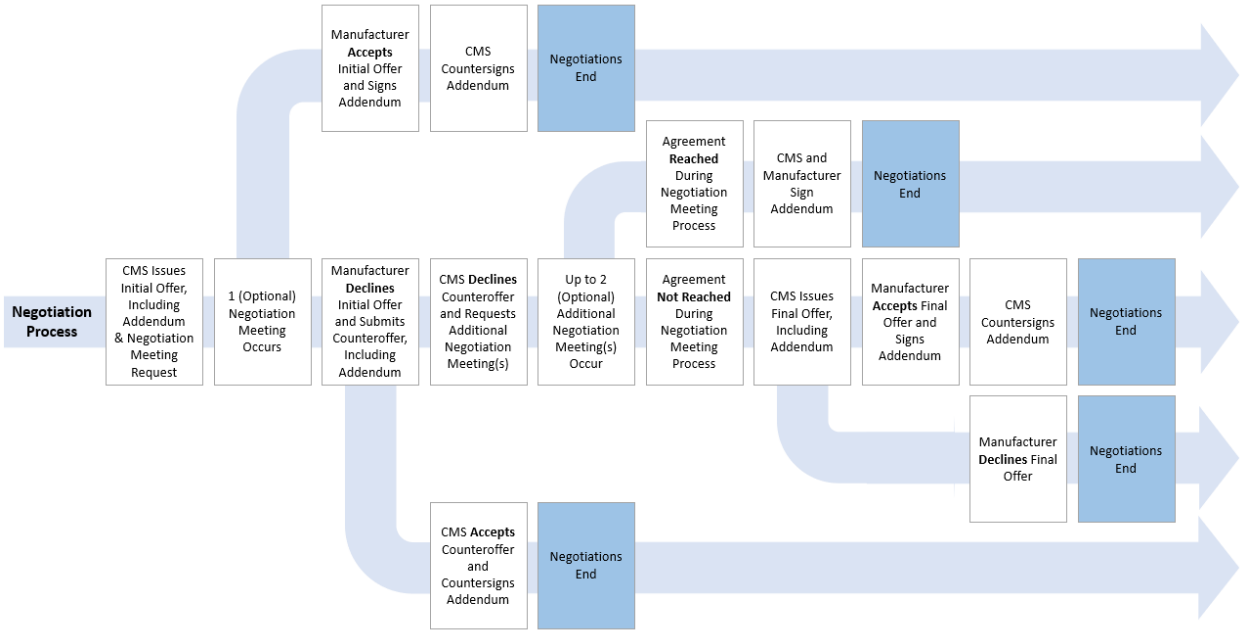
1. Section 60.4.1: CMS will host meetings with Primary Manufacturers of selected drugs that have entered into agreements with CMS and submitted section 1194(e) data, as well as public engagement events to seek input from patients and other interested parties.
2. Section 60.4.2: In accordance with section 1194(b)(2)(B) of the Act, CMS will provide a written initial offer and concise justification to the Primary Manufacturer with CMS' proposal for the MFP for a selected drug for initial price applicability year 2028 no later than June 1, 2026. This written initial offer will be accompanied by an Addendum to the Agreement populated with the proposal for the MFP, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP if such agreement is reached at this stage. CMS also will offer the Primary Manufacturer an optional negotiation meeting that would occur after CMS provides the written initial offer to the Primary Manufacturer and

before the deadline for the Primary Manufacturer's statutory written counteroffer described in section 1194(b)(2)(C) of the Act.

3. Section 60.4.3: In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will respond to CMS' written initial offer no later than 30 days after the date of receipt of the written initial offer from CMS. If the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer will submit a written counteroffer (hereinafter the "statutory written counteroffer"), including an Addendum populated with the proposal for the MFP. In accordance with section 1194(b)(2)(D) of the Act, CMS will provide a written response to the statutory written counteroffer. CMS will provide this response within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the written initial offer, whichever is later.
4. Section 60.4.4: If the Primary Manufacturer's statutory written counteroffer is not accepted by CMS, CMS will host up to two additional negotiation meeting(s) between the Primary Manufacturer and CMS.
5. Section 60.4.5: 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 by September 18, 2026, whichever is earlier, CMS and Primary Manufacturers can choose to initiate additional, written offers or counteroffers via the additional price exchange module in the CMS HPMS.
6. Section 60.4.6: If no agreement is reached during the processes described above, CMS will provide to the Primary Manufacturer a final written offer, including an Addendum containing the final proposal for the MFP by September 30, 2026, as described in section 60.4.6 of this final guidance.

Every written offer and counteroffer will include an Addendum populated with the proposal for the MFP. If an agreement on the MFP is reached at any point during the negotiation process as described in this section, the Addendum to the Agreement, as described in section 40.3 of this final guidance, will be executed by both parties and will constitute agreement on the MFP. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2028, subject to the conditions and timing described in section 70 of this final guidance and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. Refer to section 60.6 of this final guidance for information on how the MFP will be updated for subsequent years in the price applicability period. The diagram below provides a non-exhaustive list of possible paths the negotiation process could take after CMS' initial offer, for a process taking place within the statutorily specified timelines.

Figure 5: Possible Negotiation Paths[173]



During the entire negotiation process, 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 described in section 60.2 of this final guidance.

If the Primary Manufacturer is delayed in meeting one or more deadlines related to establishing the Agreement, submitting required data, and/or submitting the statutory written counteroffer, CMS will continue to engage in the negotiation process and will take the time to complete the established process as described in this section. For example, if a Primary Manufacturer does not submit required data, CMS may be delayed in sending the initial offer by the statutory deadline. During the period of time from when the Primary Manufacturer fails to meet a deadline until the date the Primary Manufacturer comes into compliance with the negotiation process, CMS will consider the Primary Manufacturer in violation of the Agreement and the Primary Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act. Sections 90.3 and 100 of this final guidance further describe possible actions to address noncompliance.

60.4.1 Engagement with Primary Manufacturers and Interested Parties Prior to Initial Offers
After the submission of the section 1194(e) data by Primary Manufacturers and other interested parties by March 1, 2026, CMS will host meetings with Primary Manufacturers of selected drugs that have submitted section 1194(e) data. CMS will invite the Primary Manufacturer for each selected drug to one meeting in Spring 2026 after the data submission deadline. The purpose of this meeting will be for the Primary Manufacturer to provide additional context on its data submission and share new section 1194(e)(2) data, if applicable, as CMS begins reviewing the data and developing an initial offer. While Primary Manufacturers may share new information on

[173] Mention of the "negotiation meeting process" in this figure is inclusive of the additional price exchange functionality described in section 60.4.5 of this final guidance.

section 1194(e)(2) data during meetings before the initial offer, new manufacturer-specific data (described in section 1194(e)(1) of the Act) will not be considered; rather, any information shared during these meetings and materials shared afterwards should only contextualize the Primary Manufacturer's March 1, 2026 submission of manufacturer-specific data. The Primary Manufacturer may bring materials to facilitate discussion, and CMS may request any presented or discussed materials afterwards. Each Primary Manufacturer is limited to sharing 50 pages (or a combination of pages, slides, and/or charts and graphs totaling 50 pages) of material in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting. CMS anticipates that these materials may contain cross-references to other material, particularly other material already submitted to CMS.

CMS acknowledges that a Primary Manufacturer may benefit from having access to the section 1194(e)(2) data submitted by other interested parties during the negotiation period. In addition to offering the meetings described below, CMS will aim to share redacted section 1194(e)(2) data with the Primary Manufacturer of a selected drug during the negotiation process when feasible. The data will be redacted as per the confidentiality standards described in section 40.2 of this final guidance and will not include proprietary information, PHI / PII, or information that is protected from disclosure under other applicable law.

CMS will also host public engagement events to seek input from patients and other interested parties. These events are intended to bring together patient-focused interested parties to share feedback with CMS on patient experiences with the conditions or diseases treated by the selected drugs, as well as with the selected drugs and therapeutic alternatives to the selected drugs, and other information as CMS reviews section 1194(e)(2) data submissions and develops an initial offer for each selected drug. CMS will use information shared during these patient-focused events to better understand patients' experiences with the conditions and diseases treated by the selected drugs 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. For patient-focused events for initial price applicability year 2028, CMS will host up to 15 patient-focused roundtable events, which will be open to patients, patient advocacy organizations, and caregivers and will allow for discussion among speakers. These patient-focused roundtable events will group selected drugs by condition when appropriate as determined by CMS. CMS will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. This town hall meeting may be divided into multiple sessions and may be held across multiple days. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register to participate. CMS will have the opportunity to ask follow-up questions of participants at the town hall meeting. CMS will engage a moderator to facilitate discussions for both the patient-focused roundtable events and the town hall meeting. These events will be held in Spring 2026. CMS 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 section 130.4.4 of this final guidance. More information about these events will be forthcoming.

Both the patient-focused roundtable events and the town hall meeting will be held in a virtual environment. The patient-focused roundtable events will not be livestreamed; however, CMS

will make the transcripts public after all the events have ended, with individual identifiable information redacted. The town hall meeting will be livestreamed, and CMS also will release a redacted transcript after the meeting concludes. These redacted transcripts will omit names and other identifying information for patients, according to the Safe Harbor de-identification method under the HIPAA Privacy Rule,[174] as well as omit identifying information for patient advocacy organization representatives and family members/caregivers. More information on these events and how interested parties can participate is forthcoming.

60.4.2 Provision of CMS' Initial Offer and Concise Justification

In accordance with section 1194(b)(2)(B) of the Act, the written initial offer from CMS, provided no later than June 1, 2026, must include a concise justification for the offer based on the data described in section 50 of this final guidance. The justification will include a qualitative description of the factors from section 1194(e) of the Act (further described in sections 50 and 60.3 of this final guidance) and a description of the methodology that CMS used to develop the initial offer (described in section 60.3 of this final guidance). The information contained in the concise justification will provide the Primary Manufacturer with information on the range of evidence and other information considered pursuant to section 1194(e) of the Act that CMS found compelling during the development of the initial offer, which includes the identification of therapeutic alternatives. CMS believes this will provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the initial offer. The initial offer and justification will not include information that CMS determines 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, or the starting point. This written initial offer will be accompanied by an Addendum to the Agreement populated with the proposal for the MFP, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP if such agreement is reached at this stage.

No offer can exceed the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this final guidance. As feasible, CMS will provide information on the calculation of the statutorily determined ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer within 45 days of the Primary Manufacturer's submission of data that complies with the requirements described in section 50.1 of this final guidance. As described in section 40.2.3 of this final guidance, CMS may reach out to the Primary Manufacturer for clarity on its data submission if CMS determines the information is not complete or accurate. In situations when additional outreach to the Primary Manufacturer is required to clarify the submitted data such that there are delays in CMS receiving necessary data, CMS may be delayed in providing information on the calculation of the statutorily determined ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer. In these situations, CMS will aim to provide this information as close to 45 days from the subsequent submission of data necessary to perform these calculations, as feasible. As described in section 40.5 of this final guidance, a Primary Manufacturer will have 21 days to submit, after receipt of this information, a suggestion of error regarding the calculation of

[174] See: 45 C.F.R. § 164.514(b)(2); https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#safeharborguidance.

the ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths for CMS' consideration.

In addition to the initial offer and concise justification, CMS will provide an attachment to the initial offer which applies the single initial offer price at the NDC-9 unit price and HCPCS code dosage price levels, as applicable, to demonstrate how this initial offer price will apply to the dosage forms and strengths as identified on the list of NDCs of the selected drug. The initial offer consists of a single proposal for the MFP and the provision of these NDC-level price applications does not constitute a separate offer. These calculations may also be updated during the negotiation process, for example, to reflect new NDCs of the selected drug or new information informing the NDC-level price applications.

CMS will reach out to the Primary Manufacturer of a selected drug and offer to schedule an optional negotiation meeting during the time period after the initial offer is issued and before the statutory written counteroffer is due, which CMS believes will allow CMS and the Primary Manufacturer to begin negotiation discussions early in the negotiation period. The purpose of this meeting is to allow both parties to begin discussion related to negotiating an MFP for the selected drug, including with respect to CMS' initial offer for the MFP. Discussion of disputes and program policies regarding the negotiation process will be considered out of scope. CMS anticipates that discussion might focus on CMS' initial offer and the evidence CMS used to develop the initial offer; nevertheless, as applicable, both CMS and the Primary Manufacturer could discuss other potential offers or counteroffers during this meeting, including discussion of the Primary Manufacturer's forthcoming statutory written counteroffer, should the Primary Manufacturer choose to make one. Consistent with the statutory framework, CMS anticipates that any oral potential counteroffers discussed during this meeting might be provided later in writing consistent with section 1194(b)(2)(C) of the Act. Accordingly, while CMS may engage in discussion about an oral potential counteroffer, CMS does not intend to accept or reject any such oral potential counteroffer in this first meeting and intends to respond to any later statutory written counteroffer consistent with the agency's obligations to respond in writing under section 1194(b)(2)(D) of the Act. CMS will provide information on the timing for developing the agenda and submitting meeting materials when CMS invites the Primary Manufacturer to this first negotiation meeting. This first negotiation meeting will last no more than two hours and may be conducted in-person at CMS or HHS facilities in the Washington-Baltimore area and will follow the same standards around number of attendees as the post-statutory written counteroffer negotiation meetings described in section 60.4.4 of this final guidance. If necessary, due to distance or scheduling challenges, this optional meeting may be held virtually or may accommodate a hybrid arrangement (where a portion of attendees are in-person and a portion of attendees are virtual). If a Primary Manufacturer declines this optional first negotiation meeting, CMS will not increase the number of negotiation meetings it offers in a subsequent stage of the negotiation process, but the Primary Manufacturer and CMS may still conduct up to two negotiation meetings if CMS rejects the Primary Manufacturer's statutory written counteroffer.

60.4.3 Required Components of Primary Manufacturers' Statutory Written Counteroffer and CMS Response in Writing

In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will 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 section 50 of this final guidance. Any statutory written counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the factors described in section 1194(e) of the Act and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the data in section 1194(e)(1) or (e)(2) of the Act, 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.

The Primary Manufacturer should provide a proposal for the MFP for the selected drug in its statutory written counteroffer. As described in section 60.1 of this final guidance, the proposal for the MFP should be made consistent with the manner that CMS' written initial offer was made; that is, a single proposal for the MFP for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. In accordance with section 1194(b)(2)(F) of the Act, 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 60.2 of this final guidance.

As described in section 50 of this final guidance, CMS published a Drug Price Negotiation ICR for initial price applicability year 2028 in the Federal Register for a 60-day public comment period on June 30, 2025. This ICR includes instructions and a form for a Primary Manufacturer to submit a statutory written counteroffer in the case where the Primary Manufacturer does not accept CMS' written initial offer. CMS intends to publish a revised version of the ICR for a 30-day comment period during Fall 2025, and there will be an additional opportunity to submit comments on this ICR at that time.

For a statutory written counteroffer to be considered complete, a Primary Manufacturer must complete an Addendum in the CMS HPMS in addition to filling out the Statutory Written Counteroffer Form in the CMS HPMS, as described in section 40.3 of this final guidance. A completed Addendum would include, but is not limited to, the proposal for the MFP the Primary Manufacturer is counteroffering and a signature by an authorized representative.

In accordance with section 1194(b)(2)(D) of the Act, CMS will 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, negotiations for initial price applicability year 2028 must end prior to November 1, 2026, i.e., an agreement on MFP for the selected drug must be reached no later than October 31, 2026, for the Primary Manufacturer to avoid potential excise tax liability under section 5000D(b)(2) of the IRC.

In the case CMS' written initial offer is not accepted and the Primary Manufacturer submits a statutory written counteroffer, CMS will 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, CMS will 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.

60.4.4 Negotiation Meetings for CMS and Primary Manufacturers

As described in section 60.4.2 of this final guidance, CMS will offer each Primary Manufacturer of a selected drug one optional negotiation meeting after CMS provides the written initial offer and before the statutory written counteroffer is due. In addition, if CMS' written response to the statutory written counteroffer described in section 60.4.3 of this final guidance rejects the Primary Manufacturer's statutory written counteroffer, CMS will extend an invitation to the Primary Manufacturer for an optional negotiation meeting to occur by August 14, 2026. If agreement upon an MFP is not reached in that meeting or via the additional price exchange, as described in section 60.4.5 of this final guidance, by August 14, 2026, CMS will extend an invitation for an additional optional meeting to occur by September 11, 2026. This additional optional meeting may occur even if a Primary Manufacturer declines the first post-statutory written counteroffer negotiation meeting.

The scope for these negotiation meetings will focus on the section 1194(e) data, including the therapeutic alternative(s) for the selected drug, how these data should inform the MFP, and other topics aimed at working toward an agreement on an MFP. During these negotiation meetings, discussion of disputes and program policies regarding the negotiation process will be considered out of scope. CMS and the Primary Manufacturer will each be permitted to bring up to eight meeting attendees and both parties must share their participant lists ahead of each meeting. CMS arrived at 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. Each meeting will last no more than two hours and may be conducted in-person at CMS or HHS facilities in the Washington-Baltimore area. If necessary, due to distance or scheduling challenges, meetings may be held virtually or may accommodate a hybrid arrangement. CMS believes the duration and format of the negotiation meetings (of which there can be up to three meetings, as applicable) is sufficient for a fruitful discussion and is appropriate considering time and scheduling constraints. CMS' notes from negotiation meetings will be retained as part of the meeting record in compliance with applicable federal law including the Federal Managers' Financial Integrity Act and the Federal Records Act and will be subject to the confidentiality policy described in section 40.2.1 of this final guidance. Attendees on behalf of the Primary Manufacturer may take and keep notes of the meetings. Audio and/or video recording of negotiation meetings will not be permitted.

Correspondence regarding negotiation meetings will be conducted over email using the IRARebateandNegotiation@cms.hhs.gov mailbox. The Primary Manufacturer may propose a meeting agenda for CMS' consideration. The Primary Manufacturer must submit the agenda via email at least one week ahead of the meeting. CMS will circulate a final agenda approximately two business days or more prior to the negotiation meeting. If a Primary Manufacturer would like to share materials at a negotiation meeting, such materials should be limited to 15 pages (or a combination of pages, slides, and/or charts and graphs totaling 15 pages) and no more than 30

citations, in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting.[175] CMS revised the page and citation limits for meeting materials for initial price applicability year 2028 to accommodate the shorter negotiation meeting period, as described below. CMS anticipates that these materials may contain cross-references to other material, particularly other material already submitted to CMS. Such materials must be submitted at least one week ahead of the meeting. While the agency intends to limit substantive discussion to the negotiation meetings, CMS anticipates there may be some opportunity for exchange of additional information related to the section 1194(e) data on an ad hoc basis via email after receipt of a statutory written counteroffer and before the end of the statutory negotiation period.

These meetings will occur between the time the Primary Manufacturer's statutory written counteroffer is not accepted by CMS, which will be within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later, if applicable, and September 11, 2026. As described in section 60.4.2 of this final guidance, an optional negotiation meeting occurring after the initial offer is issued and before the statutory written counteroffer is due may precede these meetings. There would be at least six weeks' time between CMS' rejection of the Primary Manufacturer's statutory written counteroffer (approximately July 31, 2026), if applicable, and the deadline for negotiation meetings to conclude (September 11, 2026). CMS requires that all negotiation meetings end no later than September 11, 2026 to allow CMS sufficient time to prepare a final offer (if an MFP was not reached during the negotiation meeting process or via the additional price exchange functionality), send that final offer to the Primary Manufacturer by September 30, and allow the Primary Manufacturer time to consider the final offer and accept or reject the final offer by October 31, 2026, as all negotiations must be concluded prior to November 1, 2026. These dates assume that a Primary Manufacturer is timely in entering into an Agreement, submitting information, and meeting deadlines related to the Negotiation Program. CMS recognizes that this negotiation meeting period is shorter compared to the timeframe for previous initial price applicability years. As described, and for the reasons set forth, in section 40.6 of this final guidance, CMS is compressing this timeframe for initial price applicability year 2028.

Negotiation meetings will allow both parties to discuss any new information consistent with the data described in section 1194(e)(2) of the Act that may have become available about the selected drug and its therapeutic alternative(s), and that may affect the determination of the MFP. Negotiation meetings will be attended solely by representatives of the Primary Manufacturer and of CMS. A written record will be developed and retained by CMS in compliance with applicable federal laws. The Primary Manufacturer can also develop and retain its own written record. As described in section 40.2.2 of this final guidance, CMS will 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 its 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, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

[175] Submission of internal studies by the Primary Manufacturer to CMS that do not reflect publicly reported data and are not publicly available (e.g., data on file) will not count toward the 15-page limit or the 30-citation limit.

60.4.5 Additional Price Exchange Opportunities

CMS is providing 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 by September 18, 2026, whichever is earlier. CMS believes this functionality will enable both parties to have additional flexibility to extend and consider offers and counteroffers during this time period. If an agreement on the MFP is not reached earlier, this time period will conclude on September 18, 2026 to provide CMS the time necessary for adequate consideration of any outstanding counteroffers prior to CMS issuing the final offer by September 30, 2026. As described in section 60.4.4 of this final guidance, CMS and the Primary Manufacturer can participate in up to two negotiation meetings per selected drug during this period, and the opportunity for additional written offers and counteroffers during this period will not replace an optional negotiation meeting. CMS believes that if a Primary Manufacturer or CMS makes an offer or counteroffer via the additional price exchange functionality, the negotiation meetings will provide an opportunity for both parties to discuss their justifications for the offer or counteroffer and rationale for determinations with respect to the offer or counteroffer. The additional price exchange functionality in the CMS HPMS will include an optional text field to enable either party to include additional contextual information for the offer or counteroffer. Only one offer or counteroffer per selected drug may be active at a time in the CMS HPMS as part of the additional price exchange functionality. An offering/counteroffering party may revise its offer/counteroffer in the period before the other party accepts or rejects it, but not afterwards. Parties do not need to alternate making offers and counteroffers.

As described in section 60.6.1 of this final guidance, in the public explanation for the MFP, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, the exchange of offers and counteroffers, and the negotiation meetings while abiding by the confidentiality policy described in section 40.2 of this final guidance.

60.4.6 Notification of Final Offer and Determination that Negotiations Have Finished

In accordance with section 1194(b)(2)(E) of the Act, all negotiations between CMS and the Primary Manufacturer of the selected drug must end prior to November 1, 2026, for initial price applicability year 2028 to avoid potential excise tax liability.

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 meeting process or via the additional price exchange functionality, CMS will send the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" and an Addendum with the final offer MFP by September 30, 2026. This will serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. This final offer will be sent only if, by September 30, 2026, 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. 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, 2026. For initial price applicability year 2028, CMS is providing the final offer to

the Primary Manufacturer sooner in the negotiation period than what the agency described in the draft guidance for the reasons set forth in section 40.6 of this final guidance. Table 8 details CMS' timing for the negotiation process for initial price applicability year 2028.

Table 8: Negotiation Process Milestones for Initial Price Applicability Year 2028

Date[176]	**Milestone**
June 1, 2026	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer
Date after CMS issues the initial offer and before the response to the initial offer and any manufacturer statutory written counteroffer is due, if applicable (After June 1st and before July 1st if the offer is made by CMS on June 1, 2026)	Optional negotiation meeting (in-person, virtual, or hybrid), if applicable
30 days after receipt of written initial offer from CMS (July 1st if the offer is made by CMS on June 1, 2026)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a statutory written counteroffer to CMS
30 days after receipt of the manufacturer statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later (July 31st if the initial offer is made on June 1, 2026 and manufacturer statutory written counteroffer is made on July 1, 2026)	Date by which CMS will provide a written response accepting or rejecting the manufacturer statutory written counteroffer
Date that the Primary Manufacturer's statutory written counteroffer is not accepted by CMS through August 14, 2026 or the day an MFP is agreed upon, whichever is earlier	Optional negotiation meeting (in-person, virtual, or hybrid), if applicable
August 17, 2026 (the next business day after August 14, 2026) through September 11, 2026 or the day an MFP is agreed upon, whichever is earlier	Optional negotiation meeting (in-person, virtual, or hybrid), if applicable
Date that the Primary Manufacturer's statutory written counteroffer is not accepted by CMS through September 18, 2026 or the day an MFP is agreed upon, whichever is earlier	Additional price exchange, if applicable

[176] These dates are contingent on CMS and the Primary Manufacturer meeting the deadlines described in this final guidance and in statute. If the Primary Manufacturer is delayed in meeting one or more deadlines, CMS intends to continue to engage in the negotiation process and will take the time to complete the established process as described in this section. If a statutory deadline is missed, the Primary Manufacturer may be subject to a civil monetary penalty or excise tax, as applicable.

Date[176]	**Milestone**
September 30, 2026	Date by which CMS will issue a "Notification of Final Maximum Fair Price Offer" to the Primary Manufacturer, if the written initial offer or Primary Manufacturer statutory written counteroffer was not accepted and an MFP was not agreed upon during the negotiation meeting process or via the additional price exchange functionality
October 31, 2026	Date by which the Primary Manufacturer must respond to (i.e., accept or reject) CMS' "Notification of Final Maximum Fair Price Offer," if applicable
October 31, 2026	Statutory deadline for all negotiations to end; CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences thereof if agreement upon the MFP is not reached by October 31, 2026
November 1, 2026	Statutory end of negotiation period

In all instances, to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Agreement (described in sections 40.3 of this final guidance) that sets forth the agreed-upon MFP. For example, when CMS prepares a written offer, CMS also completes the Addendum with the offered MFP and sends the Addendum along with the written offer to the Primary Manufacturer via the CMS HPMS. If the Primary Manufacturer accepts the written offer, it will sign the Addendum after which CMS will countersign the Addendum. Similarly, a Primary Manufacturer's statutory written counteroffer is not considered complete unless the Primary Manufacturer submits a complete response using the Statutory Written Counteroffer Form (as described in the Drug Price Negotiation ICR) in the CMS HPMS, submits an Addendum for the MFP consistent with the counteroffer proposal for the MFP in the CMS HPMS, and signs that Addendum. If CMS accepts the statutory written counteroffer, CMS will countersign the Addendum. Further, for any additional offers and counteroffers exchanged in the negotiation meetings described in section 60.4.4 of this final guidance or via the additional price exchange functionality described in section 60.4.5 of this final guidance, an Addendum would be populated consistent with CMS HPMS functionalities to allow for signature by the Primary Manufacturer and countersignature by CMS.

If CMS and the Primary Manufacturer do not agree to an MFP by the statutory end of the negotiation period, the Primary Manufacturer will 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, as described in section 60.8 of this final guidance; meeting the statutory criteria for the suspension of tax; or terminating its Agreement in the manner described in section 40.6 of this final guidance, which includes sending a notice terminating all of its applicable agreements under the Medicare and Medicaid programs and establishing that none of the Primary Manufacturer's drugs are covered by an agreement under section 1860D-14C of the Act.

60.5 Application of the MFP Across Dosage Forms and Strengths

An MFP that is agreed upon as described in section 60.4 of this final guidance establishes one price for the selected drug. In accordance with section 1196(a)(2) of the Act, 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 or package size or package type of such drug.

As described in section 60.1 of this final guidance, the MFP will reflect a single price for the selected drug per 30-day equivalent supply. 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), however, CMS will publish the MFP at the per-unit (e.g., tablet) level for each NDC-9, at the package (e.g., bottle) level for each NDC-11, and per billing unit for each HCPCS (hereinafter the "billing unit") associated with the selected drug based on the list of NDCs and HCPCS codes determined pursuant to section 40.2 of this final guidance. CMS advises supply chain entities to use the NDC-9 per unit price when effectuating the MFP for a selected drug with a formulation covered under Part D to ensure accuracy (e.g., in the event of partial package dispense). This final guidance does not address the effectuation of the MFP for drugs payable under Part B in 2028; CMS will describe how the MFP will be effectuated for drugs payable under Part B (for example, whether all selected drugs will be granted a unique HCPCS code or Part B providers will bill for a selected drug using a combination of HCPCS code and claim modifier—or some other mechanism) in the future.

The following methodology will be used to apply the single MFP across NDC-9s and/or HCPCS codes for a 30-day equivalent supply and to calculate an MFP per unit for each NDC-9 of the selected drug and/or an MFP per billing unit associated with the selected drug. CMS will use a methodology that scales the MFP per unit and/or the MFP per billing unit based on price differentials across different dosage forms and strengths. For initial price applicability year 2028, CMS will use the Primary Manufacturer reported WAC from CMS HPMS (see section 40.2 of this final guidance) of the selected drug in this calculation. CMS will first calculate annual calendar year 2025 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 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. The annual calendar year 2025 WAC per unit for each NDC-11 will then be converted into an amount for a 30-day equivalent supply (using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for PDE records or the methodology described in section 60.2.1 of this final guidance for Part B data), so that the WAC will be comparable to the negotiated single MFP. CMS intends 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 will then be used to calculate a WAC price ratio for each NDC-9 of the selected drug. The ratio derived from the WAC per 30-day equivalent supply for each NDC-9 will 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. Lastly, to determine the per unit MFP for an NDC-9, CMS will convert from an MFP for a 30-day equivalent supply to an MFP per unit based on the average number of units in a 30-day equivalent supply. For selected drugs payable under Part B, CMS will further convert

the MFP per unit of each NDC-9 into an MFP per billing unit by converting the per-unit amount into an amount per billing unit as necessary (to account for any differences in the NDC-9 unit versus the billing unit, e.g., if the NDC-9 unit is per mL and the billing unit is 5 mL), then taking an average of the MFP per billing unit across all NDC-9s belonging to the selected drug in the HCPCS code, weighted by the ASP units reported as sold for each NDC-9 as reported by manufacturers for each NDC-11 within an NDC-9 in the ASP portal.

For the process described above, CMS will apply the MFP to any NDCs of the selected 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 calendar year 2025. For such NDCs of selected drugs covered under Part D, CMS would use calendar year 2025 PDE records where the PDE record is associated with a prescription filled between January 1, 2025, and December 31, 2025, and meets the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance. With respect to Part B data, CMS would use calendar year 2025 FFS Part B claims data and/or MA encounter data for Part B items and services where the claim and/or record is associated with a service date between January 1, 2025 and December 31, 2025, and meets the inclusion and exclusion criteria described at the beginning of section 30 of this final guidance. CMS also will apply the MFP to any new NDCs or HCPCS codes, NDCs with insufficient PDE or WAC data in calendar year 2025, or HCPCS codes with insufficient Part B data in calendar year 2025 in accordance with section 60.5.1 of this final guidance.

The following steps provide additional detail regarding the approach CMS will use to apply the MFP across dosage forms and strengths:

1. For each NDC-11 and calendar quarter, CMS will divide the WAC quarterly units by the total WAC annual units (from manufacturer-submitted data) and multiply this quotient by the quarterly WAC per unit.
    - Note: CMS will use the WAC unit cost for the period beginning January 1, 2025, and ending December 31, 2025, for purposes of this calculation because it will be the most recent period of data available.
2. For each NDC-11, CMS will then sum the amounts calculated in step 1 to calculate the annual WAC per unit.
3. For each NDC-11, CMS will divide the total units dispensed/administered by the total 30-day equivalent supply, summed across 2025 PDE data and 2025 Part B data to calculate the average number of units per 30-day equivalent supply.
    - For NDCs present only in PDE data: total units dispensed/administered are defined as the total quantity dispensed for an NDC-11.
    - For NDCs only associated with HCPCS codes present in Part B data: total units dispensed/administered are defined as the total billing units sold for an NDC-11 as determined using the unit allocation and standardization methodology described in section 60.2.2.2 of this final guidance, adjusted to the NDC-11 level by removing step 3, changing all references to “NDC-9” in steps 4 and 5 to “NDC-11”, and changing the reference to “step 3” in step four to “step 2”.
    - 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 section 60.2.2.3 of this final guidance, adjusted to the NDC-11 level by removing step 3, changing all references to "NDC-9" in steps 4 and 5 to "NDC-11", and changing the reference to "step 3" in step four to "step 2".

4. For each NDC-11, CMS will multiply the WAC per unit calculated in step 2 by the average number of units per 30-day equivalent supply calculated in step 3 to calculate the WAC per 30-day equivalent day supply for that NDC-11.
5. For each NDC-11, CMS will divide the total 30-day equivalent supply for that NDC-11 across both PDE data and Part B data as applicable by the total 30-day equivalent supply across all applicable NDC-11s within an NDC-9 (across both PDE data and Part B data as applicable) and then multiply this quotient by the amount calculated in step 4.
6. For each NDC-9, CMS will then sum amounts calculated in step 5 across all NDC-11s to calculate the WAC per 30-day equivalent supply for that NDC-9.
7. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s and then multiply this quotient by the amount calculated in step 6.
8. CMS will then sum amounts calculated in step 7 across all NDC-9s of the selected drug to calculate the WAC per 30-day equivalent supply for the selected drug.
9. For each NDC-9, CMS will then divide the WAC per 30-day equivalent day supply for that NDC-9 calculated in step 6 by the WAC per 30-day equivalent supply for the selected drug calculated in step 8 to calculate the WAC per 30-day equivalent supply ratio for that NDC-9.
10. For each NDC-9, CMS will multiply the single MFP for the selected drug by the relative WAC per 30-day equivalent supply ratio for that NDC-9 calculated in step 9 to calculate the MFP per 30-day equivalent supply for that NDC-9.
11. For each NDC-9, CMS will divide the MFP per 30-day equivalent supply for that NDC-9 calculated in step 10 by the quotient of the total number of units dispensed divided by the total 30-day equivalent supply to calculate the MFP per unit (e.g., tablet).

For NDC-11s associated with HCPCS codes present in Part B data, CMS will further convert the MFP per unit of each NDC-9 into an MFP per billing unit using the following steps:

12. For each NDC-9, CMS will convert the MFP per unit as calculated in step 11 to an MFP per billing unit, as necessary. For example, if the unit of the NDC in PDE data is 1 mL but the billing unit associated with which that NDC is 5 mL, CMS would multiply the MFP per unit calculated in step 11 by 5.
13. For each NDC-9, CMS will sum the units reported by manufacturers in the ASP portal for all quarters in 2025 for all NDC-11s associated with that NDC-9 within a given HCPCS code.
14. For each NDC-9, CMS will divide the amount calculated in step 13 by the sum of units reported by manufacturers in the ASP portal for all quarters in 2025 for all NDC-11s that share the same HCPCS code and belong to the selected drug.
15. For each NDC-9, CMS will multiply the MFP per billing unit calculated in step 12 by the quotient calculated in step 14.
16. For each HCPCS code, CMS will sum the value calculated in step 15 across all NDC-9s for which the corresponding NDC-11 is associated with the HCPCS code to yield the MFP per billing unit.

CMS will include the MFP per billing unit, calculated in step 16 above, and the MFP per-unit price for each NDC-9 of the selected drug, calculated in step 11 above in the publication of MFPs as described in section 60.6 of this final guidance. CMS recognizes there may be other ways to apply the MFP to dosage forms and strengths and will monitor whether this policy serves the intent of the Negotiation Program. As noted throughout this final guidance, the policies described for the Negotiation Program are for initial price applicability year 2028 and CMS may consider additional policies for future years of the Negotiation Program. Due to potential for confusion arising from differences between the NDC-11 package price as published by CMS (calculated without rounding any values in interim steps) and the NDC-11 package price that would result if another entity were to take the product of the published NDC-9 unit price (rounded to six decimals) and the package size, CMS will remove the NDC-11 package price from the public pricing file and only list the NDC-9 unit price (rounded to six decimals).

60.5.1 Application of the MFP to New NDAs / BLAs or NDCs and to NDCs with Insufficient PDE, Part B Data, or WAC Data in Calendar Year 2025

Consistent with CMS' process for identifying a qualifying single source drug described in section 30.1 of this final guidance, if the Primary Manufacturer for an initial price applicability year 2026, 2027, or 2028 selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient (or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients) as the selected drug, CMS will include the NDCs associated with the new NDA or BLA, as appropriate, on the list of NDCs of the selected drug determined pursuant to section 40.2 of this final guidance and require that the MFP apply to such NDCs. If the new NDA or BLA is associated with NDCs that are assigned to a HCPCS code that is not already included on the list of HCPCS codes of an initial price applicability year 2028 selected drug determined pursuant to section 40.2 of this final guidance, CMS will include the new HCPCS code, as appropriate, on the list of HCPCS codes of the selected drug and require that the MFP apply to such HCPCS codes. Similarly, after the drug is selected for an initial price applicability year 2026, 2027, or 2028, if the Primary Manufacturer for such drug receives approval or licensure for a new drug or biological product that is marketed pursuant to a supplement to an existing NDA or BLA, or otherwise launches a new NDC for the selected drug or (for initial price applicability year 2028 selected drugs only) is assigned a new HCPCS code for the selected drug, CMS will include such NDCs and HCPCS codes, as appropriate, on the list of NDCs and HCPCS codes of the selected drug determined pursuant to section 40.2 of this final guidance and require that the MFP apply to such NDCs and HCPCS codes.

Additionally, an NDC (or all NDCs assigned to a HCPCS code, for initial price applicability year 2028 selected drugs) that has been included on the list of NDCs of the selected drug pursuant to section 40.2 of this final guidance may lack sufficient PDE, Part B data, or WAC data in the calendar year used to apply the MFP across that dosage form and strength during the negotiation period as described above. New NDCs and HCPCS codes of selected drugs will also be added after the initial calculation of WAC ratios, as appropriate. For such NDCs and HCPCS codes described above, CMS will determine whether there is an existing NDC that is comparable to such NDC (or comparable to the NDCs associated with such HCPCS code) and to which the MFP for the selected drug has been applied. CMS will determine which existing NDC is

comparable based on review of the FDA-approved label of the selected drug and other relevant sources. If an existing, comparable NDC exists, CMS will use the quotient of total units dispensed/administered to 30-day equivalent supply (adjusted as necessary to reflect dosing or unit type differences between the NDCs) and the WAC ratio that was calculated for the existing, comparable NDC to apply the MFP to the new NDC or NDC that lacks sufficient data to be used in the calculation. If a comparable NDC does not exist, CMS will impute the quotient of total units dispensed/administered to 30-day equivalent supply using sources such as the FDA-approved label and other sources associated with the NDC that lacks sufficient PDE, Part B data, and/or WAC data, but will use a WAC ratio of 1.0 to apply the MFP to the NDC that lacks sufficient PDE, Part B data, and/or WAC data. 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.

As described in section 40.5 of this final guidance, as feasible, CMS will provide Primary Manufacturers with information on certain CMS calculations, including updates to CMS' computation of how the agency will apply a single MFP across dosage forms and strengths of the selected drug such as to account for the addition of new NDCs, and CMS will allow a Primary Manufacturer that believes in good faith that CMS has made an error in this computation to submit a suggestion of error for CMS' consideration. Comments related to statutorily-required criteria or the policies adopted in Negotiation Program guidance are outside the scope of the suggestion of error process. For example, comments on calculation methodology will be considered out of scope.

For new NDCs and HCPCS codes where CMS imputed the quotient of total units dispensed/administered to 30-day equivalent supply, CMS will adjust the MFP application by updating the quotient of total quantity dispensed to 30-day equivalent supply based on observed PDE data and Part B data for existing NDCs and HCPCS codes that lacked sufficient WAC, PDE data, or Part B data to be included in the initial calculation of WAC ratios (described in step 9 of section 60.5 of this final guidance), and new NDCs and HCPCS codes launched after the initial calculation of WAC ratios, when CMS accrues sufficient data for such NDCs and HCPCS codes. Specifically, for these NDCs and HCPCS codes, CMS will monitor total quantity dispensed 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 CMS' computation of how the agency will apply a single MFP across dosage forms and strengths of the selected drug. CMS will 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) CMS determines the variation in average total quantity dispensed and 30-day equivalent supply is stable over time; (2) 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 (3) 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. After CMS recomputes the application of the single MFP across dosage forms and strengths for these NDCs and/or HCPCS

codes, CMS will provide Primary Manufacturers with information on certain CMS calculations and allow a Primary Manufacturer that believes in good faith that CMS has made an error in this computation to submit a suggestion of error for CMS consideration, as described above and in section 40.5 of this final guidance.

60.6 Publication of the MFP

In accordance with section 1195(a)(1) of the Act, CMS will publish by November 30, 2026, the MFP for each drug selected for initial price applicability year 2028 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file, and the explanation for the MFP (published at a later date—see section 60.6.1 of this final guidance). The MFP file[177] will contain the single MFP for a 30-day equivalent supply of the selected drug, NDC-9 per unit price and HCPCS code dosage price and will be updated annually to show the inflation-adjusted MFP for the selected drug. CMS will 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 per unit price or HCPCS code dosage price is updated as a result of additional data. Further, CMS will publish on the CMS website when a drug is no longer a selected drug and the reason for that change, and when an MFP between a Primary Manufacturer and CMS is not agreed upon.

In accordance with section 1195(b)(1)(A) of the Act, for each selected drug, for each year subsequent to the first initial price applicability year of the price applicability period (unless renegotiation occurs), CMS will publish an updated MFP no later than November 30 of the year that is two years prior to such subsequent year. The updated MFP for each selected drug will 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, 2026, CMS will publish on the CMS website updated amounts for any MFPs for initial price applicability year 2027 selected drugs for which a manufacturer agreement is in effect. Those updated MFPs will take effect in 2028 and will be equal to the initial price applicability year 2027 MFP for the selected drug increased by the percent increase in CPI-U from July 2025 to July 2026. In accordance with section 1192(c)(2) of the Act and subject to the timeline and situations discussed in section 70 of this final guidance, a selected drug with an agreed-upon MFP may cease to be a selected drug and no longer subject to an MFP if CMS determines that a generic drug or a biosimilar for the reference drug is approved or licensed by the FDA and—as discussed in section 70 of this final guidance—is bona fide marketed. CMS further recognizes 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 pursuant to section 1194(f)(3) of the Act), as discussed in section 130 of this final guidance.

[177] The Maximum Fair Price Layout file will display the NDC-9 per unit price to six decimal places. Publishing an NDC-9 per unit price rounded to the sixth decimal point place aligns with how CMS publishes other prices. Furthermore, publishing an NDC-9 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.

60.6.1 Explanation for the MFP

Section 1195(a)(2) of the Act requires CMS to publish public explanations for the MFPs no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2027, for initial price applicability year 2028. CMS will strive to publish these MFP explanations earlier than March 1, 2027, if feasible. The MFP explanations will focus on the section 1194(e) data that had the greatest impact in determining the MFPs and include a discussion of the other section 1194(e) data, as applicable. It may also note any data or circumstances that may be unique to the selected drug. Alongside the narrative explanation, CMS will release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS will develop and publish the MFP explanations in accordance with the confidentiality policy described in section 40.2 of this final guidance.

If an agreement for an MFP is not reached for a selected drug, neither an MFP nor an MFP explanation will be published. Instead, CMS will indicate on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where an MFP is finalized after the statutory deadline for the conclusion of negotiations, the MFP and MFP explanation will be posted in accordance with section 60.8 of this final guidance.

60.7 Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability

In accordance with section 1192(c)(2) of the Act and subject to the timeline and situations discussed in section 70 of this final guidance, a selected drug will no longer be subject to the negotiation process, with respect to its initial price applicability year, if CMS determines that at least one generic drug or biosimilar satisfies the following criteria: (1) it is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product; and (2) it is marketed pursuant to such approval or licensure. The approach CMS will take to make this determination is described in section 70 of this final guidance.

When the drug is no longer subject to the negotiation process based on the criteria in section 1192(c)(2) of the Act, the selected drug will continue to be considered a selected drug with respect to such initial price applicability year regarding the number of negotiation-eligible drugs on the list published under section 1192(a) of the Act (see section 70 of this final guidance for additional details).

60.8 Establishment of MFPs After the Negotiation Deadline

Section 1194(b)(2) of the Act contemplates that agreement upon an MFP must be reached for initial price applicability year 2028 by November 1, 2026 in order 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. As a general matter, if the Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, CMS will continue to engage in the negotiation process described in section 60.4 of this final guidance. Certain actions or delays by the Primary Manufacturer may delay the process such that the MFP is established after the end of the negotiation period. If this occurs, in accordance with section 1194(b)(1) of the Act, CMS will follow timelines consistent with the negotiation process established in this final guidance and

take the time to complete the established process so described as appropriate for the selected drug. Likewise, 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, in accordance with section 1194(b)(1) of the Act, when CMS initiates or resumes the negotiation process, CMS will apply the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including beginning in 2028, which may have potential implications with respect to the renegotiation process as discussed in section 130 of this final guidance.

If the manufacturer and CMS have completed each step of the negotiation process as detailed in section 60.4 of this final guidance, including CMS' issuance of a "Notification of Final Maximum Fair Price Offer" 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 last offer of an MFP from CMS, as reflected in the "Notification of Final Maximum Fair Price Offer." In accordance with section 1195(b)(2) of the Act, 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, CMS shall publish the MFP no later than 30 days after the date such MFP is so determined. In accordance with section 60.6 of this final guidance, CMS will publish the MFP and the MFP explanation on the CMS website. CMS will follow timelines consistent with the established process for publishing the public explanation of the MFP and will not expedite its timeline due to late action from the Primary Manufacturer.

70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations discussed below, if CMS determines: (1) 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.

The approval (or licensure, as applicable) and marketing of an authorized generic drug (which includes authorized generic drugs and certain biological products as defined in section 1192(e)(2) of the Act) would not qualify as meeting the statutory requirement that a generic drug or a biosimilar is being marketed. In accordance with section 1192(e)(2)(B)(i) of the Act, an authorized generic drug as defined in section 505(t)(3) of the FD&C Act is treated as the same qualifying single source drug as a qualifying single source drug that is the listed drug, for the purposes of the Negotiation Program. Likewise, section 1192(e)(2)(B)(ii) of the Act indicates that the same rule applies to a biological product that is approved under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or 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 trademark.

The determination whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list will be informed by CMS' review of PDE and AMP data (as well as any other data CMS reviews, such as ASP data, Medicaid SDUD, and/or data from a nationally representative and commercially available database) for the generic drug or biosimilar for which the selected drug is the listed drug or reference product on a monthly basis as described below. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry based on the totality of the circumstances. The sources of data described in this section 70 will be informative for that inquiry, but CMS' determination will not necessarily turn on any one source of data.

After the selected drug is removed from the selected drug list, CMS will monitor the manufacturers of such generic drugs or biosimilars to ensure they continue to engage in bona fide marketing of the generic or biosimilar based on the process described in section 90.4 of this final guidance.

Starting in March 2026, and repeated each month thereafter, for the applicable selected drugs, CMS will take the following approach in its review of data to inform its determination whether the statutory criteria in sections 1192(c)(1)(A) and 1192(c)(1)(B) of the Act for an approved generic drug or licensed biosimilar to be marketed pursuant to such approval or licensure are being met.

First, CMS will 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 for initial price applicability year 2028.

Second, if CMS determines that a generic drug or biosimilar has been approved or licensed, CMS will begin by reviewing the PDE, AMP, and ASP data (as well as any other data CMS may review, such as Medicaid SDUD and/or data from a nationally representative and commercially available database) with dates of service or sales during the most recent 12-month period available for that data source to determine if the manufacturer of the generic drug or biosimilar has engaged in bona fide marketing of that drug or product. For example, when CMS performs this assessment in March 2026, CMS will use PDE data with dates of service from April 2025 through mid-March 2026, AMP data with sales from February 2025 through January 2026, and ASP data with sales from January 2025 through December 2025. When CMS performs this assessment in April 2026, CMS will use PDE data with dates of service from May 2025 through mid-April 2026, AMP data with sales from March 2025 through February 2026, and ASP data with sales from January 2025 through December 2025.

The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry, but these sources of data over the specified intervals will be informative for that determination. The determination whether a generic drug or biosimilar is being bona fide marketed is a totality of the circumstances inquiry that will not necessarily turn on any one source of data. CMS will consider a generic drug or biosimilar to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product. Additional relevant factors may

include whether the generic drug or 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 a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar, as articulated further in section 90.4 of this final guidance.

Per section 1192(c)(2) of the Act, if CMS makes a determination regarding generic drug or biosimilar availability before the end of or during the negotiation period for an initial price applicability year, the selected drug will not be subject to the negotiation process for the negotiation period, and an MFP will not be established. Accordingly, for initial price applicability year 2028, if CMS makes this determination between the date that the selected drug list for initial price applicability year 2028 is published and November 1, 2026, the drug will remain a selected drug through 2028, but no MFP will apply, and the drug will not be replaced with another selected drug.

In accordance with section 1192(c)(1) of the Act, 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 the statutory criteria in section 1192(c) of the Act are met. Accordingly, if CMS makes this determination between November 2, 2026 and March 31, 2028, for a drug selected for initial price applicability year 2028, then the drug will cease to be a selected drug on January 1, 2029 and the MFP will apply for 2028. If CMS makes this determination between April 1, 2028 and March 31, 2029, then the selected drug will cease to be a selected drug on January 1, 2030, and the MFP will apply for 2028 and 2029. These results are summarized in Table 9.

Table 9: Removal from the Selected Drug List Following Generic Drug or Biosimilar Approval and Marketing

Date on which CMS determines that a generic drug or biosimilar is approved and marketed	**Result with respect to selected drug for the Negotiation Program**
The date that the selected drug list for initial price applicability year 2028 is published through November 1, 2026 (the end of the Negotiation Period for the initial price applicability year 2028)	Selected drug remains a selected drug for initial price applicability year 2028, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2029.
November 2, 2026 through March 31, 2028	Selected drug remains a selected drug and MFP applies for initial price applicability year 2028; selected drug ceases to be a selected drug on January 1, 2029.
April 1, 2028 through March 31, 2029	Selected drug remains a selected drug and MFP applies for initial price applicability year 2028 and calendar year 2029; selected drug ceases to be a selected drug on January 1, 2030.

CMS adds to this final guidance that if CMS determines bona fide marketing exists for a drug selected for initial price applicability years 2026 or 2027 prior to the publication of the selected drug list for initial price applicability year 2028 (including drugs selected for renegotiation), a drug selected for initial price applicability years 2026 or 2027 is not eligible for renegotiation as specified in section 1194(f)(5) of the Act. After the publication of the selected drug list for initial price applicability year 2028 (including drugs selected for renegotiation), the timeline for removal from the renegotiated selected drug list following generic drug or biosimilar approval and marketing, and the application of the renegotiated MFP follows the timeline specified in Table 9.

Regardless of when a drug is removed from selection for renegotiation for initial price applicability year 2028, the requirements for application of the originally negotiated MFP must be separately determined based on the price applicability year that the drug was originally selected for negotiation. For drugs selected for negotiation for initial price applicability year 2026, the MFP remains in effect in accordance with the table provided on page 166 of the revised guidance for initial price applicability year 2026. For drugs originally selected for negotiation for initial price applicability year 2027, the MFP remains in effect as specified in Table 9 of the final guidance for initial price applicability year 2027 on page 279.

Without regard to whether the Primary Manufacturer decides to execute an Agreement as discussed in section 40.1 of this final guidance, to terminate an Agreement as discussed in section 40.6 of this final guidance, or to transfer ownership of the selected drug as discussed in section 40.7 of this final guidance, a selected drug remains a selected drug until CMS determines otherwise under the criteria set forth in section 1192(c) of the Act.

In all cases, after CMS determines the statutory criteria in section 1192(c) of the Act for generic or biosimilar competition are met for a selected drug, CMS will publish such information on the CMS website.

80. MFP-Eligible Individuals in 2026, 2027, and 2028

For 2026, 2027, and 2028, in accordance with section 1191(c)(2)(A) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" means, with respect to a selected drug, the following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispensing entity, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan), if Part D coverage is provided under such plan for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who only uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash,[178] and for whom no PDE record is produced for the claim.

For 2026 and 2027, CMS does not expect Primary Manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with

[178] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in a Medicare Advantage plan under Part C. For 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, CMS expects Primary Manufacturers to provide access to the MFP of a selected drug to hospitals, physicians and other providers of services and suppliers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in a Medicare Advantage plan under Part C. CMS will address policies related to the effectuation of the MFP for drugs payable under Part B to Part B providers in the future.

For 2028, in accordance with section 1191(c)(2)(B) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" also means, with respect to a selected drug, the following: 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 Medicare Part B or in a Medicare Advantage plan under Medicare Part C, if payment may be made under Part B for such selected drug. CMS anticipates that Medicare Advantage plan requirements under 42 C.F.R. Part 422 will apply to selected drugs.

80.1 Direct Member Reimbursements and Access to the MFP for Selected Drugs in 2026, 2027, and 2028

Direct member reimbursement (DMR) requests are requests for reimbursement submitted by eligible individuals to Part D plan sponsors to be reimbursed for a claim in which the individual paid the cash price out-of-pocket for the drug at the dispensing entity and did not use Part D coverage when receiving the drug. While Part D plan sponsors generally may charge the enrollee for the difference between the cash price paid to the dispensing entity and the plan allowance (if out-of-network) or negotiated price (if in-network) for drugs covered under Part D accessed from both out-of-network and in-network dispensing entities, neither 42 C.F.R. § 423.124(b) nor Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual's guidance on DMRs directly addresses drugs covered under Part D that have an MFP in effect.[179]

One situation in which an individual may submit a DMR request is if they are on vacation and need a medication, but there is no network pharmacy nearby, so they fill a prescription at an out-of-network pharmacy. Another situation where an individual may submit a DMR request is if they visit a network pharmacy, but the pharmacy's technology system is temporarily not functioning and the pharmacy is unable to adjudicate the claim online. In these two scenarios, the individual may elect to pay the cash price at the pharmacy and later submit a DMR request to their Part D plan sponsor for the prescription to apply towards their out-of-pocket expenses for

[179] 42 C.F.R. § 423.124(b) establishes that a Part D plan sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs at out-of-network pharmacies to assume financial responsibility for any differential between the out-of-network dispensing entity's usual and customary price and the Part D sponsor's plan allowance (as defined at 42 C.F.R. § 423.100). Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual provides detailed guidance on how Part D plan sponsors must process DMR requests that are submitted by enrollees that paid the dispensing entity's cash price (i.e., the pharmacy did not submit a claim to the Part D plan sponsor) at both out-of-network and in-network pharmacies. Chapter 14 of the Medicare Prescription Drug Benefit Manual is available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter-14-coordination-of-benefits-v09-17-2018.pdf.

purposes of moving through the benefit and to potentially receive reimbursement from the plan for accessing a drug that is covered under their Part D benefit. CMS notes that DMR requests are exceedingly rare. In a recent internal analysis, less than one-hundredth of a percent of final action claims submitted in 2024 for the ten drugs selected for initial price applicability year 2026 were submitted as DMR requests. An individual who submits a DMR request for a selected drug accessed at either an out-of-network (in accordance with 42 C.F.R. § 423.124(a) and (c)) or at an in-network dispensing entity, when the selected drug is covered under the Part D benefit (e.g., utilization management requirements have been met) (hereinafter a "covered DMR request") and a PDE record is generated for the claim, is an MFP-eligible individual under the definition in section 1191(c)(2)(A) of the Act and section 80 of this final guidance.

Sections 1196(a)(1) and (a)(3)(A) of the Act direct the Secretary to establish procedures to ensure that the MFP for a selected drug is applied before any coverage or financial assistance under other health benefit plans or programs or other discounts, as well as to establish procedures to carry out the provisions of the IRA with respect to MFP-eligible individuals who are enrolled in a Part D plan. As discussed above, DMR requests are unique from typical claims for selected drugs and, therefore, warrant procedures to facilitate access to the MFP for MFP-eligible individuals that differ from how the MFP is normally effectuated for selected drugs. For example, when an eligible individual submits a DMR request, the Part D benefit is not used at the point of sale, the dispensing entity does not bill the individual's Part D plan but rather charges the individual the cash price established by the dispensing entity, and the individual's status as an MFP-eligible individual is not determined until after the point of sale when the individual submits the DMR request to their Part D plan. While a Primary Manufacturer of a selected drug that is participating in the Negotiation Program and reaches agreement upon an MFP remains responsible for providing access to the MFP to MFP-eligible individuals who are dispensed that selected drug during a price applicability period, CMS believes that, in light of these unique aspects of DMRs, it is necessary to establish a procedure that leverages existing Part D plan sponsor procedures for DMRs to help ensure that the MFP is available to an MFP-eligible individual that submits a covered DMR request.

For 2026, 2027, and 2028, access to the MFP for an MFP-eligible individual that submits a covered DMR request for a selected drug will be facilitated by the Part D plan sponsor. For DMRs involving in-network claims, the plan sponsor is responsible for reimbursing the individual at least the difference between the cash price paid by the enrollee to the dispensing entity and the negotiated price (which, in accordance with section 1860D-2(d)(1)(D) of the Act, shall be no greater than the MFP plus any dispensing fees for such selected drug). For DMRs involving out-of-network claims, the plan sponsor is responsible for reimbursing the individual at least the difference between the cash price paid by the enrollee to the dispensing entity and the MFP plus any dispensing fees, since there is not a negotiated price for the out-of-network dispensing entity. Accordingly, MFP-eligible individuals that submit a covered DMR request for a selected drug must not pay more than the MFP plus any dispensing fees if the individual is in the deductible phase of the benefit or their copayment or coinsurance if they are in other phases of the benefit. Primary Manufacturers and Part D plan sponsors may establish a reimbursement process related to DMR requests for MFP-eligible claims as necessary to ensure MFP effectuation for these MFP-eligible individuals.

As discussed above, a covered DMR request for a selected drug presents a unique circumstance where the dispensing entity and the plan sponsor do not have insight to the MFP eligibility of the individual at the point of sale and therefore requires an alternate procedure to effectuate the MFP for the MFP-eligible individual. In DMR situations, the dispensing entity has already received the cash payment from the individual at the point of sale, at the cash price established by the dispensing entity, and is not involved in the submission of the claim to the Part D plan or the transaction to reimburse the MFP-eligible individual. In such cases, CMS will consider the MFP to have been made available to the dispensing entity through the cash payment by the individual and, as a result, will not require the Primary Manufacturer to pay an MFP refund to the dispensing entity in connection with a covered DMR request.

90. Manufacturer Compliance and Oversight

In accordance with section 1196(b) of the Act, CMS will monitor compliance by a Primary Manufacturer with the terms of the Agreement and establish a mechanism through which violations of such terms shall be reported.

90.1 Monitoring of Manufacturer Compliance

CMS will closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program, including all processes related to renegotiation. Following the publication of selected drugs for negotiation and renegotiation for each initial price applicability year, CMS will provide information about the negotiation or renegotiation process, as applicable, to the Primary Manufacturer of each selected drug (see section 40 of this final guidance for additional details). CMS anticipates this information will include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information.

During the negotiation and renegotiation periods, CMS will track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. CMS may require additional information from the Primary Manufacturer to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. This may include requiring recurring reporting (for example, providing evidence that 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. When applicable, CMS will provide a written request to the Primary Manufacturer detailing such requests, including a date by which any requested information must be submitted. CMS is committed to providing Primary Manufacturers with reasonable timeframes to accommodate these information requests. CMS will consider written requests for deadline extensions submitted no later than three calendar days prior to the initial deadline. Extension requests must include a reasonable basis for requiring the extension as determined by CMS. CMS will only grant very limited extension requests and may be unable to fully grant requested extensions due to statutory timelines or other operational considerations.

To facilitate program operations and support manufacturer compliance, CMS may provide the Primary Manufacturer with written reminders of impending submission deadlines, with warnings of potential applicability of the excise tax (see 26 U.S.C. § 5000D for additional information

regarding the excise tax) or of potential liability for a CMP for submission violations (see section 100 of this final guidance). CMS may also provide written requests for clarifications, corrections, and/or additional information following data submissions; written notification that a Primary Manufacturer may be subject to enforcement action, as applicable; written reminders that potential compliance concerns are ongoing, as applicable; and written confirmation that potential compliance concerns have been mitigated, as applicable. As appropriate, CMS communications may take the form of Requests for Corrective Action, Notifications of Potential Noncompliance, and/or Violation Notices. If CMS makes a determination to assess a CMP, CMS will follow the procedures outlined in section 100.5 of this final guidance to notify the Primary Manufacturer and initiate the CMP process.

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 (see 26 U.S.C. § 5000D). Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in CMPs. If the Primary Manufacturer submits information that is required under the Agreement and CMS determines the information is false, the Primary Manufacturer will be determined to be noncompliant with the requirement to submit information and may be subject to a CMP. 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 section 100.5 of this final guidance.

90.2 Monitoring of Access to the MFP in 2026, 2027, and 2028

In accordance with section 1193(a)(3) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP – whether agreed upon during a negotiation or a renegotiation process – with respect to a selected drug shall be provided by the Primary Manufacturer to MFP-eligible individuals at the pharmacy, mail order service, or other dispensing entity at the point-of-sale, to dispensing entities with respect to such MFP-eligible individuals who are dispensed the selected drug and, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, to Part B providers with respect to such MFP-eligible individuals who are furnished or administered the selected drug. Although the Primary Manufacturer is obligated to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug that are dispensed, furnished, or administered to MFP-eligible individuals as described above, the Primary Manufacturer is not obligated to make any sales of the selected drug.

Further, in accordance with section 1193(a)(5) of the Act, which requires that the Primary Manufacturer comply with requirements determined by the Secretary to be necessary for purposes of administering and monitoring compliance with the Negotiation Program, and section 40.4 of this final guidance, CMS requires that the Primary Manufacturer establish processes to ensure the MFP is available as described in section 40.4 on units of the selected drug for which there are Secondary Manufacturers. CMS reiterates that the requirement for the Primary Manufacturer to provide access to the MFP applies to all sales of the selected drug by a Secondary Manufacturer to MFP-eligible individuals and to dispensing entities and Part B providers that dispense, administer, or furnish the selected drug to an MFP-eligible individual, as discussed in section 80 of this final guidance. Unless otherwise specified, the MFP effectuation

policies described in this final guidance apply only to Part D. CMS is not at this time including detailed policy on monitoring access to the MFP for drugs payable under Part B but intends to align the policies for Part B with the policies for Part D discussed in this section 90.2 of this final guidance to the extent appropriate and feasible.

The MFP effectuation policies established for 2026 and 2027 in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 are final policies that remain in effect for 2026 and 2027. In this final guidance, CMS makes updates and includes supplemental information regarding these policies for 2026 and 2027 and is extending these same policies to 2028 for drugs covered under Part D. For ease of reference, CMS is restating the MFP effectuation sections from final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 in this final guidance so that the changes and updates to those policies can more easily be read in context with the policies in the prior final guidance that CMS is modifying or supplementing. In this section, CMS adds clarifying language regarding the agency's process for determining whether MFP was made available and information that may be considered during case-specific monitoring and investigation activities.

If CMS determines through audits, investigations, or complaints from dispensing entities or other market participants, that a Primary Manufacturer has not consistently fulfilled its obligation to make the MFP available by transmitting payment of an amount that provides access to the MFP within the 14-day prompt MFP payment window (unless the MFP was provided prospectively or, as detailed in section 40.4.5 of this final guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies) for drugs covered under Part D, CMS will notify the Primary Manufacturer of its noncompliance and encourage the Primary Manufacturer to adopt process changes to address deficiencies in its MFP effectuation policies and practices as soon as possible. Failure to make the MFP available promptly may result in CMS imposing the appropriate CMPs as set forth in section 100.1 of this final guidance. Further, dispensing entities are encouraged to review their accounts receivable to determine whether a Primary Manufacturer has accurately paid all the claims the dispensing entity believes are MFP-eligible claims and to work with the Primary Manufacturer to resolve discrepancies. The dispensing entity may use the complaint and dispute process set forth in section 90.2.2 of this final guidance to alert CMS of remaining discrepancies.

As described in section 40.4 of this final guidance, CMS has engaged an MTF Contractor for the MTF DM to facilitate the exchange of data between Primary Manufacturers and dispensing entities to support the verification that the selected drug was dispensed to an MFP-eligible individual. As described in section 40.4.3 of this final guidance, CMS has also engaged an MTF Contractor for the MTF PM to provide optional facilitation of retrospective MFP refund payments from participating Primary Manufacturers to dispensing entities to help effectuate access to the MFP.

Under section 1195(a) of the Act, the MFP for a selected drug and the explanation for each MFP will be published by CMS, giving the public and other interested parties an opportunity to know the MFP for each selected drug, and will be updated as needed if any NDC-9s or NDC-11s are added or removed for the selected drug and annually to show the inflation-adjusted MFP for the

selected drug (see section 60.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable, for additional details). Under section 1195(a)(1) of the Act, the MFPs for selected drugs for initial price applicability year 2028 must be published by November 30, 2026.[180] In addition, CMS anticipates it is likely that pharmaceutical database compendia will publish the MFPs for selected drugs such that they would become easily accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they were provided access to the MFP.

As described in sections 40.4.1 through 40.4.4 of this final guidance, the Primary Manufacturer is responsible for calculating a refund amount for each MFP-eligible claim and reporting claim-level payment elements with a justification code indicating the method of calculation of that refund amount for Part D claims. This includes the reasons considered in sections 40.4.3 and 40.4.4 of this final guidance for an MFP refund payment amount that differs from the SDRA, including adjustments for differing acquisition costs, prospective purchasing by a dispensing entity at or below MFP, or the claim being excluded from MFP refunds under section 1193(d)(1) of the Act.

As related to the exclusion of a claim from MFP refunds under section 1193(d)(1) of the Act, section 40.4.5 of this final guidance describes that a Primary Manufacturer is not required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be furnished, dispensed, or administered such selected drug at the 340B covered entity if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price is lower than the MFP for such selected drug. In accordance with section 1193(d)(2) of the Act, if the MFP for the selected drug is below the 340B ceiling price in effect on the date on which the MFP-eligible individual is furnished, dispensed, or administered such selected drug by the 340B covered entity, the Primary Manufacturer is required to provide access to the MFP to the 340B covered entity with respect to such an MFP-eligible individual in a nonduplicated amount to the 340B ceiling price.

CMS recognizes that the data elements from PDE records transmitted by the MTF to Primary Manufacturers may include those from claims that should be subject to a different refund amount than the SDRA, including claims described under section 1193(d)(2) of the Act, claims for selected drugs prospectively purchased at or below MFP, or claims for which the Primary Manufacturer may claim an exception under section 1193(d)(1) of the Act. As noted in sections

[180] Section 40.2 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance describes the Primary Manufacturer's ongoing obligation to timely report any changes to the NDC-11s for the selected drug. Section 60.5.1 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance describes how CMS will apply the MFP if new NDCs are added for the selected drug list. Section 60.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance describes CMS' publication of and updates to the MFP file. Section 60.8 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance describes the MFP publication timeline that CMS will follow in the event of late action from the Primary Manufacturer.

40.4.3 and 40.4.4 of this final guidance, CMS expects Primary Manufacturers to indicate such claims in the reported claim-level payment elements, and to maintain documentation justifying the indication and MFP refund payment, if applicable.

When assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug in the course of the agency's general oversight activities, and when making case-specific determinations as to whether MFP was made available in specific circumstances, absent information available to CMS indicating otherwise, CMS will consider WAC to be an appropriate proxy for a dispensing entity's acquisition cost. Therefore, CMS will consider provision of the SDRA (which is equal to WAC minus the MFP) to meet the Primary Manufacturer's obligation to make MFP available, absent information available to CMS indicating otherwise.

When engaged in case-specific determinations as to whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug, CMS will consider contextual information available to the agency, including as applicable: the invoice amount from the dispensing entity (if available); documentation maintained by the Primary Manufacturer supporting its MFP refund amount (as described in section 40.4.3.1 of this final guidance); the MFP refund amount provided by the Primary Manufacturer, as indicated in the "Total MFP Refund Amount" field on the Primary Manufacturer's claim level payment elements, where available, or as determined based on other supporting documentation in the event the claim-level payment elements are deemed to be inaccurate; other documentation regarding the dispensing entity's actual acquisition costs such as documentation of an arrangement for prospective purchase at the MFP or other alternative arrangement evidencing acquisition cost (e.g., establishment of an agreed-upon proxy for MFP refund calculation as described in section 40.4.1 of this final guidance); and the commercial reasonableness of costs incurred by the dispensing entity related to the procurement of the selected drug (if available). CMS will make a determination based on this assessment as to whether the Primary Manufacturer made the MFP available. If CMS makes a determination that the Primary Manufacturer failed to make the MFP available, CMS will follow the process outlined in section 100.1 of this final guidance.

Consistent with section 1193(a)(5) of the Act, in the course of this assessment, to further its inquiry into whether MFP was made available, CMS may request information from relevant parties such as Primary Manufacturers, dispensing entities, or other entities involved in the supply chain. For example, documentation or data related to the Primary Manufacturer's MFP refund calculation may inform CMS' assessment of whether the MFP refund provided by the Primary Manufacturer was sufficient to make MFP available to the dispensing entity. CMS expects such information to be maintained and made available from Primary Manufacturers when requested, and CMS may also request any relevant documentation from dispensing entities, wholesalers, or other supply chain entities to better evaluate whether MFP was made available. Submitted documentation will be considered as part of CMS' fact-specific assessment of whether MFP was made available in the course of the agency's investigation, audit, and/or enforcement actions.

When a refund amount other than the SDRA is paid, Primary Manufacturers will be required to maintain supporting documentation demonstrating why MFP refunds were provided at an

amount other than the SDRA, or were not provided, for applicable claims. CMS expects Primary Manufacturers to maintain documentation that includes evidence reflecting the dispensing entity's actual acquisition cost or demonstrating a better approximation than WAC of the dispensing entity's acquisition cost. This could include, but would not be limited to, invoices from the dispensing entity, a contractual agreement with the dispensing entity establishing an acquisition cost agreed to between the Primary Manufacturer and the dispensing entity, or other evidence of the dispensing entity's acquisition cost for the selected drug. For claims filled with selected drugs prospectively purchased at or below MFP, documentation could include, but would not be limited to, invoicing documentation of the drug purchased at or below MFP or an agreement between the Primary Manufacturer and dispensing entity establishing prospective purchasing of the selected drug.

Specifically for claims subject to the exception under section 1193(d)(1) of the Act, to avoid duplication of discounts between MFP and the 340B ceiling price, Primary Manufacturers may identify Part D claims from the data elements transmitted by the MTF that are 340B-eligible (as defined in section 40.4.5 of this final guidance) and for which the 340B ceiling price is lower than the MFP. If a Primary Manufacturer determines that it will not issue an MFP refund related to a given Part D claim for which the Primary Manufacturer has received data elements from the MTF, the Primary Manufacturer must indicate in the report of claim-level payment elements that it is not paying an MFP refund for each applicable claim within the 14-day prompt MFP payment window because the Primary Manufacturer has determined, or reasonably believes, that the specified claims meet the exception described in section 1193(d)(1) of the Act. In conjunction with this indication, the Primary Manufacturer must maintain documentation demonstrating its justification of nonpayment due to the 340B eligibility of these claims and the 340B ceiling price being lower than the MFP for these claims. Documentation demonstrating that the claim is 340B-eligible should include, at a minimum, either the Primary Manufacturer's process and conclusion from its 340B nonduplication process, or confirmation from a 340B covered entity or any vendor the 340B covered entity employs to determine 340B status, that the Part D claim was 340B-eligible. CMS notes that a provider or prescriber ID alone (whether the Service Provider ID or the Prescriber ID) generally will not constitute sufficient evidence that a Part D claim was 340B-eligible as not all individuals served by covered entities are necessarily eligible to receive a drug purchased at the 340B price. If the MTF claim-level data elements include the 340B Claim Indicator, the Primary Manufacturer need only maintain documentation showing that the 340B ceiling price is lower than the MFP for the applicable claim.

If a covered entity believes that certain dispenses should have been purchased at the 340B ceiling price and the Primary Manufacturer did not make the 340B ceiling price available, then the covered entity would be able to utilize the HRSA enforcement mechanisms outside of the complaint and dispute process described in section 90.2.2 of this final guidance to pursue corrective action to receive the 340B ceiling price. If the Primary Manufacturer submits the indication in the claim-level payment elements and maintains adequate documentation to justify its nonpayment and promptly transmits payment for the remaining claims on its MTF data elements file within the 14-day prompt MFP payment window, then the Primary Manufacturer will have met its obligation to transmit payment within the 14-day prompt MFP payment window for Part D claims.

CMS will monitor the status of the unpaid claims and claims paid at a refund amount other than the SDRA that the Primary Manufacturer identified in the claim-level payment elements for Part D claims. Primary Manufacturers must maintain the documentation that justifies its nonpayment, or its payment of a refund amount other than the SDRA, and deliver documentation to CMS, if requested, for the purposes of auditing and monitoring compliance with the Negotiation Program. CMS will monitor the status of claims paid at the SDRA and may require documentation confirming MFP refund payment and payment amount, including if CMS receives a complaint related to these claims (e.g., indicating that the dispensing entity's acquisition cost was greater than WAC, and therefore, the MFP was not made available to that dispensing entity). If CMS determines upon further investigation—whether through audits of this documentation, voluntary outreach from covered entities or their TPAs, complaints from dispensing entities, or other mechanisms including the complaint process described in section 90.2.2 of this final guidance—that the Primary Manufacturer has not transmitted payment to make the MFP available within the 14-day prompt MFP payment window for Part D claims, CMS may issue the Primary Manufacturer a Notice of Potential Noncompliance, allowing 10 business days to respond with additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration consistent with the process outlined in section 100.1 of this final guidance. In the event CMS determines the Primary Manufacturer is noncompliant with the requirement to effectuate the MFP, CMS may pursue CMPs as set forth in section 100.1 of this final guidance.

90.2.1 Manufacturer Plans for Effectuating MFP

Consistent with section 40.4 of this final guidance, the Primary Manufacturer may make MFP available, including to 340B covered entities and their contract pharmacies consistent with section 40.4.5 of this final guidance, by: (1) using retrospective reimbursement to issue refunds to dispensing entities as required to ensure the MFP is made available to dispensing entities; (2) prospectively ensuring that the price paid by the dispensing entity or Part B provider when acquiring the drug is no greater than the MFP; or (3) using some combination of these two approaches.

CMS is not at this time including detailed information on the requirements of the MFP Effectuation Plan for selected drugs payable under Part B, and, unless otherwise specified, the policies in section 90.2.1 of this final guidance apply only to Part D at this time. However, CMS intends to align the policies for Part B with the policies for Part D discussed in this section of the draft guidance to the extent appropriate and feasible.

Starting with initial price applicability year 2027, CMS will split the MFP Effectuation Plan into two sections, with the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they anticipate having material cashflow concerns at the start of the initial price applicability year, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM, required to be submitted via the MTF DM by June 1 of the calendar year before the MFP goes into effect, and the remainder of the information in the MFP Effectuation Plan due September 1 of the calendar year before the MFP goes into effect. This approach is intended to allow CMS time to evaluate information on the MFP Effectuation Plan that will most directly impact dispensing entities and conduct outreach if important information,

as discussed throughout this section, is missing, while also allowing Primary Manufacturers time to finalize plans for making the MFP available. This update does not impact MFP Effectuation Plans for initial price applicability year 2026, which, as established in the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, are due in writing to CMS at least four months before the start of the first initial price applicability year for the selected drug.

To provide a clear, concise method of collecting the requested information, CMS included an MFP Effectuation Plan form in the Medicare Transaction Facilitator for Initial Price Applicability Year 2026 and 2027 ICR, published for a 60-day public comment in Fall 2024, and for a 30-day public comment period in Spring 2025; CMS published the final ICR in the Federal Register on May 9, 2025. If needed, CMS intends to publish a revised version of this ICR to address any evolving data collection needs for initial price applicability year 2028. CMS developed a standardized method of data collection to promote the Primary Manufacturer's development of a robust plan for making MFP available within the MTF DM that can be populated by a Primary Manufacturer during its enrollment and subsequently updated as needed.

For selected drugs with a first initial price applicability year of 2026, CMS required in the revised guidance for initial price applicability year 2026 that a Primary Manufacturer of a selected drug send its plan for ensuring MFP availability to CMS in writing by December 2, 2025; however, CMS revised this deadline to September 1, 2025 in the final guidance for initial price applicability year 2027 and manufacturer effectuation of the maximum fair price in 2026 and 2027. For selected drugs with a first initial price applicability year of 2027, sections of the plan related to the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they expect to experience cash flow concerns, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM will be due by June 1, 2026, with the remainder of the plan due by September 1, 2026. Likewise, for selected drugs with a first initial price applicability year of 2028, the initial sections of the plan will be due by June 1, 2027, and the remainder of the plan will be due by September 1, 2027. Upon receiving the plans for making MFP available from Primary Manufacturers, CMS will conduct a risk assessment for each submission using risk assessment criteria consistent with the requirements set forth in section 40.4 of this final guidance. Primary Manufacturers with plans that CMS identifies as having a greater risk of failing to make the MFP consistently available will be subject to increased scrutiny through CMS' monitoring and oversight activities. CMS intends to allow dispensing entities to access these plans through the MTF user interface and will redact proprietary information in those plans. In addition, CMS may release these redacted plans to other applicable stakeholders (e.g., supply chain entities) upon request.

A Primary Manufacturer must notify CMS in writing of any changes to its MFP Effectuation Plan as soon as practicable, regardless of whether the notice is provided before a selected drug's first initial price applicability year or thereafter, and subject to the terms, if applicable, of a signed MTF DM User Agreement. If the Primary Manufacturer of a selected drug with a first initial price applicability year of 2026 is also the Primary Manufacturer of a selected drug with a first initial price applicability year of 2027, then the Primary Manufacturer is not required to submit a new written plan to make MFP available for the selected drug with a first initial price

applicability year of 2027 by September 1, 2026. Instead, the Primary Manufacturer may amend its previously submitted plan for the selected drug with a first initial price applicability year of 2026 to include the newly selected drug, as long as the Primary Manufacturer aligns the amendment with the new due dates for different sections of the plan established in the preceding paragraph. That is, any amendments to sections of the plan related to the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they expect to experience material cash flow concerns, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM will be due by June 1, 2026, with any amendments to the remainder of the plan due by September 1, 2026.

A Primary Manufacturer may update its MTF account information over time using functionality available in the MTF DM user interface. For any changes to general enrollment information (e.g., points of contact), the Primary Manufacturer must notify CMS of any change to its MTF enrollment information no later than 30 calendar days following the change taking effect by updating the information in the MTF DM. In circumstances where a Primary Manufacturer has elected to use the MTF PM, the Primary Manufacturer may update its bank account and financial information at any time; however, the MTF will require up to a 30-day transition period from the date the Primary Manufacturer submits the updated information during which the MTF will continue operating with the previous information while integrating and testing the updated information into system operations to facilitate a successful transition in payment processing. The Primary Manufacturer must maintain availability of the off-boarding bank account, with sufficient funds to process MFP refunds, for the full duration of the 30-day transition period. A Primary Manufacturer may also elect to terminate use of the voluntary passing of payments through the MTF PM at any time after submission of its MFP Effectuation Plan, but must provide notice at least 90 calendar days before withdrawing from MTF PM participation, and must provide a revised MFP Effectuation Plan containing its alternative method for making MFP available. Conversely, a Primary Manufacturer may amend its plan to begin voluntarily passing payments through the MTF PM at any time, though it may take up to 30 calendar days following the Primary Manufacturers election to use the MTF PM and submission of banking information for the Primary Manufacturer to begin utilizing the MTF PM during which time the Primary Manufacturer must continue making MFP available using their previous approach without the MTF PM.

The contents of the Primary Manufacturers' plans are, in part, related to their decisions pertaining to participation in the MTF PM. While the plans will require baseline information from all Primary Manufacturers as part of their participation in the MTF DM, those that choose not to use the MTF PM, or choose to establish alternative reimbursement mechanisms, will be required to provide additional details on their approach for effectuating the MFP. A Primary Manufacturer that chooses not to use the MTF PM or that chooses to establish alternative reimbursement mechanisms must also provide a detailed plan for internal auditing to ensure all transactions effectuate MFP in compliance with this guidance and Negotiation Program requirements. The remainder of this section details the content requirements for the MFP Effectuation Plans.

All Primary Manufacturers' plans must include description(s) of the types of documentation and data they anticipate collecting, maintaining, and delivering to CMS, if requested, for the purposes of auditing and compliance with the requirement to make the MFP available. Each Primary Manufacturer's MFP Effectuation Plan will also need to indicate its general plan and procedures for contacting and receiving communications from dispensing entities. CMS understands that the Primary Manufacturer and dispensing entities may pursue alternative methods of MFP effectuation outside of retrospective reimbursements (e.g., prospective purchase agreements), and having a clear communication method between the parties may facilitate such arrangements. In addition, CMS encourages Primary Manufacturers and dispensing entities to work together to resolve potential issues related to payments (e.g., insufficient refund amount, late payments, etc.) prior to using the complaint and dispute process set forth in section 90.2.2 of this final guidance. Further, each Primary Manufacturer's plan shall include details of its process for deduplicating 340B covered units (pursuant to section 1193(d) of the Act and section 40.4.5 of this final guidance) for the selected drug. Further, beginning with initial price applicability year 2027, if a Primary Manufacturer intends to utilize the SDRA, at least in some cases, for effectuating the MFP, the Primary Manufacturer's MFP Effectuation Plan must also include information about the Primary Manufacturer's approach for calculating MFP refund amounts, if applicable, for MFP-eligible claims in the rare cases where the MTF DM will not provide the Primary Manufacturer a calculated SDRA, as discussed in section 40.4.1 of this final guidance. Primary Manufacturers are encouraged to include this information in the Primary Manufacturer's MFP Effectuation Plan for initial price applicability year 2026, as feasible.

As discussed in section 40.4.2.2 of this final guidance, CMS will allow dispensing entities to identify themselves as anticipating material cashflow concerns at the start of a price applicability period with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. In its MFP Effectuation Plan, a Primary Manufacturer must include a process for mitigating material cashflow concerns for dispensing entities. For Primary Manufacturers' consideration in developing their mitigation processes, CMS will make the list of the self-identified dispensing entities available to Primary Manufacturers in the MTF DM prior to Primary Manufacturers' submission of MFP Effectuation Plans for 2026, 2027, and 2028, and will provide updates to the list on an ongoing basis as other dispensing entities enroll in the MTF DM and self-identify as anticipating having material cashflow concerns or as dispensing entities update their self-identification over time. Primary Manufacturers will not need to update their MFP Effectuation Plans in response to updates to the list of dispensing entities who have self-identified as anticipating having material cashflow concerns. CMS views sharing this list as informational but recognizes a Primary Manufacturer may establish its own eligibility criteria for determining which dispensing entities are included in its mitigation approach; any such eligibility criteria should be outlined in the Primary Manufacturer's mitigation process. Examples of processes to mitigate material cashflow concerns for identified dispensing entities may include, but are not limited to, prospective purchasing agreements or accelerated MFP refund timelines. CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP Effectuation Plan. As stated earlier in this section 90.2.1, Primary Manufacturers with plans that CMS identifies as having a greater risk of failing to make the MFP consistently available will be subject to increased scrutiny through CMS' monitoring and oversight activities. If a Primary Manufacturer makes a

material change to its eligibility criteria or its mitigation approach, then it would be required to update its MFP Effectuation Plan with the changes and submit it to CMS as soon as practicable, and in any event, within 90 days of the change.

As discussed in sections 40.4.3 and 40.4.4 of this final guidance, a Primary Manufacturer's MFP Effectuation Plan must indicate whether it will participate in the MTF PM. If a Primary Manufacturer chooses to use the MTF PM, then the MFP Effectuation Plan will indicate this decision, and the Primary Manufacturer will acknowledge that it understands and will meet the participation requirements set forth in section 40.4.3 of this final guidance and any applicable participation agreements. If the Primary Manufacturer elects to participate in the MTF PM as its payment method, then no alternative plan to effectuate payment of MFP refunds is required. As a result of this election, and the Primary Manufacturer's timely submission of its applicable claim-level payment elements identified in section 40.4.3 of this final guidance, the MTF PM will maintain a ledger system of credits and debits, provide the ERA and electronic transfers to dispensing entities that receive electronic transfer of funds through the MTF PM, and provide the remittance and paper checks to dispensing entities that receive MFP refunds through the MTF PM via paper check. A Primary Manufacturer's decision to participate in the MTF PM does not preclude it from negotiating separate agreements with dispensing entities to provide access to the MFP outside of the MTF PM; however, the Primary Manufacturer is required to ensure that its MFP Effectuation Plan's description of these alternative arrangements is kept up-to-date, including through submission of updates, and is consistent with the requirements described below. Similarly, a dispensing entity is free to approach a Primary Manufacturer with a request to create an alternative arrangement separate from the Primary Manufacturer's choice of MTF PM participation.

If a Primary Manufacturer declines to use the MTF PM, then it is required to provide, at a minimum, a functionally equivalent electronic reimbursement mechanism to that offered by the MTF PM. In addition, the Primary Manufacturer will be responsible for ensuring that paper checks are provided as a reimbursement mechanism for dispensing entities that do not wish to be reimbursed electronically. As discussed in section 40.4.2 of this final guidance, the MTF DM will include the preferred payment method for the dispensing entity among the claim-level data elements transmitted to the Primary Manufacturer. The Primary Manufacturer is required to provide the electronic reimbursement mechanism for dispensing entities that have indicated their preference to receive electronic transfer of funds and the paper check reimbursement mechanism for dispensing entities that have indicated their preference to receive payment via paper check. The Primary Manufacturer's electronic and paper check payment facilitation methods will be assessed for their consistency with the requirements set forth in sections 40.4 through 40.4.5 of this final guidance. CMS requires that the Primary Manufacturer's MFP Effectuation Plan would include, at a minimum, information regarding its plan to meet the 14-day prompt MFP payment window for transmitting payment of an amount that provides access to the MFP, its policies and procedures for determining the methodology it will use to calculate the amount of each reimbursement due to the dispensing entity (e.g., when the Primary Manufacturer will use the applicable dispensing entity's actual acquisition cost or a standardized pricing metric, such as WAC, to calculate the MFP refund amount), confirmation that it will use a GAAP system that can be audited, and confirmation that it will submit verification of reimbursement to the MTF via the report of claim-level payment elements discussed in sections 40.4.3 and 40.4.4 of this final

guidance, as required for purposes of administering and monitoring compliance with the Negotiation Program consistent with section 1193(a)(5) of the Act. In addition, the Primary Manufacturer must describe its method of reconciling over- or under-payments arising from situations such as adjusted or updated claim information (e.g., 340B, reversals, revisions, etc.); and must provide information about their processes for creating and making available remittances for each payment made to dispensing entities (remittances for electronic payments must use the X12 835 standard adopted under HIPAA). If a Primary Manufacturer elects to operate its own system to account for this information, it must provide information regarding its method of maintaining a comprehensive, GAAP-compliant system.

There are other specific examples of criteria CMS has identified as important to make MFP available and that a Primary Manufacturer should consider including in its electronic and paper check payment facilitation methods if: (1) it chooses not to participate in the MTF PM; or (2) has, or plans to have, alternative arrangement with certain dispensing entities even if the Primary Manufacturer will ordinarily use the MTF PM to pass through MFP refund payments to dispensing entities. These examples include, but are not limited to, a Primary Manufacturer's data transmission method to return its Table 6 data to the MTF DM, frequency of returning its Table 6 data to the MTF DM, payment method, procedures for making payment of MFP refunds, calculation of refund amounts for reimbursements not consistent with the SDRA, and 340B nonduplication method. In addition, this includes information on a Primary Manufacturer's plans for meeting the 14-day prompt MFP payment window, as well as the specifics of how a Primary Manufacturer will work with Secondary Manufacturers to ensure the MFP will be passed through by Secondary Manufacturers for selected drugs dispensed to MFP-eligible individuals.

If a Primary Manufacturer and dispensing entity maintain a separate reimbursement or purchasing arrangement that changes after the submission of the plan and exists outside of the MTF PM (e.g., prospectively purchased units), then the Primary Manufacturer must update the MFP Effectuation Plan within 90 days of the creation of the new or updated unique arrangement. If a Primary Manufacturer fails to provide an updated MFP Effectuation Plan within the 90-day period, the Primary Manufacturer may be considered out of compliance with the terms of its Agreement. In such cases, the Primary Manufacturer should notify CMS as soon as possible to enable CMS to coordinate with the Primary Manufacturer regarding necessary updates to its plan.

Consistent with the standard business practices of each dispensing entity, dispensing entities should review their accounts receivable and determine whether a Primary Manufacturer has paid all the claims the dispensing entity believes are MFP-eligible claims, in the amounts the dispensing entity believes are sufficient to effectuate the MFP. Further, dispensing entities should understand that alternative arrangements made with a Primary Manufacturer outside of the MTF PM are private contracts between the Primary Manufacturer and the dispensing entity; thus, any disputes arising under or related to such private contracts may be subject to various laws and should be resolved between the parties. However, dispensing entities may use the complaint and dispute process described in section 90.2.2 of this final guidance to raise any identified issues with the MFP refund payment amount or suspicion that MFP has not been made available. Both Primary Manufacturers and dispensing entities should maintain documentation of their

communications and agreements and CMS may request this documentation as part of the complaint and dispute process set forth in section 90.2.2 of this final guidance.

In accordance with its oversight responsibilities under section 1196(b) of the Act, CMS will monitor for compliance, and will audit as needed, to ensure that the Primary Manufacturer is complying with the terms of its Agreement and that the MFP is being made available for the selected drug. A Primary Manufacturer must retain for at least 10 years from the date of sale any records relating to sales of the selected drug to wholesalers and entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensing entities for Part D. By submitting its MFP Effectuation Plan, the Primary Manufacturer acknowledges it will use the processes outlined in the plan to effectuate MFP consistent with the statute. A Primary Manufacturer's MFP Effectuation Plan describing its plan to ensure MFP availability is considered in effect until it is superseded by the submission of a new MFP Effectuation Plan, or is considered terminated because the submitting entity is no longer the Primary Manufacturer of a selected drug (e.g., a drug is removed from the selected drug list, divestiture, etc.), subject to the requirements of section 40.4 of this final guidance. A Primary Manufacturer may submit a new MFP Effectuation Plan at any time and, in conjunction with this submission, must also provide CMS with a summary of the changes contained in its updated plan.

90.2.2 Centralized Intake System for Complaints and Disputes Related to MFP Availability and MTF Functionality

In accordance with sections 1196(a)(3)(A) and 1196(b) of the Act, which require in part that the Secretary establish procedures to carry out the Negotiation Program with respect to MFP-eligible individuals and monitor compliance with the terms of the Agreement, CMS will establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and the pharmacies, mail order services, and other dispensing entities that provide drugs to MFP-eligible individuals. This system is intended to address complaints and disputes related to MFP availability and MTF functionality and is not intended to receive general comments or feedback related to the implementation of the Negotiation Program as a whole. Any issues unrelated to MFP availability and MTF functionality will be directed to the appropriate review mechanism. This intake system will include an avenue to report difficulty using, or errors related to, MTF data and/or payment system functionality. Further, the complaints process described in this section and referenced in this final guidance will be available to parties notwithstanding their degree of participation in any aspect of the MTF. The complaint and dispute submission form will be available to complete and submit on a web-based portal for Primary Manufacturers, dispensing entities, and other relevant stakeholders (e.g., beneficiaries); these stakeholders will also be able to submit a complaint via a toll-free telephone number. At this time, CMS is not including detailed information on the complaints and disputes process for selected drugs payable under Part B but intends to align the policies for Part B with the policies for Part D discussed in this section of the final guidance to the extent appropriate and feasible. Unless otherwise specified, these policies only apply to Part D at this time for 2028.

Complaints and disputes must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute. Upon receipt of a reported issue, a threshold review will be completed, including a review to ensure, among other factors, that the issue is

timely, contains supporting documentation or an explanation as to why supporting documentation is not available, and contains enough information on the face of the submission for CMS to move forward with the triage process, and to identify the appropriate track, either as a complaint or dispute, as described below. Once the issue has been identified as either a complaint or dispute, it will be triaged and prioritized, taking into account market factors, including but not limited to the monetary value and/or the number of claims at issue; and the extent to which the price made available to the dispensing entity appears to differ from the MFP, among other factors. This prioritization is to ensure CMS is reviewing all submissions systematically and in appropriate order considering the potential impact on the dispensing entity, Primary Manufacturer or other stakeholder submitting the issue. For example, a complaint that includes substantial financial ramifications to either the dispensing entity or the Primary Manufacturer will be prioritized for review, investigation, and resolution compared to complaints with lesser financial impact. CMS is committed to reviewing all submitted issues in a timely and efficient manner; prioritization will allow CMS to identify and address the most urgent concerns. After a complaint or dispute is triaged, as part of the investigation, CMS may reach out to impacted parties, as appropriate, to request additional information or documentation as needed. CMS intends to include more information about the operationalization of the complaint and dispute processes in future technical instruction. While the MTF may be involved in facilitating the resolution of complaints and disputes related to its data exchange and payment facilitation functions as discussed below, under no circumstance will the MTF determine whether the Primary Manufacturer has provided access to the MFP or otherwise met its obligations under the Negotiation Program. Complaints that present evidence of potential noncompliance will be referred to CMS so they can be effectively and timely remediated.

The complaint and dispute process will be set up with two “tracks” within one overall system. The first track is a dispute functionality within the MTF for qualifying disputes from Primary Manufacturers or dispensing entities, and, beginning in 2028, Part B providers regarding a technical aspect of the MTF process. The second track is a complaint process that will intake complaints and will be available to the public as well as Primary Manufacturers and dispensing entities, and, beginning in 2028, Part B providers regardless of their degree of participation in any aspect of the MTF and will encompass any issues that do not qualify as disputes under the definition set forth below.

Under the Negotiation Program, CMS considers a dispute to be a specific, identifiable challenge to a technical aspect of the MTF and process (e.g., claims included as potentially requiring an MFP refund). CMS will evaluate disputes and issue findings as appropriate based on available relevant factual information. This category of review will apply to circumstances such as a Primary Manufacturer suggesting an error in its MTF claims data or dispensing entities suggesting an error in the calculation of the SDRA. The disputing party will need to submit evidence supporting its position when making the report. To resolve disputes, CMS will consider information from the party submitting the dispute as well as any other relevant or underlying information and issue a finding resolving the dispute (either favorably or unfavorably) based upon the facts and data present for the particular situation.

The initiation of a dispute on a claim does not negate the Primary Manufacturer’s statutory responsibility to make the MFP available to the dispensing entity for an MFP-eligible claim

subject to a dispute. Nor does initiating a dispute affect the Primary Manufacturer's obligation to transmit the claim-level payment elements for such claim within the 14-day prompt MFP payment window, including the manufacturer-determined MFP refund amount (if any) and the appropriate transaction code. As is the case for any claim, whether it is under dispute or not, the Primary Manufacturer may make individual determinations about whether an MFP refund is appropriate, and, if so, the amount of the MFP refund, to effectuate the MFP. If the Primary Manufacturer provides an MFP refund on a claim for which there is a dispute, and the dispute results in an updated amount required to make the MFP available, the Primary Manufacturer can use the manufacturer-initiated adjustment processes described in section 40.4.3.2 of this final guidance, for Primary Manufacturers utilizing the MTF PM, and resubmit a previously processed claim based on new information (i.e., the outcome of a dispute in this circumstance); a manufacturer-initiated adjustment should include the Transaction Code indicating that the claim-level payment elements are being sent independent of claim-level data elements received by the MTF DM to adjust claim-level payment elements previously sent by the Primary Manufacturer. Primary Manufacturers who elect not to use the MTF PM can utilize the method they have established for handling changes to payment amounts, as discussed in section 40.4.4.4 of this final guidance; and then complete the manufacturer-initiated adjustment in the MTF DM, utilizing the Transaction Code described in section 40.4.3.2 of this final guidance, as this Transaction Code is available to all Primary Manufacturers, regardless of whether they utilize the MTF PM or not.

CMS will also collect complaints. Under the Negotiation Program, CMS considers a complaint as any issue brought forward by an individual or entity that does not fall under the above definition of dispute; this covers a wide range of concerns from a broad range of interested parties. Below, CMS has provided two examples of types of complaints; however, CMS understands that the types of complaints likely to be received would not be limited to the examples below.

One type of complaint may include operational issues with the MTF originating from MTF users participating in the MTF DM or the MTF PM. For this type of complaint, CMS will provide (through a CMS contractor(s)) help desk support to resolve these types of issues promptly to ensure that the system operates smoothly. The MTF help desk will be accessible to quickly provide answers to Primary Manufacturers and dispensing entities regarding daily operations of the MTF.

A second type of complaint may include reports that the MFP was not made available, including instances where a dispensing entity expresses concern that they have not received a timely retrospective refund payment that effectuates the MFP or that the Primary Manufacturer did not transmit payment within the 14-day prompt payment window. This may also include instances where an agreed-upon MFP after renegotiation is not made available. This type of complaint could also originate from manufacturers, beneficiaries, or other interested parties, and should include supporting documentation, such as an open accounts receivable demonstrating that the Primary Manufacturer did not provide access to a price for the selected drug that is equal to or less than the MFP. Dispensing entities and Primary Manufacturers may also use the complaint process if they have a concern regarding the credit/debit ledger system established in section 40.4.3 of this final guidance. Before submitting a complaint to CMS, CMS encourages

dispensing entities and Primary Manufacturers to work together in good faith to resolve any issues regarding MFP availability. Contact information for dispensing entities and/or Primary Manufacturers will be made available to facilitate these efforts. Proof of any efforts to resolve the issue should be submitted once the complaint is filed. If, as a result of these efforts, the Primary Manufacturer determines that an additional MFP refund amount is needed to make the MFP available to the dispensing entity, the Primary Manufacturer can follow the process for submitting revised claim-level payment elements in section 40.4.3.2 of this final guidance, or a method for handling changes to payment amounts outside of the MTF PM, depending on whether or not the initial payment was made through the MTF PM. All complaints submitted will receive a response from CMS explaining the next steps that CMS may take.

Complaints related to a lack of MFP availability may not always require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability. Investigations may lead to enforcement action, as described in section 100 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this final guidance, as applicable, or audits. In response to a complaint, CMS may request supplemental information from the complainant or other relevant parties for purposes of conducting an investigation and may allow parties opportunities to respond and submit evidence. One example of supplemental information CMS may request is documentation related to the Primary Manufacturer's attempts to make the MFP available. CMS intends to respond as quickly and efficiently as practicable to address concern(s) raised in a complaint or dispute and seeks to gain more practical experience implementing the complaint and dispute process before establishing further timelines.

CMS intends to track complaints and disputes over time to monitor overall trends, including those related to entities other than Primary Manufacturers and dispensing entities and emerging compliance issues, and to make process improvements in the implementation of the complaint and dispute process as applicable.

90.3 26 U.S.C. Section 5000D Excise Tax on Sale of Designated Drugs

The IRS is responsible for administering and enforcing the excise tax, not CMS. The Department of the Treasury has established regulations that govern the administration of the excise tax.[181]

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar

If CMS determines that either:

1. a potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028 because any strength or dosage form of the potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic drugs or biosimilars that CMS determined are

[181] See Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507, available at https://www.federalregister.gov/documents/2024/07/05/2024-14706/excise-tax-on-designated-drugs-procedural-requirements; See also: Notice 2023-52, Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax, available at https://www.irs.gov/pub/irs-drop/n-23-52.pdf. Revenue Procedure 2025-9, available at https://www.irs.gov/pub/irs-drop/rp-25-09.pdf. Excise Tax on Designated Drugs; Notice of Proposed Rulemaking, available at https://www.federalregister.gov/documents/2025/01/02/2024-31462/excise-tax-on-designated-drugs.

approved or licensed and marketed based on the process described in section 30.1 of this final guidance; or

2. a selected drug is no longer subject to the negotiation process and ceases to be a selected drug because (a) 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 (b) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure in accordance with section 1192(c) of the Act and under the process described in sections 60.7 and 70 of this final guidance, then CMS will monitor, after such an above determination is made, whether meaningful competition continues to exist in the market by ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing. Such monitoring by CMS may include, but is not limited to, whether the generic drug or 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 a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar.

CMS is aware that marketing or other agreements between the Primary Manufacturer and generic drug or biosimilar manufacturers may limit the availability of the generic drug or biosimilar for purchase through the pharmaceutical supply chain, and CMS will attempt to identify when such agreements exist as a factor in determining whether bona fide marketing exists, although such agreements would not by themselves be dispositive of that determination. CMS notes that any agreements limiting the availability of a generic drug or biosimilar may be subject to scrutiny and potential enforcement under antitrust laws (including laws prohibiting unfair methods of competition) as well as laws prohibiting unfair or deceptive acts or practices in or affecting commerce.

In addition, CMS will analyze the share of generic drug or biosimilar units identified in PDE data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the generic drug or biosimilar as part of their AMP reporting responsibilities under section 1927(b)(3)(A) of the Act, and the trend in reporting of such AMP units. CMS reserves the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar, for example, but not limited to, the sources included in section 70 of this final guidance.

100. Civil Monetary Penalties

In accordance with section 1197 of the Act, Primary Manufacturers of selected drugs that enter into an Agreement may be subject to CMPs for: (1) failure to ensure access to a price that is less than or equal to the MFP, as described in section 40.4 of this guidance, for MFP-eligible individuals and pharmacies, mail order services, and other dispensing entities and to hospital, physicians or other providers of services or suppliers that dispense, furnish or administer the selected drug with respect to MFP-eligible individuals; (2) failure to pay the rebate amount for a biological product for which inclusion 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 Agreement; and (4) the provision of false information as described in section 1197(d) of the Act.

CMS' primary goal is to successfully administer all aspects of the Negotiation Program; 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. Such instances may include, but are not limited to, the examples shown in Table 10 below, such as failure to make the MFP available to MFP-eligible individuals; 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 Agreement or other Negotiation Program requirements; or egregious and/or knowing violations of Negotiation Program requirements. Note that these examples are not an exhaustive list of violations that could warrant CMPs. CMS reserves the authority to issue CMPs for other violations as required to effectively administer and monitor the Negotiation Program.

Table 10: Examples of Substantive Violations

Category	Example of Substantive Violations
Violations of the Agreement	• Failure to submit data required under section 1194(e)(1) of the Act, including failure to engage in requested corrective action to mitigate such failures. • Omission or inaccuracy of manufacturer-submitted information that is critical to the negotiation and/or renegotiation processes (e.g., non-FAMP data from the Primary Manufacturer, including non-FAMP data for a selected drug sold by any Secondary Manufacturer(s), required for ceiling calculation) or other efforts to administer or monitor the Negotiation Program (e.g., reporting new NDC-11s, information requested during an audit), including failure to engage in requested corrective action to mitigate such omissions or inaccuracies. • Failure to meet the MTF reporting requirements (see section 40.4) within the 14-day prompt MFP payment window. • Failure to enroll in the MTF DM (see section 40.4.2). • Failure to submit a plan for making the MFP available (see section 90.2.1). • Submission of false information that interferes with the negotiation process (e.g., submission of false data on unit costs of production or research and development costs). • Knowing submission of false information to CMS for use in applying the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception. • Knowing provision of false information to CMS for use in applying the aggregation rule in section 1192(f)(1)(C) of the Act of the Biosimilar Delay. • Failure to provide information requested by CMS in accordance with CMS' oversight responsibilities under section 1196(b) of the Act. • Failure to provide information required as part of the renegotiation process (see section 130.3)

Category	Example of Substantive Violations
MFP Availability	• Failure to make the MFP available to MFP-eligible individuals, and to pharmacies, mail order services, or other dispensing entities, and, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, hospitals, physicians and other provider of services and suppliers (see section 100.1). • Failure to process timely and complete reimbursement under a retrospective reimbursement structure (see section 40.4).
Biosimilar Delay Rebates	• Failure to pay a biosimilar delay rebate by the deadline established by CMS in future rulemaking.

Broadly, CMS is establishing 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 statutory timeframes.

This final guidance addresses violations by a Primary Manufacturer for failure to ensure access to a price for a selected drug less than or equal to the MFP, violation of terms of the Agreement, and provision of false information as related to the aggregation rule for the SBE and the Biosimilar Delay. CMS provides details about the process for CMP imposition in section 100.5 of this final guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP in 2026, 2027, and 2028

In accordance with section 1197(a) of the Act, CMS may impose a CMP on a Primary Manufacturer of a selected drug that has entered into an Agreement with CMS upon failure to provide access to a price that is less than or equal to the MFP to MFP-eligible individuals dispensed the selected drug and to dispensing entities, or, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, Part B providers with respect to MFP-eligible individuals who are furnished or administered the selected drug. This includes failure to provide access to a price that is less than or equal to the MFP in connection with sales of the selected drug by a Secondary Manufacturer.

As described in section 40.4 of this final guidance, a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity and, starting in 2028 as applicable, the Part B provider when acquiring the drug, is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's, and starting in 2028 as applicable, the Part B provider's, acquisition cost and the MFP. Although CMP liability may be imposed if a Primary Manufacturer fails to provide such access to the MFP, the statute does not obligate a Primary Manufacturer to make sales of selected drugs. Upon discovery and confirmation of a failure to make the MFP available, CMS

intends to send the Primary Manufacturer a Notification of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS intends to establish a process in which the Primary Manufacturer will have 10 business days to respond to the Notice of Potential Noncompliance to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration. CMS intends to consider the materials provided by the Primary Manufacturer when determining the Primary Manufacturer's CMP liability, including any technical failures outside the control of the Primary Manufacturer related to the transmission of payment.

If the Primary Manufacturer fails to ensure access to a price less than or equal to the MFP, the statute provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed, furnished, or administered (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals or dispensing entities and, beginning in 2028 as applicable, Part B providers that dispense, furnish, or administer the selected drug with respect to MFP-eligible individuals, and the MFP for such drug for such year. For the purposes of calculating this CMP in instances where CMS has determined that a Primary Manufacturer failed to make MFP available to a dispensing entity, CMS will engage in the assessment described above in section 90.2 of this final guidance to determine the price made available to the dispensing entity and the difference between such price and the MFP. As discussed in section 90.2 of this final guidance, CMS is not at this time including detailed policy on monitoring access to the MFP for drugs payable under Part B but intends to align the policies for Part B with the policies for Part D discussed in section 90.2 of this final guidance to the extent appropriate and feasible. As described in sections 40.5 and 90.2 of this final guidance, CMS will monitor for compliance and audit, as needed, to ensure that the MFP or a price lower than the MFP is being made available for the selected drug.

In an instance where an updated MFP is reached through renegotiation as described in section 130 of this final guidance, CMS may impose a CMP if the Primary Manufacturer fails to make the renegotiated MFP available in accordance with sections 40.4 and 130 of this final guidance. The calculation for this CMP would follow the same formula established above, i.e., a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed, furnished, or administered (during such year) and the difference between the price for such drug made available to the MFP-eligible individual, the dispensing entity or Part B provider and the renegotiated MFP for such drug for such year.

100.2 Violations of the Agreement

Pursuant to section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS under section 1193 of the Act 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 pursuant to section 1193(a)(5) of the Act or fails to provide the information required under section 1193(a)(4) of the Act, including data required to carry out the renegotiation process (see section 130.3 of this final guidance), may be subject to a statutorily-specified CMP for each day of such violation. The amount of $1,059,232 a day is applicable for any CMP that may be assessed under this provision in 2025 and will be updated yearly per the Federal Civil Penalties Inflation

Adjustments Improvements Act of 2015.[182] In applying CMPs for Primary Manufacturer violations of the Agreement, CMS intends to use discretion such that CMPs are reserved for instances of substantive noncompliance.

One example of when CMS may impose a CMP is 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 section 50.1.1 of this final guidance) for each NDC-11 of the selected drug for the applicable period, by March 1, 2026 for initial price applicability year 2028. In this example, when the Primary Manufacturer failed to submit timely non-FAMP, CMS would engage in outreach that would include a Request for Corrective Action Plan to address the failure and a Violation Notice. If the issue is not mitigated following this outreach and corrective action process, CMS may choose to assess a CMP. In a case where a CMP is pursued, CMS intends to send a written CMP Notification that reflects the number of days in which the Primary Manufacturer is in violation of the Agreement, which may initiate on the day after the applicable submission deadline (e.g., March 2, 2026) depending on the manufacturer's engagement in corrective action. The CMP will accrue for each day of the violation thereafter until the day the Primary Manufacturer demonstrates compliance and provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. The CMP will not include the day that information is submitted by the Primary Manufacturer. In the event the Primary Manufacturer never provides the required information, the daily CMP will continue to accrue until the end of the negotiation period (i.e., the final deadline for reaching an agreed-upon MFP). Upon reaching that deadline, certain sales of the selected drug may be subject to a potential excise tax as the result of the Primary Manufacturer failing to reach an agreed-upon MFP (see 26 U.S.C. § 5000D(b)(2)). CMS plans 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 (see section 130 of this final guidance) 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 end of the renegotiation process (i.e., the final deadline for reaching an agreed upon renegotiated MFP). Upon reaching that deadline, certain sales of the selected drug may be subject to a potential excise tax as the result of the Primary Manufacturer failing to reach an agreed-upon renegotiated MFP (see 26 U.S.C. § 5000D(b)(3)). 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 and may be assessed a CMP under section 100.1 of this final guidance for failure to do so, until a renegotiated MFP takes effect.

[182] This CMP amount, set forth in the statute as $1,000,000 is updated to reflect required annual inflation-adjusted increases to civil money penalty amounts under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of P.L. 114-74) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (P.L. 401-410, 104 Stat 890 (1990)), which is intended to improve the effectiveness of civil monetary penalties (CMPs) and to maintain the deterrent effect of such penalties, requires agencies to adjust the CMPs for inflation annually. In accordance with the Office of Management and Budget (OMB) Memorandum for the Heads of Executive Agencies and Departments, M-25-02, "Implementation of Penalty Inflation Adjustments for 2025, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015," the cost of living multiplier for 2025 is 1.02598.

Another example of when CMS may impose a CMP for violation of the Agreement is if the Primary Manufacturer submits information that is required under the Agreement and CMS determines the information is false. In this example, the Primary Manufacturer will 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 Agreement, CMS intends to determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the established deadline for submission of information under the Agreement as the first day of violation, with each additional day of violation thereafter counted until the day the Primary Manufacturer provides a complete and accurate submission of the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. 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 section 100.5 of this final guidance.

100.3 Provision of False Information Related to the SBE and the Biosimilar Delay

In accordance with section 1197(d) of the Act, if CMS determines that any manufacturer knowingly provides false information to CMS for use in applying the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception, such manufacturer may be subject to a statutorily-specified CMP for each item of such false information. Likewise, if CMS determines that any Biosimilar Manufacturer knowingly provides false information to CMS for use in applying the aggregation rule in section 1192(f)(1)(C) of the Act for the Biosimilar Delay, such manufacturer may be subject to a statutorily-specified CMP for each item of such false information. The amount of $105,923,201 per item is applicable for any CMP assessed in 2025 and will be updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.[183]

CMS adopts a standard for "knowingly" that conforms with the Office of Inspector General definition at 42 C.F.R. § 1003.110 in the application of other CMPs. Knowingly means that a manufacturer, for purposes of section 1197(d) of the Act for the Small Biotech Exception or a Biosimilar Manufacturer under section 1192(f)(1)(c) of the Act for the Biosimilar Delay: (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 either of these provisions, CMS intends to provide the Manufacturer with a CMP Notification detailing the final CMP amount and the basis for that amount, requesting payment, outlining the payment process, outlining the available appeals process, and establishing applicable deadlines for resolution.

100.4 Failure to Pay a Biosimilar Delay Rebate

Where a Manufacturer, pursuant to section 1192(f)(4) of the Act and section 30.3.1.5 of this final guidance, owes a rebate to CMS on the basis of a biological product for which inclusion on the selected drug list was delayed and with respect to which the biosimilar product that was the subject of the successful Initial Delay Request or Additional Delay Request has failed to be

[183] The CMP amount authorized by section 1197(d) of the Act is set forth in the statute as $100,000,000 and is updated to reflect required annual inflation-adjusted increases to civil money penalty amounts under the Federal Civil Penalties Inflation Adjustments Act Improvements Act of 2015.

licensed or marketed, and the Manufacturer fails to pay the rebate by the deadline, to be established by CMS in future rulemaking, in accordance with section 1197(b) of the Act, the Manufacturer may be subject to a CMP equal to 10 times the amount of the rebate the Manufacturer failed to pay. When CMS makes a determination to assess a CMP under this section of the Act, CMS intends to follow the procedures established in section 100.5 of this final guidance.

100.5 Notice and Appeal Procedures

Where CMS makes a determination to assess a CMP, CMS intends to provide a written CMP Notification that the manufacturer has engaged in a substantive compliance violation and is subject to a CMP. As required by section 1128A of the Act, the CMP Notification will 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;
- Instructions for submitting the CMP payment;
- The Primary Manufacturer's right to a hearing (see below); and
- Information about where to file the request for a hearing.

In the case of violations associated with CMPs with daily accruals (e.g., failure to provide required information as described in section 100.2 of this final guidance), CMS intends to send the CMP Notification after the noncompliance has ended in order to reflect both the start date, end date, and total amount of penalty assessed within the notice as required by section 1128A of the Act.

Per section 1128A of the Act, CMPs are due 60 calendar days after the receipt of the CMP Notification, unless the Primary Manufacturer chooses to initiate an appeal. At the conclusion of any appeal process initiated by the Primary Manufacturer, where there is still a CMP amount owed, the CMP is due within 60 calendar days of the appeal decision. CMS intends to send a reminder notice to the Primary Manufacturer, including the date the penalty is due and will restate the instructions for submitting the CMP payment.

To operationalize the CMP appeal process in the Negotiation Program, CMS is adopting the existing procedures as codified in C.F.R. Part 423 Subpart T: Appeal Procedures for Civil Money Penalties (see § 423.1000 through § 423.1094) that currently apply to Part D sponsors and to manufacturers under the Manufacturer Discount Program. Pursuant to this appeals process, the manufacturer will have 60 calendar days from the date of receipt of the CMP Notification to request a hearing (§ 423.1020). The date of receipt is defined as the calendar day following the day on which the CMP Notification is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by 42 C.F.R. Part 423 Subpart T will 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 will be deposited in accordance with section 1128A(f) of the Act.

110. Part D Formulary Inclusion of Selected Drugs

In accordance with section 1860D-4(b)(3)(I) of the Act, and except as permitted under section 1860D-4(b)(3)(I)(ii) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies during contract year 2026, if an MFP is in effect for that drug with respect to that year, and during each subsequent year for which the MFP of the selected drug is in effect during the price applicability period. Section 1860D-4(b)(3)(I)(ii) of the Act specifies that nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation).[184]

For contract year 2028, CMS will continue the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 and final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 (described further below in this section). At this time, CMS does not have sufficient information to determine whether changes to these formulary inclusion policies are warranted. The formulary inclusion requirement in section 1860D-4(b)(3)(I) of the Act has not taken effect yet, and plan sponsors did not submit their formularies for the first contract year in which MFPs are in effect (i.e., contract year 2026) until June 2, 2025. In light of the substantial time required for CMS to complete the formulary review process and analyze the impacts of the formulary inclusion requirement, information is not yet available to inform whether changes to formulary inclusion policies are warranted. For these reasons, CMS will continue monitoring Medicare Part D plans' compliance with all applicable formulary requirements and treatment of drugs and may further address formulary inclusion policies in the future.

Because the selected drug includes all dosage forms and strengths to which the MFP applies for initial price applicability year 2028, the statute 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. For contract year 2028, CMS will not implement explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies but will apply the process described below.

CMS understands that not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics Committees with the same formulary considerations and the same formulary placement might not be warranted in all situations. However, CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.

CMS reminds Part D sponsors of the 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 sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and

[184] See section 110.1 of this final guidance for additional detail related to the identification of the successor regulation to § 423.120(b)(5)(iv) for purposes of the exception to the formulary inclusion requirement for selected drugs in section 1860D-4(b)(3)(I)(ii) of the Act.

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) states: "CMS does 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." In addition, § 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.

Given CMS' statutory obligation to monitor Medicare Part D plans' compliance with all applicable formulary requirements, CMS will use its formulary review process to assess: (1) any instances where Part D 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 sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (e.g., step therapy and/or prior authorization) for a selected drug compared to a non-selected brand drug in the same class.

For this review, CMS will consider class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action. Specifically, as part of the contract year 2028 Part D formulary review and approval process, CMS will expect Part D sponsors to provide a reasonable justification to support the submitted plan benefit design and formulary design that includes any of the practices noted above 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 (e.g., 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 will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D sponsor only if the plan benefit design and formulary design complies with those requirements.

CMS 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, i.e., in the contract year prior to the selected drug's MFP taking effect. While CMS did not see this occur in contract year 2025 with respect to selected drugs for initial price applicability year

2026, CMS will continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year (e.g., contract years 2026, 2027, 2028, and each additional year in the selected drug's price applicability period, if an MFP is in place with respect to that year).

110.1 Formulary Inclusion Exception Successor Regulation for 2027 and 2028

Section 1860D-4(b)(3)(I)(ii) of the Act specifies that nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) (or any successor regulation). As described in the Final CY 2026 Part D Redesign Program Instructions, issued on April 7, 2025, CMS identified § 423.120(e)(2)(i), and the corresponding notice requirements at § 423.120(f)(2), (3), and (4), as the successor regulation.[185] Under § 423.120(e)(2)(i), Part D sponsors may, as an immediate substitution, remove a selected drug from the formulary and replace it with a new generic or interchangeable biological product of the selected drug if such sponsor meets the regulatory notice and timing requirements. Specifically, any such substitution of a selected drug would be subject to the timing requirements specified in § 423.120(e)(2)(i) and notice requirements specified in § 423.120(f)(2), (3), and (4). CMS herein incorporates section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extend the policies therein to 2027 and 2028.

Section 70 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, and this final guidance specify that, in accordance with section 1192(c)(1) of the Act, 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 the statutory criteria in section 1192(c) of the Act are met. For example, CMS stated in the revised guidance for initial price applicability year 2026 that if CMS makes this determination between April 1, 2026 and March 31, 2027 for a drug selected for initial price applicability year 2026, then the selected drug will cease to be a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027.

As CMS stated in the Final CY 2026 Part D Redesign Program Instructions, a Part D sponsor is permitted to remove the selected drug from its formulary for the remainder of 2026, if such removal meets the requirements specified in § 423.120(e)(2)(i) and the notice requirements specified in § 423.120(f)(2), (3), and (4). Additionally, in accordance with section 1192(c) of the Act and section 70 of the revised guidance for initial price applicability year 2026, CMS may make a determination with respect to such selected drug that the statutory criteria in section 1192(c) of the Act have been met. For the purposes of this example, if such a determination were made between April 1, 2026 and December 31, 2026, then the MFP for such selected drug would continue to apply through 2027. CMS is clarifying here that removals under the formulary inclusion exception cannot be carried over to subsequent years within the price applicability

[185] See Final CY 2026 Part D Redesign Program Instructions (April 7, 2025), available at https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf. CMS notes that prior to finalizing this policy, CMS voluntarily solicited public comment through the Draft CY 2026 Part D Redesign Program Instructions, issued on January 10, 2025, available at https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf.

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. For example, removal in accordance with section 1860D-4(b)(3)(I)(ii) of the Act of the selected drug in its price applicability period from a formulary could apply to 2026 and 2027 plan years if the requirements under § 423.120(e)(2)(i) and § 423.120(f)(2), (3), and (4) permitting immediate substitutions are met with respect to both 2026 and 2027.

120. Application of Medicare Part B and Part D Drug Inflation Rebate Programs to Selected Drugs

This section of the guidance describes the application of Medicare Part B and Part D drug inflation rebates to selected drugs. As background, section 11101 of the IRA added a new section 1847A(i) to the Act to require that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Likewise, section 11102 of the IRA added a new section 1860D-14B to the Act, which 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.[186]

The Medicare Part B and Part D Drug Inflation Rebate Programs apply to selected drugs, regardless of the status of the drug as a selected drug. Alternatively said, 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 Programs, as applicable. 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 discussed further below.

The Medicare Part B Drug Inflation Rebate Program is applicable to certain drugs that meet the definition of a Part B rebatable drug and are furnished or administered under Part B and paid under Part B for each calendar quarter, starting with the applicable calendar quarter beginning January 1, 2023. These rebates are paid by manufacturers to the Federal Supplementary Medical Insurance Trust Fund.

The Part B drug inflation rebate calculation is based on changes in the lower of ASP or WAC over time.[187]

The statutory formula to determine the Part B drug inflation rebate amount owed by manufacturers for each Part B rebatable drug consists of various components, including the calculation of an "inflation-adjusted payment amount." The inflation-adjusted payment amount for a Part B rebatable drug for an applicable calendar quarter is calculated by dividing the rebate period CPI-U by the benchmark period CPI-U and multiplying the quotient by the payment

[186] See: https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other.
[187] The calculation of the Part B rebate amount is codified at 42 C.F.R. § 427.301.

amount in the payment amount benchmark quarter. The "payment amount in the payment amount benchmark quarter" is calculated based on the published payment limit for the billing and payment code in the "payment amount benchmark quarter" for each Part B rebatable drug as established at section 1847A(i)(3)(D) of the Act for drugs first approved or licensed on or before December 1, 2020, and at section 1847A(i)(4)(A) of the Act for drugs first approved or licensed after December 1, 2020. The "benchmark period CPI-U" for a Part B rebatable drug is established at section 1847A(i)(3)(E) of the Act for drugs first approved or licensed on or before December 1, 2020, and at section 1847A(i)(4)(A) for drugs first approved or licensed after December 1, 2020. These definitions are codified at 42 C.F.R. § 427.20.

For each applicable calendar quarter before a Part B rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part B drug inflation rebate amount (which may equal $0) based on the Part B rebatable drug's payment amount benchmark quarter and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, the statute at section 1847A(i)(4)(C) of the Act specifies a different "payment amount benchmark quarter" and a "benchmark period CPI-U" for each Part B rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part B rebatable drug is no longer a selected drug, the payment amount benchmark quarter is reset as the calendar quarter beginning January 1 of the last year during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the July of the year preceding such last year beginning during such price applicability period. Identification of the payment amount benchmark quarter and identification of the benchmark period CPI-U are codified at 42 C.F.R. § 427.302(c) and (e), respectively.

The Medicare Part D Drug Inflation Rebate Program is applicable to certain drugs that meet the definition of a Part D rebatable drug and are dispensed under Part D and covered by Part D plan sponsors for each 12-month applicable period, starting with the applicable period beginning October 1, 2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

The Part D drug inflation rebate calculation is based on changes in the AMP over time.[188] MFP is excluded from AMP and thus does not affect the rebate calculation.[189]

The statutory formula to determine the Part D drug inflation rebate amount owed by manufacturers for each Part D rebatable drug consists of various components, including the calculation of an "inflation-adjusted payment amount." The inflation-adjusted payment amount for a Part D rebatable drug for an applicable period is the benchmark period manufacturer price of the drug increased by the percentage by which the applicable period CPI-U exceeds the

[188] Section 1860D-14B(g)(6) of the Act defines AMP to have the meaning, with respect to a Part D rebatable drug of a manufacturer, given in section 1927(k)(1) with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Section 1927(k)(1) defines AMP, with respect to a covered outpatient drug of a manufacturer for a rebate period, to mean the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail community pharmacies, and (ii) retail community pharmacies that purchase directly from the manufacturer, subject to certain exclusions.

[189] Section 1927(k)(1)(B)(i)(VI), as amended by section 11001(b)(3) of the IRA.

benchmark period CPI-U. The "benchmark period manufacturer price" is calculated based on a weighted AMP for the quarters in the "payment amount benchmark period" for each Part D rebatable drug and is established at section 1860D-14B(g)(3) of the Act for drugs first approved or licensed on or before October 1, 2021, and at section 1860D-14B(b)(5)(A) of the Act for drugs first approved or licensed after October 1, 2021. The "benchmark period CPI-U" for a Part D rebatable drug is established at section 1860D-14B(g)(4) of the Act for drugs first approved or licensed on or before October 1, 2021, and at section 1860D-14B(b)(5)(A) of the Act for drugs first approved or licensed after October 1, 2021. These definitions are codified at 42 C.F.R. § 428.20.

For each applicable period before a Part D rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part D drug inflation rebate amount (which may equal $0) based on the Part D rebatable drug's payment amount benchmark period and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, section 1860D-14B(b)(5)(C) of the Act specifies a different payment amount benchmark period and benchmark period CPI-U for a Part D rebatable drug in the case where such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period will be reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U will be the January of the last year beginning during such price applicability period. Identification of the payment amount benchmark period and identification of the benchmark period CPI-U are codified at 42 C.F.R. §§ 428.202(c) and (e), respectively.

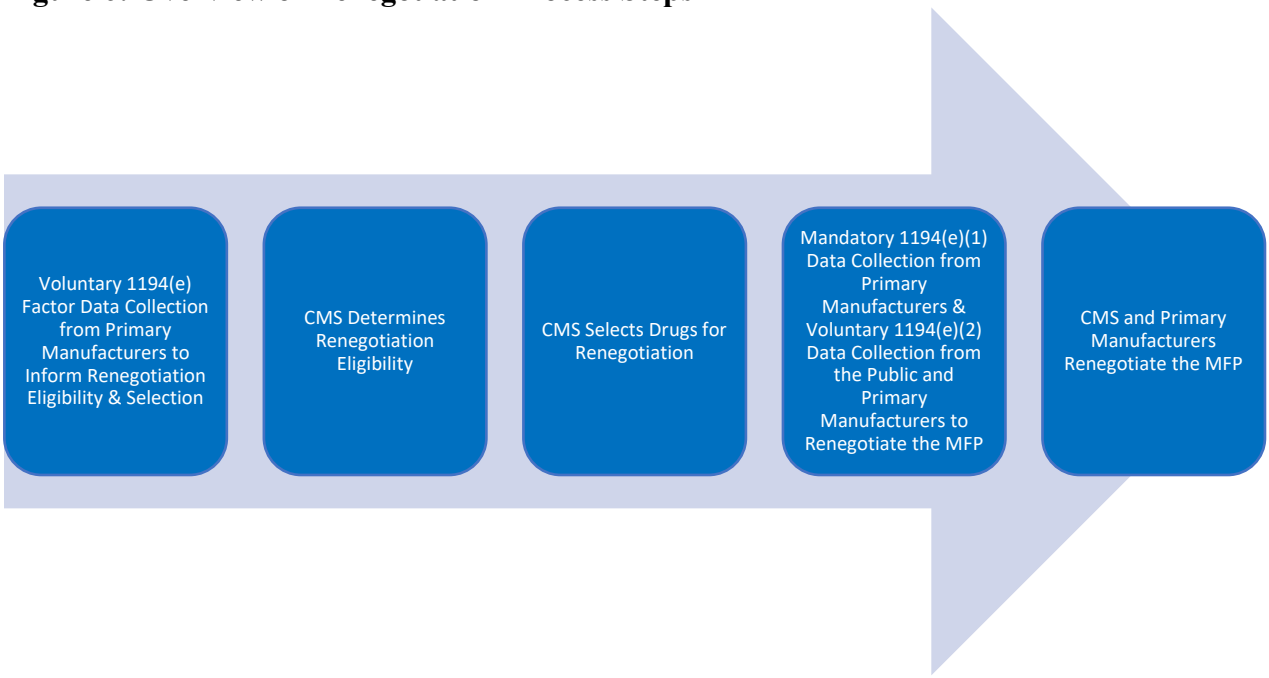
130. Renegotiation of a Maximum Fair Price for Initial Price Applicability Year 2028

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. CMS will identify renegotiation-eligible drugs in accordance with section 1194(f)(2) of the Act, as described in section 130.1 of this final guidance. Next, CMS will select certain renegotiation-eligible drugs for renegotiation in accordance with section 1194(f)(3) of the Act, as described in section 130.2 of this final guidance. Finally, CMS will renegotiate MFPs for such drugs selected for renegotiation, in accordance with section 1194(f)(4) of the Act, as described in section 130.4 of this final guidance. Figure 6 depicts an overview of this process. As described more fully in section 70 of this final guidance, section 1194(f)(5) of the Act clarifies that a renegotiation-eligible drug for which the Secretary makes a bona-fide marketing determination before or during the renegotiation period shall not be subject to the renegotiation process.

CMS notes that renegotiation is a component of the Negotiation Program. A Primary Manufacturer that has an Agreement in effect, as discussed in section 40 of this final guidance, will be required to adhere to the process and deadlines described in this section 130 of this final guidance as well as previous sections. For example, the policies described in sections 40.5, 90, and 100 of this final guidance are applicable to renegotiation. The renegotiation process will conclude with an agreed-upon MFP (the "renegotiated MFP"), unless the Primary Manufacturer chooses not to participate or chooses not to agree upon a new MFP. To meet their MFP

effectuation obligations, Primary Manufacturers must make the initial agreed-upon MFP available as set forth in section 40.4 of this final guidance, for all dispenses on or before December 31, 2027 (including based on any claim adjustments to previously processed claims); and Primary Manufacturers must make the renegotiated MFP available, if applicable, as set forth in section 40.4 of this final guidance, when their selected drug is dispensed, furnished, or administered to MFP-eligible individuals on or after January 1, 2028.

Figure 6: Overview of Renegotiation Process Steps



130.1 Identification of Renegotiation-Eligible Drugs for Initial Price Applicability Year 2028

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 1198(4) of the Act, there will be no administrative or judicial review of CMS' determinations 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.

In accordance with section 1194(f)(1) of the Act, CMS will review selected drugs from initial price applicability years 2026 and 2027 for renegotiation eligibility in initial price applicability year 2028. CMS interprets 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. Because calendar year 2028 will be a year within the price applicability period for drugs selected for initial price applicability years 2026 and 2027, such selected drugs may be eligible for renegotiation in calendar year 2026 (i.e., for initial price applicability year 2028) and may be

selected for renegotiation if certain criteria are met (as discussed in sections 130.1 and 130.2 of this final guidance). Renegotiation eligibility will be based on the four eligibility categories in section 1194(f)(2) of the Act and as described in sections 130.1.1 through 130.1.4 of this final guidance.

As a matter of operations, first, CMS will identify selected drugs which are renegotiation-eligible due to a change in monopoly status. Then, CMS will review the remaining selected drugs and identify those for which a new indication has been added. Next, CMS will review the remaining selected drugs (excluding those which are already eligible due to a change in monopoly status or the addition of a new indication) for a material change in any section 1194(e) factor. CMS' approach to a selected drug that becomes renegotiation-eligible more than once over multiple renegotiation cycles will be discussed in future rulemaking.

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. For purposes of initial price applicability year 2028, CMS does not expect Primary Manufacturers to provide access to the MFP of a selected drug negotiated for initial price applicability years 2026 or 2027 to Part B providers for Part B utilization with respect to a drug furnished or administered to MFP-eligible individuals and payable under Part B; rather selected drugs from initial price applicability years 2026 and 2027 with Part B utilization may be determined to be renegotiation-eligible drugs pursuant to section 1194(f)(2) of the Act and as discussed in this section 130.1 of the final guidance; may be selected for renegotiation, pursuant to section 1194(f)(3) of the Act and as discussed in section 130.2 of the draft guidance; and may have an agreed-upon renegotiated 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 will apply for initial price applicability year 2028 and will apply to claims payable under Part B and dispenses covered under Part D, as applicable. For drugs selected for renegotiation for initial price applicability year 2028, any renegotiated MFP will apply to all formulations across dosage forms and strengths of the selected drug, which will 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.

130.1.1 Selected Drugs for Which There is a Change in Status to an Extended-Monopoly Drug
Section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030 from the definition of an "extended-monopoly drug."[190] CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for initial price applicability year 2028, and therefore no selected drug will have a monopoly status change to extended-monopoly for purposes of renegotiation-eligibility under section 1194(f)(2)(B) of the Act.

[190] Section 1194(c)(4)(A) of the Act defines an extended-monopoly drug, for an initial price applicability year, as "a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable," excluding vaccines licensed and marketed per section 351 of the PHS Act as described in section 1194(c)(4)(B) of the Act. See sections 30.1 and 60.2.3 of this final guidance for more information about extended-monopoly drugs.

130.1.2 Selected Drugs for Which There is a Change in Status to a Long-Monopoly Drug
Section 1194(c)(5) of the Act defines a long-monopoly drug as, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term "long-monopoly drug" does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section. To meet the definition of a long-monopoly drug for initial price applicability year 2028, the first approval date under section 505(c) of the FD&C Act or the earliest licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients)[191] must be on or before January 1, 2012 (see Table 7 in section 60.2.3 of this final guidance for more information on monopoly types). Therefore, in accordance with section 1194(f)(2)(C) of the Act, a selected drug that meets this definition and that did not qualify as a long-monopoly drug when the drug was selected for negotiation will be determined to be renegotiation-eligible due to a change in status to a long-monopoly drug.

130.1.3 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. For consistency with CMS' approach to identifying indications for selected drugs during the negotiation process (as described in section 60.3.1 and as further defined in Appendix A of this final guidance), CMS will consider an "indication" to be the condition or disease state that the selected drug treats.

As described in section 130.3.1 of this final guidance, CMS will 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[192] for a selected drug, CMS will use a number of sources including the Drugs@FDA database.[193] CMS will also review voluntary submissions from Primary Manufacturers. CMS will deem a drug 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.[194] Conversely,

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[191] As noted in section 30.1 of this final guidance, 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 biologics license applications (BLAs) under section 351 of the PHS Act, effective March 23, 2020, pursuant to section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (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.

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

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

[194] CMS clarifies that "new" in the renegotiation context means not considered in the negotiation process to achieve an agreed upon MFP. For example, in the event CMS previously considered an off-label use during negotiation because such off-label use was, at that time, included in evidence-based clinical practice guidelines and considered

CMS will not deem 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. This approach complements the requirement in section 1194(f)(2)(D) of the Act for CMS to consider any material change in a section 1194(e)(2) factor, which includes "prescribing information" (see section 1194(e)(2)(B) of the Act). As part of that inquiry, CMS will review the FDA-approved labeling for a material change in prescribing information per section 130.1.4 of this final guidance and, in doing so, would also capture the impact of labeling updates within a previously indicated disease or condition during such review (e.g., expansion of an existing indication to include an additional age group(s)). That is, labeling updates within a previously indicated disease or condition will not be regarded as a "new indication" for renegotiation eligibility under section 1194(f)(2)(A) of the Act, but will 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, as discussed in section 130.1.4 of this final guidance.

CMS will review off-label uses when identifying indications for renegotiation eligibility and selection if the Primary Manufacturer of a selected drug submits the off-label use through the voluntary information submission process. CMS will apply the standards outlined in section 60.3.1 of this final guidance when reviewing an off-label use submitted by a Primary Manufacturer for consideration as a new indication for the purpose of renegotiation eligibility. That is, CMS will only consider an off-label use when identifying indications for purpose of renegotiation eligibility under section 1194(f)(2)(A) of the Act 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 and/or accepted standards of medical practice. 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 is included in evidence-based clinical practice guidelines, and if 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, and/or accepted standards of medical practice. New off-label uses identified in a voluntary submission from a Primary Manufacturer for a selected drug within a previously indicated disease or condition will not be regarded as a "new indication" for renegotiation eligibility under section 1194(f)(2)(A) of the Act, but will 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, as discussed in section 130.1.4 of this final guidance.

To align with the voluntary information submission process and to ensure CMS has appropriate time to consider applicable data, the new indication must be added to the FDA-approved labeling for the selected drug on or before November 30, 2025 and any information voluntarily submitted on off-label use must be submitted by the same date (refer to section 130.3.1 of this final guidance for additional information regarding the Drug Selection ICR). CMS notes that the submission due date for the Drug Selection ICR is expected shortly after the end of the

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to be a medically-accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice, and then the Primary Manufacturer received FDA approval for that off-label use, CMS would not consider the now on-label use to be a new indication in accordance with section 1194(f)(2)(A) of the Act.

negotiation period for initial price applicability year 2027 selected drugs. Thus, it is unlikely a selected drug negotiated for initial price applicability year 2027 would have a new indication that had not been considered during negotiation by this date.

130.1.4 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."

CMS will 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 CMS' consideration of that factor within the context of renegotiation offers and counteroffers, including the initial offer, as compared with its consideration of that factor within the context of offers, including the initial offer and, if applicable, counteroffers, during the most recent prior negotiation process for the selected drug. CMS will review available information pertaining to section 1194(e) factors to determine if there is a material change. CMS will also consider voluntary submissions by a Primary Manufacturer of the information discussed in section 130.3.1 of this final guidance.

To align with the information collection reporting periods and to give CMS sufficient time to consider the applicable information to determine whether a change in a section 1194(e) factor is material, CMS will collect information on the applicable 1194(e)(1) factors from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through September 30, 2025 (with only a few exceptions related to, for example, the expansion of reportable R&D costs for initial price applicability period 2028). CMS will collect information on section 1194(e)(2) factors from the date of the initial agreed-upon MFP for the selected drug through November 30, 2025. As stated previously, CMS acknowledges that for initial price applicability year 2027 selected drugs, the time between the negotiation period and the deadline for submission of section 1194(e)(2) information for CMS' consideration is limited.

Table 11 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 for a selected drug with an agreed-upon MFP. CMS reiterates that these are illustrative examples and the potential results may vary in all cases depending on the fact patterns of a given drug.

Table 11: Illustrative Example Scenarios and Potential Result in Determination of Material Change

Example Scenario	Potential Result for Changes in 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 drug.	CMS determines that in this scenario that this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(C) in the context of offers and counteroffers. Therefore, this change may be considered a material change.

Example Scenario	Potential Result for Changes in 1194(e) Factor
Unit cost of production and distribution increases from $1.00 per unit to $1.50 per unit.	CMS determines that in this scenario this change would not likely meaningfully impact CMS' consideration of section 1194(e)(1)(B) 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 determines 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 determines that in this scenario the net impact of these changes would not meaningfully impact CMS' consideration of section 1194(e)(2)(C) in the context of offers and counteroffers. Therefore, these changes alone may not be considered a material change.

130.2 Selection of Drugs for Renegotiation for Initial Price Applicability Year 2028

Section 1194(f)(3) of the Act directs CMS to select drugs for renegotiation from the identified renegotiation-eligible drugs (described in section 130.1 of this final guidance). Sections 1194(f)(3)(A) and (B) of the Act require all drugs eligible for renegotiation due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug, as described in sections 130.1.1 and 130.1.2 of this final guidance, be selected for renegotiation. Section 1194(f)(3)(C) of the Act requires that among the remaining renegotiation-eligible drugs (i.e., 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 maximum fair price otherwise negotiated." As noted previously, CMS will publish the list of drugs selected for renegotiation, if any, not later than February 1, 2026, at the same time CMS publishes the list of up to 15 selected drugs for negotiation for initial price applicability year 2028 (described in section 30.4 of this final guidance). 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. Further, in accordance with section 1198(4) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1194(f)(3) of the Act.

This section describes how CMS will approach making a determination about whether renegotiation is likely to result in a significant change in the MFP otherwise negotiated.

130.2.1 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, CMS will select remaining renegotiation-eligible drugs (i.e., 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 CMS expects renegotiation is "likely to result in a significant change" in the MFP. This applies to renegotiation-eligible drugs that are not automatically selected for renegotiation due to a change in monopoly status.

To determine whether renegotiation is likely to result in a significant change in the MFP, CMS will consider two criteria, as discussed in greater detail below. CMS' review of these two criteria will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug. First, CMS will consider 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 upon engaging in renegotiation with the Primary Manufacturer. Second, CMS will consider whether such a change in the MFP for the renegotiation-eligible drug would have a significant impact on the Medicare Program. Importantly, CMS does not presume that the result of a renegotiation will reflect these approximations, rather, these criteria 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. CMS' review of these two criteria 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, and will support CMS' determination of whether renegotiation is likely to result in a significant change to the MFP for the renegotiation-eligible drug. The scope of information considered may extend beyond the scope of information reviewed for renegotiation eligibility to include a CMS-led review of the information sources discussed in section 50 of this final guidance pertaining to section 1194(e)(1) and section 1194(e)(2) factors.

CMS will consider both of these criteria when determining whether a renegotiation-eligible drug will be selected for renegotiation and believes 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. CMS believes that when considering drug selection for renegotiation from among renegotiation-eligible drugs, described above, such review will indicate that renegotiation is both likely to change the MFP and that the change in MFP will be significant, pursuant to section 1194(f)(3)(C) of the Act.

In establishing the first criterion (the likelihood that the new indication or material change would result in a renegotiated MFP, which would likely represent a 15 percent or greater change relative to the current MFP) CMS 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 section 60.2 of this final guidance).

Given that, under section 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 selection for renegotiation, CMS believes this range of percent change is informative for deciding when renegotiation is likely to result in a significant and large enough change to the MFP to warrant CMS and the Primary Manufacturer

investing the resources to renegotiate. For the first cycle of renegotiations for initial price applicability year 2028, CMS plans to select drugs for which renegotiation would likely result in a 15 percent or greater change in the MFP. This amount of change is consistent with the range of percent reductions in the ceiling that is statutorily defined for drugs selected for renegotiation due to monopoly status changes. Further, this criterion of considering the likelihood that the new indication or material change 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 can help provide clarity for interested parties and the public on when CMS may select remaining renegotiation-eligible drugs pursuant to section 1194(f)(3)(C) of the Act.

With regard to the second criterion for determining whether renegotiation is likely to result in a significant change in the MFP, CMS will consider the impact on the Medicare program of such a change in the renegotiated MFP. For example, if CMS determined 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, CMS 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, CMS seeks 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 percent change in the MFP would be greater than 15 percent. However, in this scenario patents on the selected drug will have expired before a renegotiated MFP would take effect, and CMS determines that this patent expiration will likely result in the introduction of robust generic competition. In this scenario, CMS believes 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, 2028, as it would no longer be single-source. As such, CMS 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.

CMS will 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 will include a preliminary review 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 also maintains consistency with CMS' process for developing the initial offer, which considers the totality of available evidence as described in section 60.3 of this final guidance.

CMS notes 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, CMS does not presume that the result of a renegotiation will reflect these approximations, for example, with

respect to the impact of a renegotiated MFP on the Medicare program. These criteria only 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.

Table 12 provides illustrative examples of how CMS may consider these criteria to determine whether a renegotiation-eligible drug will be selected.

Table 12: 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 (e.g., 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 (e.g., 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 (e.g., 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 section 130.4.1 of this final guidance for additional detail on the ceiling that will be used for renegotiation.

CMS also notes that renegotiation eligibility and selection will begin approximately 15 months after the end of the negotiation period for initial price applicability year 2026 selected drugs

(August 1, 2024) and immediately after the end of the negotiation period for initial price applicability year 2027 (November 2025).

130.2.2 Publication of List of Drugs Selected for Renegotiation
CMS will publish the list of drugs selected for renegotiation at the same time as the publication of the selected drug list for negotiation for initial price applicability year 2028, as described in section 30.4 of this final guidance.

130.3 Data Collection to Inform Renegotiation Drug Eligibility, Selection, and Renegotiation of the MFP for Initial Price Applicability Year 2028
In order for CMS to: determine which selected drugs are renegotiation-eligible drugs (in accordance with sections 1194(f)(1) and (2) of the Act as described in section 130.1 of this final guidance); select drugs for renegotiation (in accordance with section 1194(f)(3) of the Act as described in section 130.2 of this final guidance); and renegotiate the MFP of drugs selected for renegotiation (in accordance with section 1194(f)(4) of the Act as described in section 130.4 of this final guidance), CMS will collect certain data from Primary Manufacturers and other interested parties necessary in the renegotiation process as discussed in this section 130.3.

130.3.1 Voluntary Information Submission from Primary Manufacturers to Inform Renegotiation Drug Eligibility and Selection
Selected drugs with agreed-upon MFPs that have a change to long-monopoly status, as described in section 130.1.2 of this final guidance, will automatically be selected for renegotiation per section 1194(f)(3)(B) of the Act. Since the addition of a new indication or a material change in any section 1194(e) factor does not need to be considered for a monopoly status change, as described in section 130.1.2 of this final guidance, CMS does not need to collect or consider data related to the addition of a new indication or material change in a section 1194(e) factor prior to selection for renegotiation for these selected drugs.

Section 1194(f) of the Act does not require CMS to collect data from Primary Manufacturers to determine if a new indication has been added to the selected drug or if there has been a material change in any of the section 1194(e) factors. However, CMS believes that it may be helpful to permit submission of new information regarding the addition of a new indication to the selected drug or new information regarding the section 1194(e) factors prior to the CMS determination of renegotiation eligibility and selection. Therefore, CMS will collect a subset of new section 1194(e)(1) data as a voluntary submission from Primary Manufacturers of selected drugs that do not have a change to long-monopoly status, as described in section 130.1.2 of this final guidance, based on a structured and limited set of CMS-specified questions with data points and free response fields prior to determining renegotiation eligibility and selection. CMS includes instructions and questions for Primary Manufacturers to answer and submit via Box if they choose to do so via the Drug Selection ICR. The Drug Selection ICR includes a free response opportunity for Primary Manufacturers of a selected drug to also voluntarily provide new information about section 1194(e)(2) data for CMS' consideration for purposes of renegotiation eligibility and selection.

To provide CMS with the voluntary information, a Primary Manufacturer will need to email CMS via IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit the

information described in this section by the date and time to be specified by CMS upon approval from the Office of Management and Budget for this information collection. Primary Manufacturers are encouraged to use the email template included in the Drug Selection ICR. Once CMS receives notification of the Primary Manufacturer's intent to provide the information, CMS will respond by providing access to a Box[195] folder specific to the Primary Manufacturer. No parties other than the Primary Manufacturer and CMS and its contractors will have access to this folder. To voluntarily provide CMS with information prior to renegotiation eligibility determination and selection, the Primary Manufacturer must have uploaded its submission to the Box folder or used an alternative submission approach approved by CMS by the date and time to be specified by CMS upon approval from the Office of Management and Budget for the Drug Selection ICR. If a Primary Manufacturer is unable to use Box, it should include an explanation in its initial notification email to CMS and request an alternative submission method.

130.3.2 Data Collection from Primary Manufacturers and Other Interested Parties for Renegotiation

Once a renegotiation-eligible drug is selected for renegotiation, CMS will collect new information for all section 1194(e)(1) data elements from all Primary Manufacturers with a drug selected for renegotiation (in addition to any voluntary information provided for the process of selecting the drug for renegotiation as set forth in section 130.3.1 of this final guidance). This includes all drugs selected for renegotiation regardless of the basis for the drug's renegotiation eligibility or selection. CMS will collect the new section 1194(e)(1) factor data for renegotiation post-selection consistent with the submission process and submission due date used for negotiation and the Drug Price Negotiation ICR, which is described in sections 50 and 50.1 of this final guidance. The data collection for Primary Manufacturers will include NDC-11s of the selected drug that may be payable under Part B (if any) but are not covered under Part D, consistent with the collection of NDC-11s discussed in section 50.1 of this final guidance.

Section 40.2.1 of this final guidance applies to data submitted as part of the renegotiation process. If CMS believes the data provided by a Primary Manufacturer may be incomplete or inaccurate, CMS will follow the process established in section 40.2.3 of this final guidance to seek clarification from the Primary Manufacturer.

Additionally, once a renegotiation-eligible drug is selected for renegotiation, CMS will solicit new data for all section 1194(e)(2) factors from the Primary Manufacturer and other interested parties who choose to submit. This solicitation and collection of data will include all drugs selected for renegotiation regardless of the basis for the drug's renegotiation eligibility or selection. CMS will collect the new section 1194(e)(2) data for renegotiation post-selection consistent with the process used for negotiation and the Drug Price Negotiation ICR, which is described in sections 50 and 50.2 of this final guidance.

130.4 Renegotiation Process

As stated in section 1194(f)(4)(B) of the Act, CMS shall, to the extent practicable, establish a renegotiation process that is consistent with the negotiation process under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. Section 130.4.1 of this final

[195] If CMS specifies an alternative secure location to Box, CMS will provide updated instructions and information to Primary Manufacturers.

guidance describes how the ceiling will be calculated for renegotiation. The methodology for developing an initial offer for renegotiation is described in section 130.4.2 of this final guidance, and the renegotiation process is described in section 130.4.3 of this final guidance. Finally, plans for publication of the renegotiated MFP and an explanation of the renegotiated MFP are discussed in sections 130.4.4 and 130.4.5 of this final guidance, respectively.

130.4.1 Determining the Ceiling

Consistent with section 1194(b)(2)(F)(i) of the Act, in renegotiating the MFP of a selected drug, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling determined under section 1194(c) of the Act, and adjusted, if applicable, as described below. To determine the ceiling for renegotiation, CMS will maintain the underlying data that was used to calculate the amounts considered for the ceiling at the time of negotiation in accordance with section 1194(c) of the Act but will make the following adjustments to the calculations: (1) incorporate Part B data in accordance with sections 60.2.1, 60.2.2.3, and 60.2.3 of this final guidance, as applicable (i.e., for selected drugs for initial price applicability years 2026 and 2027 that are also payable under Part B and selected for renegotiation); (2) update the applicable percent applied to the average non-FAMP amount(s) to reflect the appropriate monopoly status with respect to the initial price applicability year for which an agreed-upon MFP after renegotiation will apply (i.e., initial price applicability year 2028), as applicable; and (3) adjust the amounts considered for the ceiling (i.e., the sum of the plan-specific enrollment amounts and the average non-FAMP amount) for inflation (percent increase in CPI-U as explained below).

Prior to adjusting the applicable percent applied to the average non-FAMP amount (as necessary) or adjusting for inflation as described below, CMS will update the amounts considered for the ceiling to incorporate NDC-11s that may be payable under Part B if a drug that was originally selected for initial price applicability year 2026 or 2027 (and so did not include such NDC-11s in its original ceiling calculations since such drugs were not considered negotiation-eligible drugs under section 1192(d)(1) of the Act) is selected for renegotiation and has such NDC-11s. Specifically, for selected drugs that are payable under Part B and that are paid based on section 1847A(b)(4) of the Act, CMS will:

- Calculate the payment amount under section 1847A(b)(4) of the Act using ASP/WAC and Part B data from the calendar year three years prior to the initial price applicability year of the MFP previously agreed upon (to mimic what the payment amount under section 1847A(b)(4) of the Act would have been if CMS had calculated it at the time of negotiation), as described in section 60.2.2.2 of this final guidance;
- Calculate the payment amount for the selected drugs covered under both Part D and Part B using ASP/WAC and Part B data from the calendar year three years prior to the initial price applicability year of the MFP previously agreed upon with the Part D data previously used to calculate the sum of the plan-specific enrollment weighted amounts at the time of negotiation, as described in 60.2.2.3 of this final guidance; and
- Calculate the average non-FAMP amount using the non-FAMP and Part B utilization data for calendar years 2021 (or the first full year following market entry of the selected drug) and 2024 (for initial price applicability year 2027 selected drugs) for NDC-11s of the selected drug that are not covered under Part D but may be payable under Part B with the non-FAMP and Part D utilization data previously used (or the non-FAMP amounts currently used, newly incorporating Part B utilization as well, for NDCs that are both

covered under Part D and payable under Part B) to calculate the average non-FAMP at the time of negotiation, as described in section 60.2.3 of this final guidance.

As stated in section 60.2.2.2 of this final guidance, for single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP), but are not covered under Part D (meaning CMS is unable to calculate the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount), CMS would default to the ceiling amount determined under section 1194(c)(1)(C)(ii) of the Act. That is, for selected drugs payable under Part B but not paid based on section 1847A(b)(4) of the Act, CMS would calculate the ceiling based on the applicable percent of average non-FAMP.

As stated in section 60.2.2.3 of this final guidance, for single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source drugs and biological products which are paid on the basis of 95 percent of AWP), and covered under Part D, CMS will calculate the ceiling amount based on the lower of the applicable percent of average non-FAMP, as outlined in section 60.2.2.2 of this final guidance and the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this final guidance.

In cases where a selected drug's monopoly status with respect to the initial price applicability year of the negotiated price is different than the selected drug's monopoly status with respect to the initial price applicability year to which a renegotiated price would apply, CMS will update the applicable percent in accordance with section 1194(f)(4)(B) of the Act which specifies that CMS should apply the applicable percentage described in section 1194(c)(3)(B) of the Act for purposes of calculating the non-FAMP ceiling under section 1194(c)(1)(C) for drugs selected for renegotiation due to a change to extended-monopoly status, and should apply the applicable percent under section 1194(c)(3)(C) for purposes of calculating the non-FAMP ceiling under section 1194(c)(1)(C) for drugs selected for renegotiation due to a change to long-monopoly status. The applicable percent applied to the average non-FAMP amount(s) is as follows:

- Short-monopoly drugs and vaccines (a selected drug other than a long-monopoly drug): 75 percent.
- Long-monopoly drugs (a selected drug for which, with respect to the initial price applicability year for which an agreed-upon MFP after renegotiation would apply, at least 16 years have elapsed since the date of approval of such drug under section 505(c) of the FD&C Act or since the date of licensure of such drug under section 351(a) of the PHS Act, as applicable[196]): 40 percent.

CMS will also increase the ceiling amounts by the percent increase in the CPI-U from July of the calendar year that is two years prior to the initial price applicability year of the most recent MFP to which CMS and the Primary Manufacturer has agreed 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)(3)(C) and 1195(b)(1)(A) of the Act. Under section 1195(b)(1)(A) of the

[196] The first approval date under section 505(c) of the FD&C Act or the earliest licensure date under section 351(a) of the PHS Act, as applicable, is the approval or licensure date as identified in section 30.1 of this final guidance.

Act, for each selected drug for which there was an MFP, for each year subsequent to the first initial price applicability year of the price applicability period, CMS will publish an updated MFP no later than November 30 of the year that is two years prior to such subsequent year which is the previous MFP 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, 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 in early 2026 for renegotiation for initial price applicability year 2028, CMS 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 2025. This increase represents the cumulative inflation adjustment that CMS 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, 2027, published in November 2025). If CMS did not similarly increase the amounts considered for the ceiling by the same inflation adjustment that CMS applies to the MFP under section 1195(b)(1)(A) of the Act, the inflation-adjusted MFP would, over time, approach and/or exceed the original ceiling amount. This could preclude CMS' ability to select for renegotiation, and renegotiate MFPs for, selected drugs for which CMS expects renegotiation would be likely to result in an increase in the MFP due to changes to factors listed in sections 1194(e)(1) and 1194(e)(2) of the Act. This 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 CMS expected renegotiation would be likely to result in an increased MFP.

130.4.2 Methodology for Developing an Initial Offer

In accordance with section 1194(f)(4)(B) of the Act, CMS shall, to the extent practicable, establish a renegotiation process that is consistent with the methodology and process established for negotiation under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. With respect to the methodology for developing an initial offer for the purpose of renegotiating an MFP for a selected drug, CMS will follow the process described in section 60.3 of this final guidance. CMS will: (1) identify a therapeutic alternative(s), if any, for the selected drug, as described in section 60.3.1 of this final guidance; (2) use the lowest of the following prices of a therapeutic alternative(s) covered under Part D to determine the starting point for developing the initial offer (described in section 60.3.2 of this final guidance): Net Part D Plan Payment and Beneficiary Liability, WAC, or the MFP; for a therapeutic alternative(s) payable under Part B, use the lower of ASP or WAC; and for a therapeutic alternative(s) that is both covered under Part D and payable under Part B, use an approach that combines the two lowest relevant prices to determine a starting point similar to the methodology described in section 60.2.2.3 of this final guidance; (3) 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, including but not limited to comparative effectiveness of the selected drug and therapeutic alternatives, including the selected drug's impact on specific populations, the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need, the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) and the cost of such therapeutic

alternative(s), and the prescribing information approved by the FDA for the selected drug and its therapeutic alternatives, as described in section 60.3.3 of this final guidance (resulting in the "preliminary price"); and (4) further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act (described in section 60.3.4 of this final guidance and collected in accordance with section 130.3.3 of this final guidance) to determine the initial offer price.

130.4.3 Renegotiation Process

In accordance with section 1194(f)(4)(B) of the Act, CMS intends, to the extent practicable, for the renegotiation process to 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 as set forth in section 60.4 of this final guidance. CMS 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.

If the Primary Manufacturer is delayed in meeting one or more deadlines, such as submitting the written counteroffer for renegotiation, CMS will continue to engage in the renegotiation process and will complete the established process as described in section 60.4 of this final guidance. During the period of time from when the Primary Manufacturer fails to meet a deadline until the date the Primary Manufacturer comes into compliance with the renegotiation process, CMS will consider the Primary Manufacturer in violation of the Agreement and the Primary Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act and as described in section 100 of this final guidance. 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)).

130.4.4 Publication of the MFP

For drugs for which there is agreement on a renegotiated MFP, CMS will publish and update the renegotiated MFP and related information in accordance with section 60.6 of this final guidance.

130.4.5 Explanation for the MFP

CMS will release a public explanation for each selected drug with a renegotiated MFP following the completion of the renegotiation process in accordance with section 60.6.1 of this final guidance and in accordance with the confidentiality policy described in sections 40.2.1 and 50.2 of this final guidance. CMS does not intend to include redacted information from any voluntary information submitted by a Primary Manufacturer to CMS in response to the Drug Selection ICR if the selected drug of the Primary Manufacturer is selected for renegotiation and there is an agreement for a renegotiated MFP, in accordance with section 130.3.1 of this final guidance. 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 in response to the Drug Price Negotiation ICR, in accordance with section 130.3.2 of this final guidance, CMS may redact and include information provided in response to the Drug Price Negotiation ICR in the MFP explanation of a renegotiated MFP in accordance with section 60.6.1 of this final guidance and in accordance with the confidentiality policy described in sections 40.2.1 and 50.2 of this final guidance

If an agreement for a renegotiated MFP is not reached for a drug selected for renegotiation by the same statutory deadline as the negotiation process, i.e., November 1, 2026, CMS will follow the procedures outlined in section 60.4.6 of this final guidance and the Primary Manufacturer may be subject to potential excise tax liability (see 26 U.S.C. § 5000D(b)(3)). Additionally, if there is no agreed-upon MFP then neither a renegotiated MFP nor a public explanation for the renegotiated MFP will be published. Instead, CMS will indicate on the CMS website that a renegotiated MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where a renegotiated MFP is finalized after the statutory deadline for the conclusion of negotiations, for which CMS is adopting the same statutory deadline as the negotiation process, i.e., November 1, 2026, the renegotiated MFP and the MFP explanation for the renegotiated MFP will be posted in accordance with section 60.8 of this final guidance.

Appendix A: Definitions for Purposes of Collecting Data for the Negotiation Program

For the purposes of describing the data at sections 1194(e)(1), 1194(e)(2), 1193(a)(4)(A), and 1194(f) of the Act to be collected for use in the Negotiation Program, as described in sections 40.2, 50.1, 50.2, and 130 of this final guidance, CMS will apply the following definitions and standards to the Drug Selection ICR and the Drug Price Negotiation ICR, and to this final guidance, for initial price applicability year 2028.[197] As described in sections 30.1.2 and 30.3.1 of this final guidance, CMS is publishing the Drug Selection ICR concurrent with the publication of this final guidance for a final, 30-day public comment period. Additionally, as described in section 50 of this final guidance, CMS published the Drug Price Negotiation ICR for a 60-day public comment period, which closed in late Summer 2025, and CMS intends to publish a revised version of the Drug Price Negotiation ICR for a final, 30-day public comment period in Fall 2025. The Drug Price Negotiation ICR includes instructions on how Primary Manufacturers and members of the public may submit relevant data for initial price applicability year 2028, including the optional data described in this Appendix (relating to Evidence About Alternative Treatments).

General

- When calculating and reporting monetary values, do not adjust for cost of capital.

Selected Drug Information

- Average Manufacturer Price (AMP) unit: The unit type, as reported monthly by the manufacturer, used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, or microcurie.
- Drug sample: A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug (Section 503(c)(1) of the Federal Food, Drug, and Cosmetics Act).
- Labeler code: The first segment of the FDA-assigned NDC (21 C.F.R. § 207.33(b)(1)(i)). Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under 21 C.F.R. Part 207 must apply for an NDC labeler code (21 C.F.R. § 207.33(c)(1)).
- Private label distributor: With respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed (21 C.F.R. § 207.1).
- Total AMP Units per Package: The total number of AMP units per NDC-11 package size.
- Total NCPDP Units per Package: The total number of NCPDP units per NDC-11 package size.

[197] CMS includes instructions specifying the applicable reporting period for data under the Drug Selection ICR and Drug Price Negotiation ICR within the instructions for the applicable ICR.

Non-FAMP

- Non-FAMP: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) for the four calendar quarters of the year involved.[198] For initial price applicability year 2028, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and 2025 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2026). When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such 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, the Primary Manufacturer should submit 2021 data—to the extent that it exists—for all NDC-11s of the selected drug. For a given NDC-11 of such drug, when there are at least 30 days of commercial sales 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 2025, the non-FAMP reported by the Primary Manufacturer to CMS 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.[199] Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.
- Non-FAMP package: Non-FAMP package is the package unit as described in 38 U.S.C. § 8126(h)(6) and represents the NDC-11 package (e.g., for an NDC-11 that represents a bottle of 30 tablets, the non-FAMP package would be the bottle; for an NDC-11 that represents a single dose vial containing 25 mg/mL, the non-FAMP package would be the vial).

Research and Development (R&D) Costs

R&D costs is defined as a combination of costs incurred by the Primary Manufacturer of a drug falling into two categories: (1) Costs Related to the Selected Drug, Including Basic Pre-Clinical Research of the Selected Drug, Post-Investigational New Drug (IND) Costs of the Selected Drug, and Other Allowable Costs and (2) Costs for Failed and Abandoned Products Related to the Selected Drug.

- Basic pre-clinical research costs are defined as the sum of (1) direct research expenses; and (2) the appropriate proportion of indirect research

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[198] The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account— (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount. 38 U.S.C. § 8126(h)(5).

[199] See: https://www.va.gov/opal/docs/nac/fss/pl102585-2025-pbm-fcp-guidance-for-new-covered-drugs.pdf. Archived Dear Manufacturer Letters from the VA are available at: https://www.va.gov/opal/nac/fss/publicLaw.asp.

expenses (defined below).
    - Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (monetary and non-monetary compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
    - Indirect basic pre-clinical research costs and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological products.
- Post-IND costs are defined as direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials. Post-IND costs also include direct costs associated with completed FDA-required, postmarketing trials that are conducted after the FDA has approved a product.
    - Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel (compensation for investigators and staff) researching the selected drug, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials. Direct post-IND costs also include personnel, patient recruitment, and per-patient costs, research and data collection costs, and facility costs that are directly related to conducting the completed FDA-required, postmarketing trial.
        - Personnel, patient recruitment, and per-patient costs include monetary and non-monetary compensation. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided.
- Other allowable costs for costs related to the selected drug are defined as direct costs associated with conducting FDA-required postmarketing trials and other FDA post-marketing requirements and commitments that were not completed, Phase IV postmarketing studies, direct post-IND costs (following the definitions and instructions for calculating direct post-IND costs above), direct costs associated with researching and utilizing devices for the selected drug, direct costs to support or satisfy a postmarketing requirement or commitment, and direct costs for patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting Phase IV and postmarketing trials.

- Failed or abandoned product costs are defined as the sum of (1) direct *basic pre-clinical research* costs on drugs with the same mechanism of action as the selected drug that did not make it to clinical trials and (2) direct *post-IND costs* for drugs with the same mechanism of action as the selected drug that did not receive FDA approval.

CMS is including both the global and U.S. net revenue for the selected drug in its consideration of the extent to which the Primary Manufacturer has recouped R&D costs.

- Recoupment: Global and U.S. Net Revenue for the Selected Drug.
  - Global net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
  - U.S. net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

Current Unit Costs of Production and Distribution

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (e.g., capsule or tablet, milligram of molecules, grams, international units) of the drug or biological product that is dispensed, furnished, or administered.
  - Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS).[200] The three NCPDP Billing Unit Standards (BUS) are: each (EA), milliliter (mL), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Costs of <u>production</u> are defined as all (direct and allocation of indirect) costs related to:
  - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
  - Formulation and preparation of the finished drug product;
  - Quality control and testing of the drug; and
  - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of <u>distribution</u> are defined as all (direct and allocation of indirect) costs related to:
  - Packaging and packaging materials;

[200] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

    - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
    - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
    - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:
    - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
    - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
    - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third-party vendors (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
    - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug do not include:
    - R&D costs;
    - Marketing costs; and
    - Transfer prices.
- "Marketing costs" are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, including providing free products to health professionals or patients, and other paid promotion.
- "Transfer prices" are defined as prices charged for goods, services, or other intangible assets in transactions between two members of the same controlled group of the Primary Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property. For the purposes of the definition of transfer prices, "controlled group" of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of the Treasury regulations thereunder.

Prior Federal Financial Support

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of office/laboratory space or equipment), and any other funds provided by the

federal government that support discovery, research, and/or development related to the selected drug.
- Prior Federal financial support includes the manufacturer's reasonable estimate of the dollar value of in-kind contributions and Cooperative Research and Development Agreements (CRADAs) that do not have a readily ascertainable value.
- Direct prior federal financial support costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of the selected drug.

Patents, Exclusivities, and Approvals
- CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
    - All patents issued by the United States Patent and Trademark Office (USPTO), both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents relevant to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
- Patents and patent applications relevant to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book;[201] patents that claim the drug product (e.g., the final product taken by or administered to a patient), drug substance (active ingredient) or other chemicals related to the active ingredient of a selected drug (e.g., crystalline forms, polymorphs, salts, metabolites, or intermediates); patents that claim a formulation of the drug; method-of-use patents (e.g., patents that claim an indication or use of the drug for treating a particular disease); process patents (e.g., patents that claim technologies and method(s) of manufacturing the drug); device patents (e.g., patents that claim the device used to administer the selected drug); and design patents (e.g., patents that claim a design on the packaging of the selected drug).
- Relevant patents and patent applications do not include patent applications that were denied by the USPTO.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays on the submission or approval of applications for competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[202]
    - New Chemical Entity Exclusivity (NCE);[203]

[201] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.
[202] Section 527 of the FD&C Act.
[203] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.

  - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[204]
  - New Clinical Investigation Exclusivity (NCI);[205]
  - Pediatric Exclusivity (PED);[206] and
  - Reference Product Exclusivity for Biological Products.[207]
- Active and pending FDA applications and approvals include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided.

Market Data and Revenue and Sales Volume Data

- Wholesale Acquisition Cost (WAC) unit price: 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.
- The three NCPDP BUS[208] are: each (EA), milliliter (mL), and gram (GM). For certain volume data of the selected drug, CMS will request units be reported using the NCPDP BUS for all but Medicaid best price to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Average sales price (ASP): The manufacturer's average sales price is defined in 42 C.F.R. § 414.902.
- ASP Unit: The unit type used by the manufacturer to report ASP as specified in 42 C.F.R. § 414.802.
- Medicaid best price: The Medicaid best price is defined in 42 C.F.R. § 447.505. The Medicaid best price is reported at the NDC-9 level.
- AMP unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Federal supply schedule (FSS) price: The price offered by the VA in its FSS program, by delegated authority of the General Services Administration.[209] The FSS price is reported at the NDC-11 level.

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[204] Section 505E(a) of the FD&C Act.
[205] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[206] Section 505A(b) & (c) of the FD&C Act.
[207] Section 351(k)(7) of the PHS Act.
[208] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.
[209] See: https://department.va.gov/administrations-and-offices/acquisition-logistics-and-construction/freedom-of-information-act-requests/#toc_Historical_VA_Pharmaceutical_Prices.

- Big Four price: The Big Four price is described in 38 U.S.C. § 8126.[210] The Big Four price is reported at the NDC-11 level.
- Manufacturer U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for private health insurance plans, including small group and individual plans on- and off-Exchange and large group plans, excluding Medicare fee-for-service (Part A and Part B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The following items should be deducted from gross revenue in your calculation: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The following items should not be deducted from gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price is reported at the NDC-11 level.
- Manufacturer U.S. commercial average net unit price─ net of patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer U.S. commercial average net unit price─ net of patient assistance is the manufacturer U.S. commercial average net unit price, with the additional following items deducted: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price─ net of patient assistance program is reported at the NDC-11 level.
- Manufacturer U.S. commercial average net unit price─ best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer U.S. commercial average net unit price─ best is the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The following items should be deducted from gross revenue in your calculations: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers. The following items should not be deducted from the gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price─ best is reported at the NDC-11 level.

[210] The Big Four price is the maximum price a drug manufacturer is allowed to charge the Big Four federal agencies, which are the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard. See: https://www.cbo.gov/publication/57007.

- Manufacturer net Medicare Part D average unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price as calculated by the Primary Manufacturer. The following items should be deducted from gross revenue in your calculation: coverage gap discounts for calendar years prior to the calendar year date specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price is reported at the NDC-11 level.
- Manufacturer net Medicare Part D average unit price – best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price – best is the lowest manufacturer net Medicare Part D average unit price offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any Part D plan sponsors in the U.S. The following items should be deducted from gross revenue in your calculation: coverage gap discounts for calendar years prior to the calendar year specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price – best is reported at the NDC-11 level.

Evidence About Alternative Treatments **(Optional)**

- Therapeutic Advance: CMS intends to examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression) and will consider the costs of the selected drug and its therapeutic alternative(s). CMS may consider the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for an indication(s)[211] when determining the extent to which a selected drug represents a therapeutic advance. For purposes of the Negotiation Program, anytime

[211] For purposes of this final guidance, the Drug Selection ICR, and the Drug Price Negotiation ICR, CMS distinguishes between the use of the word "indication" and the term "FDA-approved indication" such that "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s), and "indication" refers to the condition or disease state for which the selected drug is used.

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: A therapeutic alternative must be a pharmaceutical product or group of pharmaceutical products that is clinically comparable to the selected drug (in other words, a medicine other than the selected drug that may be used to treat the same condition or disease state). CMS intends to consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS intends to identify 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 then also consider therapeutic alternatives in different pharmacologic classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug.
- Outcomes: Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes of interest to CMS may include direct clinical outcomes (e.g., cure, mortality) and/or validated or reasonably likely surrogate endpoints (e.g., serum hemoglobin A1c). In determining outcomes of interest, CMS will consider patient-reported outcomes and outcomes of importance to patients, if available. CMS may also consider additional outcomes and contextual factors, such as health-related quality of life or patient/caregiver preferences regarding treatment, to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternatives. The caregiver perspective may be considered to the extent it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.
- Patient-centered outcome: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves.[212]
- Specific populations: Specific populations may include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries.
- Unmet medical need: 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.[213] 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

[212] A patient-centered outcome is defined as: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves. (Source: https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary.)

[213] CMS will consider the nonbinding recommendations in FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" (May 2014) when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program.

information at such time of consideration. Under section 1194(e)(2) of the Act, CMS intends to consider the extent to which a selected drug and its therapeutic alternatives address an unmet medical need.

- Indication: Indication refers to the condition or disease state that the selected drug treats. An indication may include any FDA-approved indication included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s) and off-label use(s) that are included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication covered under Part D and/or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice. For the purpose of an ICR submission, a respondent may combine FDA-approved indications (e.g., identical adult and pediatric indications) and off-label use(s). The respondent may also choose not to report on certain FDA-approved indications or off-label uses.
- Off-label Use: Off-label use means a use of a selected drug or therapeutic alternative that is not approved by the FDA but is included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted use covered under Part D or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

Appendix B: List of DDPS Edits Directly Related to MFP Eligibility

Table 13 contains the list of DDPS edits that CMS identified as directly relating to the determination and verification of MFP eligibility for the purposes of the Negotiation Program. As described in section 40.4.2.1 of this final guidance, if a claim has any of the DDPS edits that are included on this list of edits directly related to MFP eligibility, the MTF DM will not transmit the claim-level data elements to the Primary Manufacturer because it has not been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual.

Table 13: DDPS Edits that Directly Relate to the Determination and Verification of MFP Eligibility for the Purposes of the Negotiation Program[214]

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
603	Missing/ Invalid	Medicare Beneficiary Identifier (MBI)	MBI is missing. The Medicare Beneficiary Identifier must not be <SPACE>.
607	Missing/ Invalid	Date of Service (DOS)	DOS is missing or invalid. DOS must be in CCYYMMDD format and be a valid date.
608	Missing/ Invalid	Date of Service (DOS)	The DOS must be on/after 1/1/2006.
609	Missing/ Invalid	Date of Service (DOS)	DOS must be on or before PDE submission date.
612	Missing/ Invalid	Prescription Service Reference Number	Prescription Number Service Reference Number is missing or invalid. Prescription Service Reference Number must be numeric.
613	Missing/ Invalid	Product Service ID	Product Service ID is missing. Product Service ID must not be <SPACE>.
614	Missing/ Invalid	Service Provider ID Qualifier, Non-Standard Format Code	Service Provider ID Qualifier is missing or invalid. Service Provider ID Qualifier must be '01', '06', '07', '08', '11', or '99' for non-standard format PDEs or ’01’ or ‘07’ for standard format PDEs.
615	Missing/ Invalid	Service Provider ID	The Service Provider ID is missing or invalid.
616	Missing/ Invalid	Fill Number	Fill Number is missing or invalid. Fill Number must be a value between ‘00’ and ‘99’.

[214] The full list of DDPS edits is located at https://www.csscoperations.com/internet/csscw3.nsf/T/Prescription%20Drug%20Program%20(Part%20D)~References.

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
618	Missing/ Invalid	Compound Code	Compound Code is missing or invalid. Compound Code must be ‘0’, ‘1’, or ‘2’.
620	Missing/ Invalid	Quantity Dispensed	Quantity Dispensed is missing or invalid. Quantity Dispensed must be >= ‘0.001’.
621	Missing/ Invalid	Days Supply	Days Supply is missing or invalid. Days Supply must be a value between ‘000’ and ‘999’.
622	Missing/ Invalid	Prescriber ID Qualifier	Prescriber ID Qualifier is missing. Prescriber ID Qualifier must not be <SPACE>.
623	Missing/ Invalid	Prescriber ID Qualifier	Prescriber ID Qualifier is invalid. Prescriber ID Qualifier must be '01'.
624	Missing/ Invalid	Prescriber ID	The Prescriber ID is missing. Prescriber ID must not be <SPACE>.
626	Missing/ Invalid	Adjustment Deletion Code	Adjustment Deletion Code is invalid. Adjustment Deletion Code must be ‘A’, ‘D’, or <SPACE>.
627	Missing/ Invalid	Non-Standard Format Code	Non-Standard Format Code is invalid. Non-Standard Format Code must be 'A', 'B', 'C', 'P', 'X', or <SPACE>. Effective 10/24/2022, 'A' is a valid value.
641	Missing/ Invalid	Filler	Filler fields are invalid. Filler fields must be <SPACE>.
662	Adj/Del	Adjustment Deletion Code	Deletion PDE not permitted. Existing PDE is deleted. Only an original PDE can be submitted.
700	Eligibility	MBI	MBI does not exist. Medicare Beneficiary Identifier does not match an existing beneficiary record.
701	Eligibility	MBI, Date of Birth (DOB)	DOB submitted does not match the beneficiary record. DOB is optional. If DOB is reported, matching to the beneficiary record is performed on month and year only.
703	Eligibility	MBI, DOB, Date of Service (DOS)	DOS must be > DOB.
704	Eligibility	MBI, DOS, Pharmacy Service Type, Patient Residence	DOS must be <= date of death (DOD) + 32 days. Applies when Pharmacy Service Type <> '01' and Patient Residence <> '01'.
705	Eligibility	MBI, DOS	Beneficiary must be enrolled in Part D on DOS.

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
713	Eligibility	Contract Number, Plan Benefit Package (PBP) ID, DOS	Submitting Contract and PBP ID does not offer Part D on DOS.
735	NDC	Product Service ID	NDC not found in NDC database. NDC not found on First Databank and/or MediSpan.
738	NDC	Product Service ID, Drug Coverage Status Code	NDC is a non-covered drug. NDC not covered by Part D. Refer to the subcategory reject code returned in the Exclusion Reason Code field from the PDE Outbound File for more information.
742	NDC	Product Service ID, Drug Coverage Status Code, Vaccine Administration Fee or Additional Dispensing Fee	Vaccine Administration Fee or Additional Dispensing Fee must be $0 for non-qualifying drugs. NDC must qualify as a valid Part D vaccine when Vaccine Administration Fee or Additional Dispensing Fee > $0. Applies to covered drugs only (Drug Coverage Status Code = 'C'). Effective 03/01/2022, edit is bypassed for oral antiviral drugs procured by the U.S. Government.
744	NDC	DOS, Product Service ID, Compound Code, Drug Coverage Status Code, Reported Gap Discount	NDC not covered under Part D on DOS. This drug is not covered under Part D because the FDA-assigned Marketing Category is NDA or BLA, and no Coverage Gap Discount Program agreement is on file for the manufacturer responsible for this labeler code for the given DOS. Applies to covered drugs only (Drug Coverage Status Code = 'C'). Edit is bypassed for compound drugs.
745	NDC	Product Service ID, Quantity Dispensed, Days Supply, Drug Coverage Status Code	NDC not covered under Part D for submitted strength and days supply. Applies to covered drugs only (Drug Coverage Status Code = 'C').
746	NDC	Product Service ID, Drug Coverage Status Code	NDC not found on NSDE file. NDC not found on current FDA NDC SPL Data Element file. Applies to covered drugs only (Drug Coverage Status Code = 'C').

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
747	NDC	DOS, Product Service ID, Drug Coverage Status Code	NDC not effective on DOS. NDC found on current FDA NDC SPL Data Element file, but is not effective for the given DOS. Applies to covered drugs only (Drug Coverage Status Code = 'C').
748	NDC	DOS, Product Service ID, Compound Code, Drug Coverage Status Code, Reported Manufacturer Discount	NDC not covered under Part D on DOS. For DOS >= 01/01/2025, this drug is not covered under Part D because the FDA-assigned Marketing Category is NDA or BLA, and no Manufacturer Discount Program agreement is on file for the manufacturer responsible for this labeler code for the given DOS. Applies to covered drugs only (Drug Coverage Status Code = 'C'). Edit is bypassed for compound drugs.
753	Eligibility	MBI, DOS, Pharmacy Service Type, Patient Residence	DOS must be <= DOD + 14 days. Applies when Pharmacy Service Type = '01' and Patient Residence = '01'.
777	Misc	Contract number, DOS, Prescription Service Reference Number, Service Provider ID, Fill Number, Adjustment Deletion Code	Duplicate PDE record exists. Applies when Adjustment Deletion Code on submitted PDE = <SPACE>, but a match is found with an existing accepted original or adjustment PDE. Prior accepted PDE must be deleted in order to submit a new original.
781	Misc	Product Service ID, Service Provider ID	Service Provider ID not found on provider file. Edit is bypassed for vaccines.
783	Misc	DOS, Service Provider ID	Service Provider ID not active on DOS. Applies when DOS > store closure date plus six months.
784	Misc	Contract number, DOS, Prescription Service Reference Number, Service	Duplicate PDE record exists from a different Submitting Contract. Applies when Adjustment Deletion Code on submitted PDE = <SPACE>, but a match is found with an existing accepted original or adjustment PDE from a different Submitting Contract. Refer to Original

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
		Provider ID Qualifier, Service Provider ID, Fill Number, Adjustment Deletion Code	Submitting Contract field from the PDE Outbound File for the contract that submitted the previously accepted PDE.
785	Misc	Contract number, PDP ID, DOS, Prescription Service Reference Number, Service Provider ID Qualifier, Service Provider ID, Fill Number	Duplicate PDE record exists on this File ID. Applies when a duplicate PDE is found on the same File ID from the PDE Inbound File submission.
789	Misc	Prescriber ID Qualifier, Prescriber ID	Prescriber ID is listed on OIG's List of Excluded Individuals and Entities and is not assigned an active sanctioned provider waiver.
790	Misc	Service Provider ID Qualifier, Service Provider ID	Service Provider ID is listed on OIG's List of Excluded Individuals and Entities and is not assigned an active sanctioned provider waiver.
833	Missing/ Invalid	Prescriber ID Qualifier, Prescriber ID	Prescriber ID not found on NPI database. NPI must be Type 1 (individual) and be found in current National Plan and Provider Enumeration System (NPPES) data.
834	Missing/ Invalid	Prescriber ID Qualifier, Prescriber ID, DOS	Prescriber ID not active on DOS. NPI must be active in current NPPES data for the given DOS. Edit is bypassed when DOS is within one year of NPI Deactivation Date when there is no NPI Reactivation Date available in current NPPES data.
835	Missing/ Invalid	Non-Standard Format Code, Pharmacy Service Type	Pharmacy Service Type is missing or invalid. Pharmacy Service Type must be '01', '02', '03', '04', '05', '06', '07', '08', or '99'. May be <SPACE> on COB PDEs (Non-Standard Format Code = 'C'). Effective 09/18/2023, may be <SPACE> on Medicaid subrogation PDEs (Non-Standard Format Code = 'A' and CPP = GDCB + GDCA).

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
844	Missing/ Invalid	Service Provider ID Qualifier, Service Provider ID, Adjustment Deletion Code	Service Provider ID is invalid. Service Provider ID must be 'PAPERCLAIM' when Service Provider ID Qualifier = '99' and submitted Service Provider ID value is non-numeric. Edit is bypassed for adjustment PDEs.
998	Misc	N/A	Internal CMS system issue regarding Contract/PBP of Record encountered. CMS issue encountered with retrieving Contract and PBP of Record. Please resubmit PDE until edit is no longer returned.
999	Misc	N/A	Internal CMS system issue encountered. CMS issue encountered with retrieving necessary data for PDE editing. Please resubmit PDE until edit is no longer returned.