CENTER FOR MEDICARE

DEPARTMENT OF HEALTH & HUMAN SERVICES
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DATE: October 2, 2024

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., 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 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

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

A. An introduction, which begins on page 1.
B. A summary of changes and clarifications to the draft guidance released on May 3, 2024, which begins on page 3.
C. A summary of the public comments received in response to the draft guidance and the Centers for Medicare & Medicaid Services' (CMS') responses, which begins on page 9.
D. Final guidance that establishes policies on the topics discussed for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, which begins on page 160 and for which a table of contents appears on page 162.

CMS may supplement this guidance with further program instruction to explain how these policies will be implemented for initial price applicability year 2027and during 2026 and 2027. Additionally, as discussed in this memorandum, CMS intends to engage in rulemaking to propose certain policies under Medicare Part D that relate to or have implications for the Negotiation Program but involve exercising authorities under the Social Security Act (hereinafter "the Act") that are not subject to the IRA's program instruction requirement.

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 In accordance with the law, on May 3, 2024, CMS issued draft guidance for implementation of the Negotiation Program for initial price applicability year

2027 and manufacturer effectuation of the MFP in 2026 and 2027. CMS also voluntarily solicited comments on the draft guidance.[1] The 60-day comment period for the draft guidance began May 3, 2024 and concluded July 2, 2024. CMS received 145 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/inflation-reduction-act-and-medicare 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. Additionally, substantively duplicative letters (e.g., submitted as part of a coordinated advocacy campaign) are combined into a single document.

After consideration of the comments received, CMS is making certain changes to the policies described in the draft guidance in this final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027.[2] Additionally, as discussed in this memorandum, CMS intends to engage in notice-and-comment rulemaking to propose certain policies under Medicare Part D, such as timing requirements for submission of prescription drug event (PDE) records for selected drugs and participation of dispensing entities in the Medicare Transaction Facilitator (MTF) Data Module for the purposes of data exchange, that may relate to or have implications for the Negotiation Program, but involve exercising authorities under the Act that are not subject to the IRA's program instruction requirement. Comments received in response to draft guidance relating to such topics may be considered as part of that rulemaking process. Additionally, these comments also may be considered in development of program guidance for initial price applicability year 2028 of the Negotiation Program, for which CMS also intends to solicit comments. 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

[1] The 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, 88 FR 67690, available at https://www.federalregister.gov/documents/2023/10/02/2023-21586/excise-tax-on-designated-drugs-proceduralrequirements and Notice 2023-53; see also, 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).

[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, and "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.

process, and comments submitted in response to the draft guidance may be considered as part of that rulemaking process.

CMS is providing a summary of significant comments that it received in response to the draft guidance, as well as the agency's responses to those significant comments, which begin on page 9. Some of the public comments received were outside the scope of draft guidance. 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 that was released on May 3, 2024. 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, as summarized below.

Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2027:

- Identifying Active Moiety / Active Ingredient: In section 30.1, CMS clarified the sources it will use to identify the active moiety / active ingredient when identifying potential qualifying single source drugs.
- Treatment of Compounded Drugs in the Selection Process: CMS revised sections 30.1.2 and 30.2 to provide that, for alignment with CMS' exclusion of selected drugs billed as compounds from MFP effectuation (described in section 40.4.2.1), CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug when calculating the low-spend Medicare drug exclusion (section 30.1.2) and the rankings of negotiation-eligible drugs (section 30.2).
- Demonstration of High Likelihood of Biosimilar Market Entry: In section 30.3.1, CMS clarified that when reviewing an Initial Delay Request to determine whether the request demonstrates a high likelihood that the Biosimilar will be licensed and marketed by February 1, 2027, CMS will consider whether, based on the totality of the circumstances, there is a high likelihood that the manufacturer of the Biosimilar will be engaged in bona fide marketing of that Biosimilar by the specified date. CMS must also determine whether each Biosimilar named in a successful Initial Delay Request has been licensed and engaged in bona fide marketing during the initial delay period. Finally, in section 30.3.1.2, CMS added certain United States Patent and Trademark Office (USPTO) decisions as information considered for the patent-related component of the high likelihood determination.
- Sources for CMS identification of NDC-11s: In section 30.4, CMS clarified that the NDC Directory's NDC Excluded Drugs Database file will be included as a source that CMS will use to identify NDC-11s of the selected drug.

Section 40 – Requirements for Manufacturers of Selected Drugs:

[3] CMS notes that sections 50, 70, 80, 110, and 120 are not included in the Summary of Changes because CMS did not make significant clarifying edits or changes to these sections.

- Sources for CMS population of NDC-11s: In section 40.2, CMS added the NDC Directory (including its NDC Excluded Drugs Database file) as additional sources that CMS will use to populate NDC-11s in the CMS Health Plan Management System ("the CMS HPMS").
- Treatment of Compounded Drugs in MFP Effectuation: CMS revised section 40.4.2.1 to provide that, for operational reasons at this time for 2026 and 2027, MFP refunds will not be required for PDE records for selected drugs that were billed as compounds.
- Opportunity for Corrective Action Following Submission: In section 40.2.3, CMS clarified the procedures related to issuance of a Request for Corrective Action Plan (CAP), as warranted, following Primary Manufacturer information submission; clarified the process by which CMS will engage with Primary Manufacturers during any necessary information corrections; and clarified CMS' authority for issuing potential CMPs related to Requests for CAP.
- Reorganization of Section 40.4: For clarity and readability, CMS modified the order of the subsections within section 40.4. CMS also added new subsections to sections 40.4.2, 40.4.3, and 40.4.4 to provide further detail on Primary Manufacturer and dispensing entity enrollment in the MTF Data Module ("MTF DM"), Primary Manufacturer participation in the MTF Payment Module ("MTF PM"), and MFP refund payments when the Primary Manufacturer makes payment outside of the MTF PM, respectively.
- Calculating the Standard Default Refund Amount (SDRA) to the Dispensing Entity: In section 40.4.1, CMS clarified that the MTF will use Wholesale Acquisition Costs (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 that will be included with the claim-level data elements provided by the MTF DM to Primary Manufacturers.
- MTF Data Flow: In section 40.4.2, CMS updated "Figure 2: Diagram of MTF Data Flow" to provide more detail on the MTF data flow.
- Claim-Level Data Elements: In section 40.4.2.1, CMS added two new data elements to Table 2, titled "MTF DM Claim-Level Data Elements." Specifically, CMS added "Prescriber ID" and "Prescriber ID Qualifier."
- Outline of MFP Refund Payment Timing Requirements: In section 40.4.2.1, CMS added a new figure titled "Table 3: Primary Manufacturer Payment Approaches to MFP Effectuation" describing the timing and required action of Primary Manufacturers to meet the 14-day prompt MFP payment window based on the Primary Manufacturer's elected MFP effectuation method. In sections 40.4 and 40.4.2.1, CMS clarified that the 14-day prompt MFP payment window requires the Primary Manufacturer to 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.
- Dispensing Entity Participation in MTF Data Facilitation: In section 40.4.2.2, CMS added that it intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM for purposes of data exchange.
- Dispensing Entity Self-Identification of Material Cashflow Concerns: In section 40.4.2.2, CMS added that during enrollment in the MTF DM dispensing entities will be asked to self-identify whether they are dispensing entities that anticipate 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.

- Selection of a Payment Facilitation Method to Refund the MFP: In section 40.4.3, CMS established that the MTF PM will facilitate the transfer of MFP refund payments by participating Primary Manufacturers to dispensing entities. The MTF PM builds on the approach described as Option 2 in the draft guidance. CMS updated section 40.4.3 to provide further details on the MTF PM, including updates to Figure 3 titled "Diagram of MTF Payment Flow."
- Claim-Level Payment Elements when Primary Manufacturers Pass Payment Through the MTF PM: In section 40.4.3.1, CMS revised the payment elements to Table 4 (retitled in this final guidance as "Example Manufacturer Claim-Level Payment Elements List for Primary Manufacturers Passing Payment through the MTF PM") and justification codes to Table 5 (retitled in this final guidance as "Examples of Justification Codes and Values for the 'Method for Determining MFP Refund Amount' Claim-Level Payment Element for Primary Manufacturers"). CMS clarified that these tables describe the claim-level payment elements that Primary Manufacturers passing payment through the MTF PM are required to report.
- Dispensing Entity Election of Pass-Through Payments from the MTF PM: In sections 40.4.3.3 and 40.4.4.3 of this final guidance, CMS clarified that 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. Upon enrollment in the MTF DM, dispensing entities will indicate whether they prefer receiving MFP refund payments in the form of electronic transfer of funds, which will be the default election for dispensing entities at the time of enrollment, or in the form of a check. If the Primary Manufacturer elects to send an MFP refund payment 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.
- Party Responsible for Transmitting the Remittance Advice: CMS added in section 40.4.2 that the MTF DM will make available to dispensing entities an Electronic Remittance Advice that uses the X12 835 standard adopted under HIPAA (ERA) (for electronic payments) or a remittance (for payment made by paper check) for all MFP refund payments by a Primary Manufacturer that are passed through the MTF PM. CMS added in section 40.4.4 that a Primary Manufacturer that chooses not to pass payment through the MTF PM is required to create and make available to the dispensing entity an ERA (for electronic payments) or a remittance (for payment made by paper check).
- Sharing of Banking Information: In sections 40.4.3.1 and 40.4.4.1, CMS stated that, for payments made outside of the MTF PM, CMS plans to make available to the Primary Manufacturer through the MTF DM the bank account information and designated destination for ERAs or remittances for dispensing entities.
- Claim-Level Payment Elements when Primary Manufacturers Make Payment Outside of the MTF PM: In section 40.4.4.2, CMS added a new Table 6 titled "Example Manufacturer Claim-Level Payment Elements List when Primary Manufacturers Make Payment Outside of the MTF PM." CMS clarified that this table describes the payment elements that Primary Manufacturers are responsible for reporting when making

payments outside of the MTF PM, regardless of whether the Primary Manufacturer has elected to participate in the MTF PM.

- Reversals and Adjustments to Paid Claims: In sections 40.4.3.2 and 40.4.4.4, CMS clarified the MTF's role in tracking Part D claims for selected drugs that are reversed or adjusted when the MFP refund has already been transmitted by the Primary Manufacturer.

Section 60 – Negotiation Process:

- Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication: In section 60.3.3.1, CMS clarified that the extent to which a selected drug represents a therapeutic advance compared to its therapeutic alternative(s) will be considered at the time section 1194(e)(2) data is submitted, in alignment with when unmet medical need will be considered for the purpose of developing the initial offer.
- Treatment of Compounded Drugs in the Negotiation Process: CMS revised portions of section 60 to indicate that, for alignment with CMS' exclusion of selected drugs billed as compounds from MFP effectuation (described in section 40.4.2.1), CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug from the calculations for determining the ceiling for the MFP (section 60.2.1), determining the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative (section 60.3.2), and applying the MFP across dosage forms and strengths (section 60.5).
- Reorganization of Section 60.4: For clarity and readability, CMS modified existing subsections and added new subsections within section 60.4 to describe public engagement events in section 60.4.1, the initial offer and first optional negotiation meeting in section 60.4.2, the statutory written counteroffer and response to this counteroffer in section 60.4.3, optional negotiation meetings in section 60.4.4, the new additional price exchange functionality in section 60.4.5, and notification of the final offer and determination that negotiations have finished in section 60.4.6.
- Public Engagement Events: In section 60.4.1, CMS provided that the agency will host up to 15 patient-focused roundtable events, organized by condition when applicable, and one clinically oriented town hall meeting for all selected drugs for initial price applicability year 2027. CMS seeks input from patients, patient advocacy organizations, and caregivers at the patient-focused roundtable events and from clinicians at the town hall meeting (although other interested parties, such as researchers, manufacturers, and members of the public, are welcome to register to speak at the town hall meeting).
- Negotiation Meetings: In sections 60.4.2 and 60.4.4, CMS described its approach to negotiation meetings for initial price applicability year 2027, in which the first negotiation meeting between CMS and a Primary Manufacturer may occur after CMS issues the initial offer and before the deadline for a Primary Manufacturer to respond to CMS' initial offer and provide a statutory written counteroffer, if applicable, and up to two more negotiation meetings may occur if CMS does not accept the Primary Manufacturer's statutory written counteroffer.
- Additional Price Exchange Opportunities: In section 60.4.5, CMS provided that CMS and Primary Manufacturers will have additional opportunities to exchange written offers and counteroffers for the MFP within the CMS HPMS during the negotiation process.

- MFP File Layout, Web File Structure, and Definitions: CMS revised section 60.6 to issue clarifying guidance on definitions in the MFP Layout file and revised the number of rounded decimal points it will use when publishing the NDC-9 per unit price.

Section 90 – Manufacturer Compliance and Oversight:

- Monitoring of Manufacturer Compliance: CMS updated section 90.1 to include information about when CMS may request information from the Primary Manufacturer as part of its obligation to administer or monitor compliance with the Negotiation Program. This section describes the type of information CMS may request, the communications CMS may send to the Primary Manufacturer regarding information needed, and processes CMS intend to follow in its compliance and oversight functions.
- Manufacturer Written Compliance Plans for MFP Effectuation: CMS revised section 90.2.1 to delay the submission deadline for Primary Manufacturers' plans to effectuate MFP availability from June 1, 2025, to September 1, 2025 for selected drugs with a first initial price applicability year of 2026 and from June 1, 2026, to September 1, 2026 for selected drugs with a first initial price applicability year of 2027. In addition, CMS added language that further explains the contents of a forthcoming Information Collection Request (ICR) that will establish a standardized form for Primary Manufacturers to use to satisfy the requirements set forth in section 90.2.1. Relatedly, CMS clarified how a Primary Manufacturer's decision to pass payment through the MTF PM or not influences the requirements for its MFP effectuation plan. CMS also specified that 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 as well as a reimbursement mechanism to provide paper checks for dispensing entities that do not wish to be reimbursed electronically. Finally, CMS revised the language regarding making the Primary Manufacturer plans publicly accessible. Instead of making the plans publicly available on the Negotiation Program's website, with proprietary information redacted, the Primary Manufacturers' plans (with proprietary information redacted) will be made available to dispensing entities via the MTF user interface. While not generally available to the public, CMS may release the redacted plans to other interested parties upon request.
- Inclusion of Mitigation Processes for Material Cashflow Concerns in MFP Effectuation Plans for 2026 and 2027: In section 90.2.1, CMS added that Primary Manufacturers must include a process for mitigating material cashflow concerns for dispensing entities in their MFP effectuation plans. For consideration in developing and implementing this mitigation process, CMS will make the list of the self-identified dispensing entities (described in more detail in section 40.4.2.2) available to Primary Manufacturers in the MTF DM prior to Primary Manufacturers' submission of their MFP effectuation plans for 2026 and 2027.
- Centralized Intake System for Complaints and Disputes Related to MFP Availability and MTF Functionality: CMS revised section 90.2.2 to establish that complaints and disputes related to MFP availability and MTF functionality must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute; state that CMS encourages dispensing entities and Primary Manufacturers work together in good faith to resolve issues before utilizing the complaint process; and express CMS' intent to track complaints and disputes over time to monitor overall trends, including those related

to parties in the supply chain other than dispensing entities and Primary Manufacturers, and emerging compliance issues and to make process improvements in the implementation of the complaint and dispute process.

Section 100 – Civil Monetary Penalties:

- Civil Money Penalties: CMS moved "Table 10: Examples of Substantive Violations to Section 100" and added examples of substantive violations related to the MTF.
- CMP Inflation Adjustment: CMS updated certain CMP amounts to reflect required annual inflation-related increases under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.
- Violations of the Agreement: In section 100.2, CMS expanded the example scenarios provided, including noting how a CMS-issued Violation Notice and a Request for Corrective Action will be included as types of communications CMS may send to a Primary Manufacturer where the Primary Manufacturer failed to provide required information to CMS.
- Notice and Appeal Procedures: In section 100.4, CMS revised the information that will be provided in a CMP Notification to include the start and end date of CMP accrual and instructions for submitting a CMP payment. CMS also clarified expectations regarding the timing of CMP payment.

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

- Definitions Related to Research and Development (R&D) Costs: CMS revised definitions related to R&D costs to specify that direct basic pre-clinical research costs include monetary and non-monetary compensation for investigators and staff researching the selected drug and that direct post-Investigational New Drug (IND) application costs include monetary and non-monetary compensations for patient recruitment, per-patient costs, and investigators and staff researching the selected drug. CMS also revised the definition of "All Other R&D Costs" to include costs associated with generating real-world evidence submitted to FDA to support the safety or effectiveness of a selected drug or to support or satisfy a postmarketing requirement or commitment.
- Prior Federal Financial Support: CMS clarified that 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.
- Patents, Exclusivities, and Approvals: CMS clarified that relevant patents and patent applications do not include patent applications that were denied by the USPTO. CMS also provided additional examples of the types of patents and patent applications CMS considers to be related to the selected drug to provide additional clarity for Primary Manufacturers regarding patent submission requirements.
- Definitions Related to Market Data and Revenue and Sales Volume Data: CMS added a definition related to manufacturer net Medicare Part D average unit price – best.

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

General Comments Related to the Implementation of the Negotiation Program

Comment: Some commenters expressed concern that the Negotiation Program, including CMS' implementation through program guidance, would increase risk and uncertainty related to developing new treatments, undermine market dynamics, and reduce access to new therapies. One commenter encouraged CMS to monitor the impacts of the Negotiation Program on the development of personalized medicines for small patient subpopulations.

Response: 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.[4] 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.[5, 6] CMS also expects the Negotiation Program to encourage drug manufacturers to create business models to stay competitive, fostering the development of new treatments and delivery methods. Only drugs that have been approved by the U.S. Food and Drug Administration (FDA) for at least 7 years and only biologicals that have been licensed by the FDA for at least 11 years are eligible for negotiation as part of the Negotiation Program. With the changes in 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. The comment encouraging CMS to monitor the effects of the Negotiation Program on the development of personalized medicines for small patient subpopulations is outside the scope of the Negotiation Program. However, CMS notes that it continues to evaluate whether there are additional actions the agency can take in its implementation of the Negotiation Program to best support drug development for patient subpopulations. Finally, 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.

Comment: One commenter noted that although the IRA permits implementation of the Negotiation Program through program guidance, doing so opens CMS to criticism for establishing an opaque process with maximum flexibility provided to CMS and without adequate clarity about CMS' implementation of various provisions. The commenter urged CMS to publicly post comments in response to the draft guidance.

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[4] 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.

[5] 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.

[6] *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.

Response: CMS thanks the commenter for this input. Sections 11001(c) and 11002(c) of the IRA direct 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. To promote transparency of the Negotiation Program and in response to feedback from interested parties, CMS voluntarily provided a 60-day comment period on the draft guidance and solicited comments on all sections of the draft guidance, except for section 90.3, which states that the 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. As CMS did in response to comments received for initial guidance for initial price applicability year 2026, in this final guidance, CMS summarizes and responds to all timely, significant comments received on the draft guidance. Additionally, similar to CMS' process in connection with the publication of the revised guidance for initial price applicability year 2026,[7] CMS is making public copies of all timely comments received for the draft guidance on the CMS IRA website at https://www.cms.gov/inflation-reduction-act-and-medicare in conjunction with CMS' publication of the final guidance. Comment letters from individuals not representing organizations will have the name, address, and contact information of these individuals removed for privacy purposes. Substantively duplicative letters (e.g., those submitted as part of a coordinated advocacy campaign) will be combined into a single document.

Comment: One commenter recommended CMS evaluate the long-term impacts of the Negotiation Program on patient access and costs and suggested that CMS implement a data collection and analysis system to conduct this evaluation. One commenter also wrote that the Negotiation Program should not create barriers to affordable and appropriate medications for any patients in the United States, and that CMS must ensure that patients taking non-selected drugs are not negatively affected by the program.

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 commenters about the importance of ensuring meaningful access to selected drugs and their MFPs and ensuring that Part D plans do not engage in behavior that hinders access to selected drugs or non-selected drugs when medically appropriate. As such, CMS will continue to monitor Part D plans' compliance with all applicable formulary requirements, including treatment of selected drugs, and may further address formulary inclusion policies in the future per section 110 of this final guidance. Consistent with CMS' response on page 83 of the revised guidance for initial price applicability year 2026, 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. 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

[7] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation/2026-policy-and-public-input.

action, as necessary. Finally, consistent with CMS' response on page 40 of the revised guidance for initial price applicability year 2026, the Negotiation Program does not regulate payment rates by payers outside of the Medicare program (e.g., in the commercial markets).

Comment: One commenter resubmitted a copy of the comment letter they submitted in response to the initial Medicare Drug Price Negotiation Program guidance for initial price applicability year 2026, stating that CMS disregarded their comments as well as comments submitted by most other interested parties. The commenter also submitted a new comment letter in response to the draft guidance for initial price applicability year 2027. The commenter recommended CMS revisit and adopt the recommendations made for initial price applicability year 2026 when implementing the Negotiation Program for initial price applicability year 2027.

Response: CMS received the commenter's resubmitted initial price applicability year 2026 comments, in addition to their separate comments on the draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027. CMS read and responded to all significant comments received timely on the 2026 initial guidance. CMS refers commenters to section C, "Summary of Public Comments on the Initial Medicare Drug Price Negotiation Program Memorandum and CMS' Responses," in the revised guidance for initial price applicability year 2026 for a summary of comments and CMS' responses.[8] Further, in developing the guidance to implement the Negotiation Program for initial price applicability year 2027 and manufacturer effectuation of the MFP for 2026 and 2027, CMS built on the revised guidance for initial price applicability year 2026 and applied experience and early lessons learned to date from implementing the Negotiation Program for initial price applicability year 2026. CMS summarizes and responds to this commenter's significant comments on the draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 elsewhere in the final guidance, including in this segment of the summary of comments and responses and in the applicable sections of the final guidance.

Comment: One commenter stated that the IRA, and CMS' implementation of the statute, are too strict and focuses too much on pharmacies.

Response: CMS thanks the commenter for the feedback. CMS notes that the agency has pursued implementation in accordance with the statutory requirements of the Negotiation Program. Regarding the comment that CMS' implementation of the Negotiation Program focuses too much on pharmacies, CMS notes that section 1193(a) of the Act requires that the Primary Manufacturer provides 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. Additionally, CMS requires that the Primary Manufacturer establish processes to ensure that entities dispensing drugs to MFP-eligible individuals—including pharmacies, mail order services, and other dispensing entities—have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in section 40.4 and section 90.2 of this final guidance.

[8] CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, June 30, 2023, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027 (Section 30.1)

Comment: One commenter suggested a specific drug be selected for initial price applicability year 2027.

Response: CMS notes that it will select drugs for negotiation in accordance with sections 11001 and 11002 of the IRA.

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 New Drug Application (NDA) or of a biological product with the same active ingredient and the same holder of a Biologics License Application (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. 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 Services 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 "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.[9] A few other commenters appreciated CMS' consistent approach to the qualifying single source drug definition and supported the current definition. These commenters stated that this policy is critical in preventing manufacturers from gaming the drug selection process and finding inappropriate ways to exclude from the Negotiation Program drug products that might otherwise be eligible and underscored that it is consistent with section 1192(d)(3)(B) of the Act. One of 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: As discussed in CMS' response on pages 11 and 12 of the revised guidance for initial price applicability year 2026, 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

[9] 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."

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 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) 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 the draft 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 identifying potential qualifying single source drugs.

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. One commenter asked CMS to explore with the wider patient community the degree to which the definition of qualifying single source drug may constitute a deterrent for investment and research into novel indications. One commenter raised concern that identifying a potential qualifying single source drug using data

aggregated across dosage forms and strengths of the drug, including new formulations, and recommended that the MFP should align to each distinct dosage form of the drug because manufacturing costs vary based on product form. One commenter recommended that CMS use a case-by-case analysis when deciding whether to aggregate products, stating that minor changes like formulation or labeling updates should be aggregated under the same qualifying single source drug and that meaningful product approval data, when available, should be considered when deciding if a product should be aggregated into a qualifying single source drug or be considered as its own standalone qualifying single source drug.

Response: CMS thanks these commenters for their input. As discussed in CMS' response on page 12 of the revised guidance for initial price applicability year 2026, 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, 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. As stated in section 60.1 of this final guidance, CMS will identify a single price for use at each step in the negotiation process described in 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. Section 60.5 of this final guidance details how the MFP will be applied across dosage forms and strengths.

Comment: A couple of commenters expressed support for the draft guidance policy on fixed combination drugs with two or more active moieties / active ingredients, which treats the distinct combination of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs. A couple of commenters raised a concern that this policy creates a gaming opportunity and a way for manufacturers to evade negotiation and frustrate competition by allowing strategic development by manufacturers of combination products that would not differ significantly from the original single product, not contribute directly to the drug's therapeutic effect, and provide minimal additional patient benefit. One commenter recommended that CMS use a case-by-case methodology for aggregating fixed combination drugs into qualifying single source drugs, and they requested that CMS treat each formulation of a vaccine as a distinct fixed combination biologic product, precluding aggregation with earlier versions of the vaccine and resetting the 11-year post licensure eligibility timeframe.

Response: As discussed in CMS' response on pages 13 and 14 of the revised guidance for initial price applicability year 2026, CMS appreciates commenters' support for its interpretation of the statutory language and acknowledges the concern outlined by commenters. CMS will treat a fixed combination drug as distinct in its composition from the individual active moieties / active ingredients and in this final guidance maintains its approach on fixed combination drugs, which

treats the distinct combination of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs. Section 30.1 of this final guidance details how CMS intends to treat fixed combination drugs and gives an example to illustrate the application. The policies described in section 30.1 of this final guidance apply no differently to vaccines than to other products.

Comment: A few 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. One commenter stated their support for statutory changes that would require CMS to treat all genetically targeted therapies as biologics that could be negotiated after 13 years since approval or licensure by the FDA.

Response: CMS thanks these commenters for their feedback and suggestions. As discussed in CMS' response on page 13 of the revised guidance for initial price applicability year 2026, 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.[10] 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.[11] CMS is implementing the Negotiation Program in accordance with these statutory requirements.

Comment: One commenter expressed concern regarding CMS' statement in section 30.1 of the draft guidance that, if there are multiple NDAs or BLAs with the same active moiety or active ingredient with non-identical names reported for the NDA or BLA holder, CMS will investigate whether such NDAs or BLAs are held by the same entity for the purposes of identifying a potential qualifying single source drug. This commenter asserted that CMS does not explain the scope of the investigation, nor the factors CMS will consider in making its determination, and asked CMS to clarify what it intends by this statement. This commenter also asked for clarity regarding whether CMS intends to aggregate across NDAs and BLAs to include NDA and BLA holders that are different entities.

Response: In the course of CMS' review of potential qualifying single source drugs, CMS has found, in rare circumstances, NDAs and BLAs with the same active moiety or active ingredient that appeared to be held by the same entity had non-identical names reported for the NDA holder or BLA holder due to inconsistencies in manufacturer reporting to FDA, such as typos or unstandardized use of abbreviations in the NDA or BLA holder name, and situations where it appears the NDA or BLA holder name has not yet been updated. In such circumstances, CMS

[10] 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.

[11] 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.

may further investigate whether such NDA(s) and BLA(s) are held by the same entity for the purposes of identifying a potential qualifying single source drug using FDA sources that are publicly available and other relevant publicly available sources as CMS deems appropriate (as described in section 30.1 of this final guidance). For example, CMS may consider manufacturer names included on FDA labels or correspondence between FDA and manufacturers, the complete applicant name in the Orange Book, and other public sources to determine whether the holders of the NDAs or BLAs are the same entity. This investigation will not be used to aggregate across NDA or BLA holder names that do not represent the same entity.

Comment: One commenter stated that CMS statements are "inconsistent and ill-defined" regarding how CMS will identify a drug's active moiety or active ingredient, and that this identification is pivotal to determining the "drug bundle." The commenter referenced an October 2023 FAQ document available on the CMS website at https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-faqs-ipay-2026.pdf for initial price applicability year 2026 that stated CMS used the National Library of Medicine's RxNorm database to identify active ingredient(s) for biological products, and a combination of RxNorm and FDA's Active Ingredient-Active Moiety Relationship / Basis of Strength file to identify active moiety(ies) for small molecule drugs. The commenter stated that, in the Proposed MFP File Layout and Definitions Document,[12] CMS changed how it identifies "active moiety" for small molecule drugs and updated its position by identifying a specific field, the "Ingredient" / IN field within RxNorm to identify active ingredient for biologics. The commenter also argued that CMS' approach could lead to inaccurate results that are contrary to determinations made by FDA. The commenter recommended that CMS refer to a drug's nonproprietary name appearing in its FDA labeling and approval documents (typically the United States Adopted Name (USAN) as identified by FDA) to identify the active moiety for small molecule drugs and active ingredients for biologics instead of relying on RxNorm and reconciling multiple, potentially conflicting, fields within that database.

Response: CMS thanks this commenter for the feedback but disagrees with the statement that CMS has been inconsistent in its approach to identifying active moiety for small molecule drugs and active ingredient for biologics; both the October 2023 FAQ document and the Proposed MFP File Layout and Definitions Document accurately state that CMS used RxNorm to identify active ingredients for biologics. As a result of operational refinements, CMS has described in section 30.1 of this final guidance that it may use additional sources beyond those specific fields in RxNorm and FDA's Active Ingredient-Active Moiety Relationship / Basis of Strength file to identify the active moiety or active ingredient of the drug, such as OpenFDA and FDALabel, for drug selection for initial price applicability year 2027. CMS may also consult with FDA as needed, for example, to clarify whether a suffix or prefix in an active moiety or active ingredient name represents a genuine difference in active moiety or active ingredient. CMS' experience to date is that the "Ingredient" / IN field within RxNorm and the "active moiety" field within FDA's Active Ingredient-Active Moiety Relationship / Basis of Strength file may not be standardized because they are derived from multiple non-standardized data sources. Therefore, the use of additional sources may on occasion be helpful to properly identify the active moiety or active ingredient consistent with the statute.

[12] Proposed Maximum Fair Price File Layout and Definitions Document. Released May 3, 2024. https://www.cms.gov/files/zip/proposed-maximum-fair-price-file-layout-and-definitions-document.zip.

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 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. A few of these 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. Therefore, the 7- or 11-year periods prior to eligibility as a qualifying single source drug should be tolled (i.e., paused or delayed) until the first day after the orphan drug no longer qualifies for the Orphan Drug Exclusion. Some commenters 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.

Response: Consistent with our response on page 14 of the revised guidance for initial price applicability year 2026, CMS does not have the statutory authority to change the starting date from which qualifying single source drug status is determined. Sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act require CMS to use the date of the approval or licensure of the drug or biological product to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act.

Comment: Some commenters asserted that CMS should interpret section 1192(e)(3)(A) of the Act such that drugs or biological products with multiple orphan 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 few commenters acknowledged that CMS does not have the authority to change the statutory requirement that prevents a drug with multiple designations from qualifying for the Orphan Drug Exclusion and urged CMS to support Congress in amending this requirement, which these commenters' view as a Congressional drafting error. Many commenters expressed concern that the current implementation of the Orphan Drug Exclusion will stymie innovation for drugs or biological products and discourage sponsors from seeking designations for more than one rare disease or condition. One commenter requested that CMS monitor impacts of the Negotiation Program on research and development of orphan products.

Response: CMS thanks these commenters for their feedback and the suggestion to work with Congress on changes to the Orphan Drug Exclusion provision. Consistent with our response on page 14 of the revised guidance for initial price applicability year 2026, section 1192(e)(3)(A) of the Act describes a drug that qualifies for the Orphan Drug Exclusion as a "drug that is designated as a drug for only one rare disease or condition under [section 526 of the FD&C Act] and for which the only approved indication (or indications) is for such disease or condition."

CMS therefore does not have the statutory authority to exclude a drug under the Orphan Drug Exclusion that has designations for multiple rare diseases or conditions, even if the drug has been approved only for indication(s) within a single rare disease or condition. The specific request that CMS monitor impacts of the Negotiation Program on research and development of orphan products is outside the scope of the Negotiation Program, although CMS notes, as stated below, that it continues to evaluate whether there are additional actions the agency can take in its implementation of the Negotiation Program to best support orphan drug development.

Comment: One commenter requested that, when a drug or biological product loses eligibility for the Orphan Drug Exclusion, CMS carve out the original approval(s) that qualified for the Orphan Drug Exclusion from the resulting qualifying single source drug, such that the qualifying single source drug includes only the subsequent or supplemental approvals of the active moiety or active ingredient that never qualified for the Orphan Drug Exclusion.

Response: This final guidance states that, to qualify for the Orphan Drug Exclusion, "all dosage forms and strengths and different formulations of the qualifying single source drug described in section 30.1 of this final guidance must meet the criteria for exclusion." Consistent with our response on pages 15 and 16 of the revised guidance for initial price applicability year 2026, because section 1192(e)(3)(A) of the Act is an exclusion from the definition of qualifying single source drug under section 1192(e)(1) of the Act, CMS must consider whether the drug, including all products that constitute the potential qualifying single source drug, meets the statutory criteria for the Orphan Drug Exclusion.

Comment: A couple of commenters expressed support for CMS' interpretation and implementation of the Orphan Drug Exclusion. These commenters opposed any policy change that would expand the Orphan Drug Exclusion's scope and stated that it strikes the right balance between maintaining strong incentives for orphan drug development while protecting patients from high prices.

Response: CMS thanks the commenters for their support.

Comment: One commenter opposed the existence of the Orphan Drug Exclusion and recommended that CMS work with Congress to revise the statute to make all orphan drugs eligible as qualifying single source drugs.

Response: CMS thanks the commenter for the feedback.

Comment: A few commenters acknowledged that CMS has limited discretion in implementing the Orphan Drug Exclusion but asserted that CMS should alleviate concerns that the Orphan Drug Exclusion will hinder innovation by revising its qualifying single source drug definition so that qualifying single source drugs are aggregated by only one NDA / BLA rather than by active moiety / active ingredient.

Response: CMS thanks the commenters for sharing this perspective. For the reasons stated above in our responses to comments on section 30.1, CMS maintains in this final guidance the approach described in the draft guidance for identifying potential qualifying single source drugs.

Comment: One commenter requested that CMS engage in meaningful dialogue with patient-centered organizations to preserve the balance in incentives and risks supporting rare and ultra-rare disease treatments. This commenter also requested this dialogue include discussion of how the Center for Medicare and Medicaid Innovation (CMMI) and CMS' general demonstration authority can support incentives for rare and ultra-rare disease treatments. Another commenter expressed disappointment that CMS removed a statement that appeared in the revised guidance for initial price applicability year 2026 noting that CMS would consider actions it can take in implementing the Negotiation Program to best support orphan drug development.

Response: CMS is committed to actively engaging with interested parties on all aspects of Negotiation Program, including on its implementation of the Orphan Drug Exclusion and on actions it can take to support orphan drug development within the scope of the Negotiation Program. CMS has clarified in section 30.1.1 of this final guidance that CMS continues to evaluate whether there are additional actions the agency can take in its implementation of the Negotiation Program to best support orphan drug development. CMS encourages interested parties to direct further feedback, queries, or meeting requests to the IRA mailbox (IRARebateandNegotiation@cms.hhs.gov). This specific request related to CMMI and CMS' general demonstration authority, however, is outside the scope of this final guidance.

Comment: Some 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 designation. To alleviate this concern, commenters recommended that CMS consult with FDA and consider written communications between FDA and the manufacturer during the review and approval process. Commenters also suggested that CMS 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.

Bona Fide Marketing (Sections 30, 60.7, 70, and 90.4)

Comment: Many commenters stated that CMS lacks statutory authority to address "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 also asserted that CMS lacks statutory authority to review product utilization or volume-based assessments or assess "robust and meaningful competition" as part of a determination of whether a generic or biosimilar is "marketed." In addition, these commenters stated that "marketing" is already a term defined in the pharmaceutical industry, including by

FDA and CMS. 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 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 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 73 of the revised guidance for initial price applicability year 2026, 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. Congress purposefully used different terminology in section 1192 of the Act than it did in section 1860D-14B of the Act, which established the new Medicare Part D Drug Inflation Rebate Program. In the latter provision, Congress 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, Congress contemplated that 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 remove the MFP for a selected drug only when there is evidence that the selected drug or biological product 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 in the way envisioned by Congress.

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 and a few other commenters shared support for the bona fide marketing review. 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, in addition to when determinations for insurance coverage are made. One commenter suggested CMS consider other sources of data or specific codes within PDE data, if available, such as the National Council for Prescription Drug Programs (NCPDP) Dispense as Written Code to indicate the multi-source status of a drug, and another commenter suggested that CMS should consider listings in a pharmaceutical compendia or Federal sources (e.g., the National Institutes of Health's DailyMed) as a "certification" of marketing of the generic or biosimilar. One commenter cautioned CMS about errors and incomplete information within the FDA Orange Book and the FDA Purple Book. Another commenter encouraged a holistic approach that would address concerns of manufacturer gaming of product availability to ensure the availability of generics beyond prescription data. One commenter expressed support for considering the existence of anti-competitive agreements as part of the bona fide marketing determination.

Response: CMS thanks commenters for these concerns and suggestions of additional sources that may include useful information to demonstrate bona fide marketing of a generic drug or biosimilar. Consistent with CMS' response on pages 76 through 78 of the revised guidance for initial price applicability year 2026, CMS reiterates that, for the purposes of the Negotiation Program, the statute instructs CMS to make a determination whether a generic drug or biosimilar "is marketed," which requires a determination whether the generic drug or biosimilar has a continuing presence on the market. Additionally, 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. Manufacturers of selected drugs can provide evidence to CMS regarding the market for the generic drug or biosimilar versions of their selected drug(s) to inform CMS' monitoring for bona fide marketing before drug selections are made, to inform a determination of removal from the selected drug list, or after removal from the selected drug list.

While CMS appreciates commenters' concerns regarding the time lag between a generic drug or biosimilar's availability and the ability to detect it in PDE data resulting from coverage determinations and filled Part D prescriptions, CMS understands that generally this timing lag is relatively short as Part D plans are instructed to submit original PDEs to CMS within 30 days following the date the claim is received or date of service (whichever is greater) and the average

turnaround time to date of submission is fewer days.[13] Average Manufacturer Price (AMP) data may capture sales transactions in the supply chain in situations when coverage and use of the generic drugs or biosimilars in Part D plans has not yet become evident in the PDE data.

Finally, CMS reiterates that CMS intends to monitor actual conditions in the marketplace through PDE and AMP data and CMS may consult with the FTC to identify the types of agreements or arrangements that limit competition.

Comment: One commenter requested clarification as to whether a biosimilar must carry all indications of the reference product to be considered marketed under the Negotiation Program, adding that FDA requirements would not require carrying every indication to gain FDA approval.

Response: CMS thanks the commenter for the question. A generic drug or biosimilar approved for fewer than all of the FDA-approved indications as the listed drug or reference product may be considered marketed for purposes of the Negotiation Program. That is, a CMS finding of bona fide marketing does not require that the generic drug or the biosimilar is labeled with all of the FDA-approved indications as its listed drug or reference product. 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 2027. CMS directs interested parties to the additional information regarding dates provided in section 70 for removal of a selected drug from selection.

Comment: One commenter suggested that CMS does not have the statutory authority to revisit the determination of whether a drug meets the definition of a qualifying single source drug through monitoring for bona fide marketing after CMS determined that a drug is not a qualifying single source drug or a selected drug is removed from the Negotiation Program. The commenter further stated that after a selected drug ceases to be a selected drug, the CMS / Primary Manufacturer agreement is terminated and there is no basis to restore the product as a selected drug or enter into a new section 1193 Agreement.

Response: CMS agrees with the commenter that the Agreement would cease when a drug is determined to not be a qualifying single source drug or if a selected drug is removed from the selected drug list. However, CMS disagrees that section 1193 of the Act does not provide authority to CMS to enter into a new Agreement with the Primary Manufacturer if such drug is determined to be a qualifying single source drug and a selected drug in a different initial price applicability year.

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

[13] See: https://www.hhs.gov/guidance/document/revision-previous-guidance-titled-timely-submission-prescription-drug-event-pde-records.

Comment: One commenter urged CMS to strictly adopt language in accordance with section 1192(e)(3)(C) of the Act rather than refer to approved product labeling to determine if products fall within the plasma-derived product exclusion. This commenter recommended CMS look to other FDA resources like the Approved Cellular and Gene Therapy Products website[14] to determine if other plasma-derived products fall within the exclusion. Additionally, one commenter supported CMS' exclusion of plasma-derived products when identifying qualifying single source drugs.

Response: CMS thanks commenters for this feedback. CMS continues to believe that referring to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[15] and databases such as FDALabel and the FDA Online Label Repository[16] are the best ways to identify plasma-derived products for the purpose of implementing the Plasma-Derived Product Exclusion in a consistent manner. As stated in CMS' response on page 18 of the revised guidance for initial price applicability year 2026, 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.[17] Cellular and gene therapies will be assessed for the Plasma-Derived Product Exclusion using the same criteria applicable to other biological products.

Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2027 (Section 30.2)

Comment: One commenter expressed concern with CMS' use of "gross covered prescription drug costs" to identify and rank negotiation-eligible drugs. The commenter argued that CMS had "reinterpreted" the regulatory definition of "gross covered prescription drug costs" at 42 C.F.R. § 423.308 (see 88 Fed. Reg. 22120, 22261 (April 12, 2023) (amending "gross covered prescription drug costs" definition at 42 C.F.R. § 423.308) and cited 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 the discounts that Part D plans currently secure on these same products. The commenter suggested CMS revert to the regulatory definition that was in effect when the Negotiation Program was enacted.

Response: In responding to this comment, 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 commenter's concern about the impacts of excluding price concessions and other rebates when identifying and ranking

[14] See: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.
[15] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[16] FDALabel: https://nctr-crs.fda.gov/fdalabel/ui/search; FDA Online Label Repository: https://labels.fda.gov/.
[17] See: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products.

negotiation-eligible drugs. Consistent with the approach discussed in CMS' response on page 18 of the revised guidance for initial price applicability year 2026, in identifying and ranking the negotiation-eligible drugs for initial price applicability year 2027, 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). 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. 22,120, 22,259-22263 (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.

Small Biotech Exception (Section 30.2.1)

Comment: One commenter expressed support for the Small Biotech Exception (SBE) and the individual evaluation of a manufacturer and its portfolio to determine SBE and qualifying single source drug eligibility.

Response: CMS thanks the commenter for the feedback.

Comment: A few commenters requested that CMS create a dispute resolution process so that a manufacturer that disagrees with CMS' determination of its eligibility for the SBE can dispute this determination. One commenter requested that CMS allow companies to provide additional data through a dispute resolution process to support their application for the exception. A couple of commenters requested that CMS initiate the SBE request submission and review process earlier to allow a dispute resolution process to conclude before the selected drug publication date for initial price applicability year 2027. One commenter requested a Submitting Manufacturer be able to resolve outstanding issues with an application if the application is incomplete or unclear to CMS.

Response: CMS thanks these commenters for their recommendations. CMS declines at this time to create a dispute resolution process for the SBE. 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. Finally, as discussed in CMS' response on page 19 of the revised guidance for initial price applicability year 2026, CMS believes that CMS requests all information necessary to determine eligibility for the SBE in the "Small Biotech Exception and

Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027" (CMS-10844, OMB 0938-1443) (hereinafter the "SBE and Biosimilar Delay ICR").

CMS is providing another opportunity for interested party engagement in October 2024 by providing a 30-day public comment period for stakeholders to make additional suggestions to improve the information collection on a revised form and supporting statement. This comment period will close in November 2024.[18] We will continue monitoring SBE information collection and process and make improvements as need for 2028.

Comment: A few commenters suggested that CMS provide more flexibility and engagement with manufacturers seeking the SBE to ensure complete and accurate data submissions. One commenter stated that this is needed so that the exception is workable for the small companies it was created to support.

Response: CMS thanks these commenters for their recommendations. CMS provided a 60-day and 30-day comment period for interested parties to provide feedback for the SBE and Biosimilar Delay ICR. In addition, CMS provided a 60-day comment period to respond to SBE policies included in the draft guidance. CMS believes these comment periods for initial price applicability year 2027, which build on public feedback provided in comment periods for policy guidance and the SBE ICR Form for initial price applicability year 2026, have provided sufficient opportunities for interested parties to share their feedback and other relevant information to CMS for its consideration. Similar to the approach for SBE request submissions for initial price applicability year 2026, CMS will provide technical assistance for access and use of the CMS HPMS and a user guide for SBE request submission via the CMS HPMS.

Comment: A couple of commenters requested further detail on the SBE for initial price applicability year 2028. Commenters also recommended that CMS introduce a streamlined application for manufacturers that had previously received the exception, and one commenter suggested previous applicants should only provide updated information to CMS. One commenter requested that CMS establish a permanent SBE.

Response: This final guidance establishes the policies CMS will use to implement the Negotiation Program for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027. Consistent with CMS' response on page 19 of the revised guidance for initial price applicability year 2026, 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 will share the submission process for the SBE for initial price applicability year 2028 in future guidance and ICR materials and appreciates the feedback received from commenters. CMS must provide separate information for each of these

[18] To view the SBE and Biosimilar Delay ICR Forms available for a 30-day public comment period, and a summary of changes made to the proposed 30-day SBE ICR Form for initial price applicability year 2027 in comparison to the 60-day SBE ICR Form proposed for initial price applicability year 2027 (CMS-10844, OMB 0938-1443), see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016. The 30-day notice for public comment for initial price applicability year 2027 includes the SBE ICR and the Biosimilar Delay ICR Forms in the same Federal Register notice (see section 30.3.1 of this final guidance). CMS believes that combining these ICR Forms into one notice will streamline review of these documents for interested parties.

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 covered under Part B starting with initial price applicability year 2028. The statute provides for an SBE only for initial price applicability years 2026, 2027, and 2028 and CMS does not have the authority to establish a permanent SBE.

Selection of Drugs for Negotiation for Initial Price Applicability Year 2027 (Section 30.3)

Comment: A few commenters requested greater transparency into the process of selecting drugs for negotiation. A couple 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. A couple commenters 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. Another commenter recommended CMS update the Medicare Part D Spending Dashboard quarterly, which they assert would enhance transparency around the drug selection process. This commenter argued that the Dashboard proved to be an unreliable indicator of which drugs would be selected for negotiation for initial price applicability year 2026 because the reference period for initial price applicability 2026 was June 1, 2022 to May 31, 2023, but the Dashboard—which the commenter stated was the only publicly available data to potentially indicate which drugs might be selected—contained data from 2021.

Response: CMS thanks the commenters for sharing their perspectives. The statute requires that CMS publish the selected drug list no later than February 1, 2025 for initial price applicability year 2027. Similar to CMS' response on pages 20 and 21 of the revised guidance for initial price applicability year 2026, 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, 2025. For example, section 1192(d)(1)(A) of the Act requires that CMS identify negotiation-eligible drugs for initial price applicability year 2027 using Total Expenditure data during the most recent 12-month period for which data are available prior to February 1, 2025. 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, 2023 and October 31, 2024. 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 have been submitted to CMS by November 30, 2024. 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 2027.

CMS appreciates feedback received on the Part D Drug Spending Dashboard. Consistent with CMS' response on page 26 of the revised guidance for initial price applicability year 2026, this dashboard allows 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. CMS plans to continue its annual updates to the Drug Spending Dashboards to provide the public with comprehensive data on trends related to drug spending for Medicare and Medicaid.[19]

Biosimilar Delay (Section 30.3.1)

General

Comment: A few commenters expressed support for the Biosimilar Delay application process.

Response: CMS thanks these commenters for the feedback.

Timing and Notice (Section 30.3.1)

Comment: One commenter raised concerns about the timing requirements for licensure of a Biosimilar[20] and requested that CMS consider revising that a high likelihood of licensure within two years of the relevant selected drug publication date be distinct from actual licensure of a Biosimilar due to the overlay of timing constraints of the FDA BLA review and approval process and the PHS Act's regulatory exclusivity provisions under Title 42, section 262. The commenter noted that more than one year is common between licensure and marketing due to the length of patent disputes. A couple of commenters requested that CMS make the delay request application deadline as close as possible to the selected drug publication date so that manufacturers may provide the best available information for the consideration of the application and requested that CMS permit broad supplementation of any additional information recently available or otherwise for good cause. One commenter expressed support for the January 15, 2025 deadline by which a BLA must be accepted for review or approved by the FDA as provided in section 30.3.1 of this final guidance.

Response: Consistent with CMS' response on page 25 of the revised guidance for initial price applicability year 2026 and in response to a similar comment to the 60-day SBE and Biosimilar Delay ICR for initial price applicability year 2027 (CMS-10844, OMB 0938-1443), CMS thanks these commenters for their feedback and reiterates that the statute is clear that an Initial Delay Request submitted with respect to initial price applicability year 2027 must demonstrate that there is a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2027. Further, the Initial Delay Request deadline has already 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 section 30.3.1.4 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 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.

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

[20] As defined in section 30.3.1 of this final guidance, 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 herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year.

Regarding commenters' requests that CMS permit broad supplementation of a timely request, CMS believes that the timeline described in section 30.3.1 of this final guidance and the SBE and Biosimilar Delay ICR allows Biosimilar Manufacturers sufficient opportunity to provide CMS with information during the Initial Delay Request process. CMS believes the SBE and Biosimilar Delay ICR asks for all information CMS needs to adjudicate Initial Delay Requests within the limitations of what statute allows CMS to consider.

Comment: A couple of commenters suggested that CMS provide greater transparency with the requirements related to the Biosimilar Delay and one commenter requested that CMS' implementation of the Biosimilar Delay promote predictability in the biosimilar marketplace. 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 Biosimilar Manufacturer, 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 Biosimilar Manufacturers 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 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. Finally, a couple commenters requested that CMS provide the underlying data used for the basis of qualifying single source drug and negotiation-eligible drug determinations. A commenter also requested timely publishing of a list of all reference products for which Biosimilar Delay requests were submitted.

Response: CMS thanks the commenters for their suggestions. The final guidance describes the timing for Biosimilar Manufacturer notice based on a set timeline in the statute and operational constraints related to the drug selection process. These timing and operational constraints do not allow for any additional notice. CMS provided a 60-day comment period and will provide a 30-day comment period for interested parties to provide feedback to the SBE and Biosimilar Delay ICR. In addition, CMS provided a 60-day comment period to respond to Biosimilar Delay policies included in the draft guidance. CMS believes these comment periods for initial price applicability year 2027, which build on public feedback provided in comment periods for policy guidance and the ICR for initial price applicability year 2026, provided sufficient opportunity for stakeholders to share their feedback and other relevant information with CMS for its consideration.

Comment: One commenter requested CMS notify the Reference Manufacturer and delay selection of the Reference Drug, while reviewing the requested information. Relatedly, a few commenters requested that CMS provide notice of its determination for a Biosimilar Delay in advance of the selected drug publication date.

Response: Information regarding the timing for manufacturer notice is included in section 30.3.1 of this final guidance. This timeline allows manufacturers the opportunity to provide information to CMS and allows CMS to review data, request additional information if needed, and make a

well-informed decision. This timeline, in addition to operational constraints, does not allow for additional notices or flexibility.

Documentation for a Request (Section 30.3.1)

Comment: One commenter requested that CMS accept and consider all information that the Biosimilar Manufacturer determines to be relevant to the request. Another commenter requested CMS review Biosimilar Manufacturer production plans to determine if an agreement incentive exists that would disqualify a request for a Biosimilar Delay due to production volume. Additionally, a few commenters requested that CMS clarify the types and terms of agreement incentives that would disqualify a request. Another commenter suggested that CMS evaluate any agreement between the Biosimilar Manufacturer and the Reference Manufacturer to determine if anti-competitive terms exist.

Response: CMS thanks the commenters for these recommendations. As stated on page 25 of the revised guidance for initial price applicability year 2026, CMS reiterates that, consistent with section 1192(f)(2)(D)(iv)(II) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will use information from the following sources when assessing whether there is clear and convincing evidence that the Biosimilar will be marketed before February 1, 2027:

- 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;
- 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 (SEC) required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the two years, as applicable) before marketing of a biosimilar biological product.

High Likelihood (Section 30.3.1.2)

Comment: A few commenters expressed general support for the policies provided in section 30.3.1.2 of draft guidance regarding the review for a "high likelihood" of marketing. Some commenters requested that CMS revise its policies regarding determination of a high likelihood of marketing. One commenter recommended that CMS distinguish high likelihood of licensure and marketing from the actual events of licensure and marketing. A few commenters stated that the approach described in the draft guidance is inconsistent with the statute, unclear, and overly rigid.

Response: CMS thanks these commenters for their feedback related to the high likelihood determination. Consistent with our response on page 22 of the revised guidance for initial price

applicability year 2026, section 30.3.1.2 of this final guidance aligns with the statutory language which requires CMS to identify whether a Biosimilar has a high likelihood of being licensed and marketed within two years after the publication of the selected drug list. CMS believes the information detailed in section 30.3.1.2 of this final guidance will allow CMS to implement the high likelihood provision of the Biosimilar Delay in a manner that benefits the Medicare program by minimizing the likelihood of CMS approving a delay request for a Biosimilar that is not highly likely to become licensed and marketed within two years after the publication of the selected drug list. Further, CMS believes this approach will support robust biosimilar competition.

Comment: One commenter stated that section 1192(f) of the Act does not require a certain level of market penetration for CMS to determine that there is a high likelihood that a Biosimilar will be licensed and marketed before February 1, 2027.

Response: CMS clarifies in section 30.3.1 of this final guidance that, consistent with the consideration of "marketing" generally under this Negotiation Program, review of marketing in the context of the Biosimilar Delay is the determination of whether the Biosimilar Manufacturer has engaged in bona fide marketing of the Biosimilar for purposes of section 1192(f)(2)(D)(iii) of the Act, or that there is a high likelihood that the Biosimilar Manufacturer will engage in bona fide marketing of the Biosimilar for purposes of sections 1192(f)(1)(A) and 1192(f)(2)(B) of the Act. Consistent with CMS' response to comments received about bona fide marketing generally (see pages 21 and 22 of this final guidance), and based on the terminology used in section 1192 of the Act, for purposes of the Negotiation Program, CMS will consider whether meaningful competition exists on an ongoing basis between a reference product and a Biosimilar and not just availability of the Biosimilar. For example, for CMS to provide a Biosimilar Delay for the Biosimilar, section 1192(f)(1)(A) of the Act requires the Secretary to determine that there is a high likelihood that the Biosimilar "will be licensed and marketed" within two years of the selected drug publication date for the initial price applicability year. Section 1192(f)(1)(B)(ii)(III)(bb) of the Act states that information and documents necessary for the Secretary to make this determination include a Biosimilar Manufacturer's disclosures "that pertain to the marketing of such biosimilar biological product," including, further, disclosures about "capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing" of the Biosimilar that pertain to marketing of the Biosimilar. The Negotiation Program statute does not refer to when a product is "first marketed" (as in section 1860D-14B of the Act, which established the new Medicare Part D Drug Inflation Rebate Program), nor does it refer to the availability of a product.

As described in section 30.1 of this final guidance, CMS will use a holistic inquiry to determine if bona fide marketing of the Biosimilar exists, if there is a high likelihood of bona fide marketing of the Biosimilar, or if the Biosimilar named in a successful Initial Delay Request has been licensed and engaged in bona fide marketing during the initial delay period, as applicable.

Comment: Some commenters requested CMS consider additional criteria and documentation to determine if there is a high likelihood that a Biosimilar will be licensed and marketed before February 1, 2027. Suggestions included, but were not limited to: USPTO decisions or other

documentation that inform a determination of the invalidity, unenforceability, or noninfringement of any potentially applicable unexpired patent; a legal agreement that permits the marketing of the Biosimilar; and an attestation that the court has not issued any injunction preventing launch by the date that is two years after the selected drug date. These commenters suggested that CMS has broad discretion to determine what information and documents constitute "clear and convincing evidence" under section 1192(f)(1)(A) of the Act to support a determination of high likelihood. Additionally, one commenter stated that additional information is needed to support a high likelihood determination because, the comment argues, there are statutory limitations on the timing to file a BLA with the FDA and patent and settlement negotiations may be lengthy. One commenter also suggested that after CMS considers all sources to ascertain a high likelihood of marketing, if there is any uncertainty regarding the possibility of launch and marketing in the required time frame, CMS resolve the uncertainty against the applicant and not provide the Biosimilar Delay.

Response: CMS thanks commenters for the recommendations. After considering comments and conducting further review, CMS understands that many patent disputes involving biosimilars are adjudicated by the USPTO's Patent Trial and Appeal Board (PTAB), in addition to the traditional forum of federal court. Because both are common venues for resolving patent disputes between biosimilar and reference product sponsors, CMS is updating the guidance to include the consideration of PTAB decisions when reviewing whether a patent is unlikely to prevent the Biosimilar from entering the market. In section 30.3.1.2 of this final guidance, CMS clarifies that CMS will consider PTAB decisions, in addition to court decisions, that establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patents relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar (refer to the second bulleted item listed on page 183 of this final guidance in section 30.3.1.2). Additionally, CMS will consider submitted information to determine whether patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed as described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act. For the comments related to other forms of documentation as criteria for biosimilar applicants, CMS will continue to consider these forms of documentation for future years of the Negotiation Program but otherwise retains the draft guidance approach for Initial Delay Requests in initial price applicability year 2027.

Comment: One commenter asked for clarification of "active litigation" from the following statement from page 26 of the draft guidance, "active litigation related to another reference product included in the Reference Drug that is not applicable to the Biosimilar will not be disqualifying."

Response: CMS recognizes that the term "active litigation" caused confusion for readers and has removed the language from section 30.3.1 of this final guidance. To clarify CMS' approach, if a court or PTAB decision has established the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent asserted as applicable to the Biosimilar, and that court or PTAB decision is pending before an adjudicator on appeal, CMS will not consider the fact that an appeal is ongoing as disqualifying; that is, CMS will consider the latest court or PTAB decision available at the time of the Biosimilar Delay request, as described in information submitted by the Biosimilar Manufacturer described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III)

of the Act, without regard to whether that court or PTAB decision is pending before an adjudicator on appeal.

Comment: A few commenters suggested that CMS clarify additional circumstances that would meet a "high likelihood" of licensure, in conjunction with the FDA, including whether the Biosimilar Manufacturer had a successful Biological Product Development Type 4 Meeting with FDA. One commenter requested that CMS include an additional option that permits the Biosimilar Manufacturer to select that the Biosimilar Manufacturer intends to submit a BLA to FDA by February 1, 2027. One commenter also suggested the following examples of such additional circumstances: the FDA's views of data and information submitted in the BLA; FDA communications about BLA status; the Biosimilar Manufacturer's production and distribution arrangements and progress; and other information the Biosimilar Manufacturer believes may be relevant to the request determination.

Response: CMS thanks commenters for their feedback. Consistent with CMS' response on page 23 of the revised guidance for initial price applicability year 2026, CMS believes that section 30.3.1.2 of this final guidance aligns with the statutory language and does not find reason to allow for additional circumstances that would meet the licensure component of the high likelihood determination.

Comment: One commenter requested that CMS clarify the meaning of the phrase "reference product included in the Reference Drug," or alternatively replace the phrase with the language "presentation included in the Reference Drug." One commenter requested clarification that a patent settlement does not need to include all dosage forms, strengths, and indications for which the reference drug has received approval. Relatedly, one commenter requested that CMS clarify that if a Biosimilar Manufacturer has carved out a patent-protected indication or method of use from the Biosimilar's labeling, then such patents would not be considered "applicable to the Biosimilar," and, therefore, will not be considered in this analysis consistent with the approach set forth in the summary of public comments in the revised guidance for initial price applicability year 2026.

Response: As described in section 30.3.1 of this final guidance, a Reference Drug is a negotiation-eligible drug that includes the reference product for the Biosimilar. In relevant part, section 351(i)(4) of the PHS Act defines "reference product" as "the single biological product licensed under [section 351(a) of the PHS Act] against which a [biosimilar] biological product is evaluated." Depending on the Reference Drug, it is possible that the Reference Drug is the reference product for the Biosimilar, for example if the Reference Drug includes only one biological product, which is identified as the reference product for the Biosimilar. Alternatively, it is also possible that the Reference Drug includes, for example, multiple biological products with the same active ingredient held by the same BLA holder, and only one such biological product is identified as the reference product for the Biosimilar per the definition of "reference product" in the PHS Act.

Consistent with CMS' response on page 24 of the revised guidance for initial price applicability year 2026, in order for CMS to grant an Initial Delay Request, the Biosimilar licensure application does not need to include all of the dosage forms, strengths, and indications for which

the Reference Drug has received approval. Further, CMS will only consider patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. CMS clarifies within section 30.3.1.2 of this final guidance that if a Biosimilar Manufacturer has obtained licensure with biosimilar labeling that omits a patent-protected indication or other patent protected information, then patents that cover the omitted indication or the omitted information would not be considered to be "applicable to the Biosimilar." CMS also reiterates that an Initial Delay Request for initial price applicability year 2027 must meet only one of the following criteria to satisfy the patent-related component of the high likelihood determination: (1) there are 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 USPTO's 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 (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before February 1, 2027 without imposing improper constraints on the Biosimilar Manufacturer.

Review of Approved Initial Delay Requests (Section 30.3.1)

Comment: One commenter suggested that the date by which CMS determines whether each biosimilar named in a successful Initial Delay Request for initial price applicability year 2027 has met the licensing and marketing requirements during the delay period be as late as possible prior to the drug selection for initial price applicability year 2028, specifically recommending January 15, 2026, to ensure that drugs that are licensed and marketed are included in the drug selection process. The same commenter requested that the agency promptly notify the Biosimilar Manufacturer of a determination that the Biosimilar has been licensed and marketed during the Initial Delay Request period within three days of the determination.

Response: CMS appreciates the comment. CMS includes the date for notification in section 30.3.1 of this final guidance. 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 2027, 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, 2025. CMS is specifying the notification date based on the comments received and operational considerations to allow for sufficient notice prior to the publication of the selected drug list for initial price applicability year 2028. CMS also considered the time needed for a Biosimilar Manufacturer to submit an Additional Delay Request, and for CMS to review such a request prior to publication of the selected drug list for initial price applicability year 2028.

Comment Solicitation for Criteria for Additional Delay Requests (Section 30.3.1)

Comment: Many commenters provided suggestions in response to CMS' request for comment regarding the types of documentation and information that may constitute "clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress…towards both such licensure and the marketing of such biosimilar biological product" under section 1192(f)(2)(B)(i)(II) of the Act for Additional Delay Requests.

A few commenters suggested that CMS should retain flexibility for the second year of biosimilar marketing review to reduce manufacturer burden. Specifically, these comments suggested: CMS should focus on the absence of new evidence of an inability to come to market, such as manufacturing scheduling changes beyond the two-year time frame; CMS should focus on negative FDA action without corresponding correction or resubmission of a BLA; and CMS should accept attestation from the Biosimilar Manufacturer that sufficient progress has been made toward marketing. These commenters requested that CMS consider as a safeguard section 1192(f)(2)(C)(II) of the Act regarding manufacturer rebates if an Additional Delay Request was granted and the drug did not come to market. One commenter suggested that a Biosimilar Manufacturer should be able to attest that progress has been made towards marketing to determine eligibility for an Additional Delay Request. One commenter also requested that CMS provide criteria for Additional Delay Requests in the final guidance for initial price applicability year 2027 and another commenter requested that CMS clarify the criteria to establish "clear and convincing evidence" to provide sufficient notice to Biosimilar Manufacturers. Finally, one commenter expressed support for CMS efforts to establish such criteria.

Response: CMS thanks commenters for their suggestions related to the request for soliciting comment regarding the types of documentation and information that may constitute "clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress towards both such licensure and the marketing of such biosimilar biological product" under section 1192(f)(2)(B)(i)(II) of the Act. CMS will consider these suggestions in CMS' policy development for this issue in future guidance or rulemaking.

Medicare Drug Price Negotiation Program Agreement (Section 40, 40.1)

Comment: A couple of commenters stated that CMS has arbitrarily offered conflicting interpretations of what entities qualify as a manufacturer for purposes of the Negotiation Program by imposing responsibility and liability on Primary Manufacturers while simultaneously asserting that only a subsidiary corporation listed on an FDA application has standing to sue.

Response: As discussed in CMS' response on page 28 of the revised guidance for initial price applicability year 2026, section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug, and the phrase "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 negotiating the maximum fair price for a given selected drug. As described in section 40 of this final guidance and pursuant to section 1191(c)(1) 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 2026, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" (referred to in this final guidance as the Primary Manufacturer) of the selected drug. CMS notes that the agency does not comment on ongoing litigation.

Comment: One commenter recommended that CMS use the unique product labeler ID assigned to each manufacturer by the FDA to identify the Primary Manufacturer instead of the holder of the NDA / BLA.

Response: CMS continues to believe that identification of the holder of the NDA / BLA reflects the best interpretation of the statute. As discussed in CMS' response on page 31 of the revised guidance for initial price applicability year 2026, when an application to market a new drug or biological product for human use is submitted to the FDA, the NDA / BLA that is submitted lists only one sponsor. The policy for identifying the Primary Manufacturer with responsibility for the selected drug based on the holder of the NDA / BLA for the selected drug under the Negotiation Program is consistent with the FDA regulatory framework under which the single sponsor of the NDA / BLA in its application describes the manufacturing process and lists the facilities that will produce the sponsor's product. In section 1191(c)(1) of the Act, the statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. CMS understands that the holder of an NDA or BLA can enter into agreements regarding the sale of drugs approved under a particular NDA or BLA with other entities that may also meet this statutory definition of "manufacturer." CMS must find a mechanism to identify the appropriate manufacturer for purposes of negotiation and ensure other aspects of the Negotiation Program apply to the selected drug. In addition, section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug and 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 negotiating the maximum fair price for a given selected drug. Thus, the most effective way to determine the "manufacturer" described in section 40 of this final guidance, and the signatory of the Agreement, is to identify the NDA / BLA holder as the Primary Manufacturer.

Comment: Some commenters stated that CMS should remove requirements on Primary Manufacturers pertaining to Secondary Manufacturers and require any Secondary Manufacturer of a selected product comply with the IRA and final guidance on its own accord. One commenter recommended that CMS should enter into separate agreements with each manufacturer, whether a Primary Manufacturer or Secondary Manufacturer, and argued that the statute already anticipates multiple agreements with multiple manufacturers.

Response: As discussed in CMS' response on page 32 of the revised guidance for initial price applicability year 2026, 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 negotiating 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).

Comment: One commenter stated that CMS should publicly announce if a Primary Manufacturer chooses not to participate in the Negotiation Program expediently to help ensure that beneficiaries, caregivers, pharmacies, and other affected parties are aware of the Primary Manufacturer's decision.

Response: As described in section 40.1 of the final guidance, a Primary Manufacturer may determine not to enter into an Agreement for the Negotiation Program and instead take steps to exit the Medicare and Medicaid programs. Consistent with CMS' approach for initial price applicability year 2026, CMS' announcement of the selected drugs for initial price applicability year 2027 will include the names of the Primary Manufacturer for each selected drug. CMS will publicly announce, as soon as practicable, the Primary Manufacturer of each selected drug that enters into an Agreement for the Negotiation Program.

Manufacturer Data Submission, Proprietary Information, and Confidentiality (Section 40.2)

Commenter: One commenter suggested that CMS should consider the potential NDC format change from 11 digits to 12 digits as the agency designs program system capabilities.

Response: CMS thanks this commenter for their input and will take the comment under advisement as CMS considers policies for future years of the Negotiation Program.

Comment: One commenter recommended that CMS consider whether the information received is truly proprietary and a couple of commenters encouraged CMS to publish as much information as possible to keep the public informed.

Response: CMS thanks these commenters for their recommendations. CMS described in section 40.2.1 of the final guidance the information CMS will keep confidential. Consistent with CMS' response on page 35 of the revised guidance for initial price applicability year 2026, CMS developed its policies pertaining to what information CMS will keep confidential and for how long in the interest of balancing transparency and confidentiality. As described in section 40.2.2 and 60.6.1 of this final guidance, as a part of the public explanation of the MFP published not later than March 1, 2025, 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, exchange of offers and counteroffers, and the negotiation meetings. CMS maintains that any information submitted by manufacturers that constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer will be considered proprietary and will be redacted.

Comment: One commenter expressed support for CMS using the standard of Freedom of Information Act (FOIA) Exemptions 3 and/or 4 for the purposes of redacting information that constitutes specific information as proprietary. A couple of commenters supported the list of

specific information that CMS has deemed to be proprietary. One commenter recommended that Primary Manufacturers have the opportunity to designate their own information as proprietary or confidential.

Response: CMS thanks these commenters for their feedback. CMS understands commenters' concerns pertaining to the confidentiality of proprietary information and will protect confidential and proprietary information as required by applicable law and as set forth in this final guidance. CMS notes that 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 40.2.2 of this final guidance.

Comment: Two commenters asked CMS to explain how it will protect a Primary Manufacturer's confidential information and establish robust safeguards to ensure that the agency is adequately handling proprietary information submitted as part of the negotiation process.

Response: CMS thanks these commenters for their comments on safeguarding data submitted by manufacturers. Over the course of the negotiation process, Primary Manufacturers will submit information to CMS via the CMS HPMS or, in some instances, Box.[21] 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.

As discussed in CMS' response on pages 38-39 of the revised guidance for initial price applicability year 2026, 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

[21] Please see CISO Memo: Guidance for Using Collaborative Tools for more information on how CMS stakeholders can keep information secure.

assessment to ensure that the system's security controls meet the CMS Acceptable Risk Safeguards (ARS).

An individual must apply for and obtain a CMS-issued user account and password to access the CMS HPMS. In addition to the CMS-issued user ID and password, internal CMS staff must use an HHS identification badge (referred to as a "PIV card") when accessing the website on the CMS network, while all users accessing the system from outside of the CMS network must use multi-factor authentication. The CMS HPMS further employs role-based access, ensuring that each user is granted access only to those functions required by their position.

The CMS HPMS is hosted at a CMS approved cloud service provider. The 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.

Comment: One commenter recommended that CMS limit access of confidential information to CMS staff on a "need-to-know" basis.

Response: CMS affirms 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, 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.

Commenter: A couple of commenters raised concern that the disclosure of information by Primary Manufacturers regarding ongoing negotiations could negatively impact a Part D plan sponsor's negotiation process for non-selected Part D drugs and asked CMS to highlight the antitrust implications for other markets. These commenters asked CMS to consider limiting disclosure of negotiation information to limit anti-competitive impacts.

Response: CMS thanks these commenters for their input. In the interest of balancing transparency and confidentiality, CMS described in section 40.2.2 of the final guidance its policies for the discussion of information during the negotiation process. As stated in section 40.2.2, information exchanges by the Primary Manufacturer during the negotiation process concerning confidential and strategic business negotiations, if made public by the Primary Manufacturer or discussed with other manufacturers, may violate the antitrust laws under certain

circumstances and lead to other anticompetitive agreements outside of the Negotiation Program. Primary Manufacturers should consider the antitrust implications of any such actions. CMS defers to the Department of Justice (DOJ) and the FTC to review any possible violations of applicable antitrust laws.

As described in section 60.6 of this final guidance, CMS will publish the selected drug, the initial price applicability year, the MFP file, and the explanation for the MFP on the CMS website. The explanation of the MFP, 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.

Providing Access to the MFP in 2026 and 2027 (Section 40.4 and 90.2)[22]

Comment: Some commenters expressed concern that pharmacies would be reimbursed by Part D plan sponsors and PBMs below the MFP for selected drugs. These commenters requested that CMS ensure Part D plan sponsors and PBMs reimburse pharmacies at the MFP, plus a dispensing fee, and without pharmacy price concessions. A few commenters suggested that CMS require that plan reimbursement for selected drugs include a professional dispensing fee commensurate with Medicaid fee-for-service, and one commenter recommended CMS require enhanced dispensing fees for selected drugs to cover increased operating costs of pharmacies related to dispensing selected drugs, such as managing inventory and reporting to manufacturers. Another commenter recommended CMS monitor and audit dispensing fee arrangements to ensure that plans are recognizing and covering new pharmacy operating costs associated with dispensing selected drugs.

Response: CMS thanks these commenters for their recommendations. CMS shares these commenters' concerns regarding the potential impact on pharmacy revenue upon availability of MFPs for selected drugs in 2026 and 2027. CMS will work to ensure plans and PBMs 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, 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 page 42 of the revised

[22] CMS notes that the section headings for the summary of public comments received in response to the draft guidance are based on the sections included in the draft guidance, but the section 40.4 headings and subheadings have been updated in final guidance.

guidance for initial price applicability year 2026, 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 also 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.

As described in section 90.2.2 of this final guidance, CMS will establish a centralized intake system for receiving reports, including complaints, related to access to the MFP, including with respect to the pharmacies, mail order services, and dispensing entities that provide selected drugs to MFP-eligible individuals. 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. Furthermore, CMS intends to closely monitor plan reimbursement for selected drugs including pharmacy price concessions, and as described in section 110 if 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). CMS may take immediate steps to ensure adequate reimbursement for and access to selected drugs as needed.

Comment: One commenter recommended CMS provide more information on the frequency with which it will proactively audit manufacturer compliance with MFP effectuation and if it will solicit feedback from dispensing entities that are dispensing selected drugs to understand concerns.

Response: As required by statute, CMS intends to develop a robust monitoring and oversight program. CMS anticipates this will include targeted, issue-specific audits based on observations during program monitoring, and/or complaints received by CMS, as well as more generalized audits of manufacturer compliance with the program's requirements. CMS may issue more specific information about the frequency and volume of anticipated audits as program implementation continues. CMS also intends to monitor trends in complaints and disputes submitted by dispensing entities and other interested parties to track key topics and issues during program implementation; information identified through these monitoring efforts may guide priorities for audits and investigations.

CMS is committed to actively engaging with interested parties, including dispensing entities, on all aspects of Negotiation Program. Since CMS announced it intended to engage with an MTF Contractor[23] to facilitate the exchange of data between pharmaceutical supply chain entities to help effectuate access to the MFP in the June 2023 revised guidance for initial price applicability year 2026, CMS accepted and held several meetings with dispensing entities on the development of policy related to and design features of the MTF. Additionally, after publishing draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS held three listening sessions on the MTF, including an individual session with

[23] For the purposes of this guidance, CMS uses the term "MTF Contractor" or "MTF Contractors" to refer generally to the contractor(s) that CMS plans to engage to provide services in connection with the MTF, including the MTF DM and MTF PM.

dispensing entities. CMS encourages interested parties to direct further feedback, queries, or meeting requests to the IRA mailbox (IRARebateandNegotiation@cms.hhs.gov).

Comment: CMS received many comments in support of the use of an MTF Contractor, with commenters providing perspective on the type of entity that could serve as the MTF Contractor and evaluation criteria for MTF vendor selection. A few commenters stated that a standardized MFP effectuation process operationalized by a single, neutral MTF is necessary for operational feasibility and that the MTF should be independent from the pharmaceutical supply chain. For example, it should not be owned by, governed by, or vertically integrated with an existing payer, PBM, or large pharmacy company. One commenter noted that the MTF should be flexible and open to operational modifications and improvements, especially in the first several years of implementation. The commenter recommended CMS address MTF changes in the guidance development for initial price applicability year 2028 and future rulemaking. The commenter also stated that CMS should move as quickly as possible to identify an appropriate entity to serve as the MTF so the entity, manufacturers, and dispensing entities can begin developing processes. One commenter recommended that the MTF remain operational after initial price applicability year 2027 to ensure continued, efficient processing of MFP refunds. One commenter stated that there should be multiple entities in the marketplace facilitating data and payment between supply chain entities, but if there is only one MTF then it should be a specific data vendor.

Response: CMS thanks these commenters for their support and recommendations. CMS has been working with, and will continue to work with, interested parties to inform the development of MTF processes. To conduct market research on the availability and potential technical ability of health care related organizations to provide MTF services, on October 18, 2023, CMS issued a Request for Information (RFI) on the MTF for the Negotiation Program, for which responses were due by November 13, 2023.[24] The goal of the RFI was to identify potential vendors who could facilitate the operational needs of the MTF and to gain insight from industry on how the MTF should function. CMS will continue to work with interested parties to inform the development of MTF processes through the MTF acquisition processes. CMS initiated the acquisition process for the MTF DM, which was made available to vendors on ebuy.gsa.gov, and the MTF PM, which was made available to Strategic Partners Acquisition Readiness Contract (SPARC) Contract Holders.

CMS is committed to the development of a process in which the MTF is efficient, neutral, and secure. CMS will ensure that the MTF Contractors comply with all applicable federal security laws, regulations, and HHS policies, including but not limited to those related to data protection and information security. Section 40.4.2 provides further details on the data exchange functionality that the MTF will provide, and section 40.4.3 provides further details on the payment facilitation functionality that the MTF will provide. Discussion of MFP effectuation for 2028 and subsequent years is out of scope for this final guidance.

Comment: One commenter expressed support for CMS bearing the cost of operationalizing the MTF and refraining from charging manufacturers and dispensing entities fees to enroll in the MTF. One commenter recommended that CMS clarify that manufacturers may not charge

[24] See: https://sam.gov/opp/f9765a945b8b4aa08b263c7ccc53ae24/view.

transaction or processing fees of dispensing entities for a process outside of the MTF to make the MFP available.

Response: As stated in sections 40.4.2 and 40.4.3 of this final guidance, Primary Manufacturers and dispensing entities will not have to pay any fees to enroll in the MTF DM, and Primary Manufacturers will not have to pay any fees to participate in the MTF PM, including but not limited to user fees or transaction fees, as CMS will bear the cost of operationalizing the MTF. In addition, and regardless of whether the MFP refund is passed 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.

Comment: A couple of commenters supported both retrospective and prospective options for manufacturer effectuation of the MFP and urged CMS to move forward in facilitating dispensing entities' access to the MFP through both options. One commenter stated that it does not support prospective or retrospective payment options to dispensing entities because, at the point of sale, the payer type is not known. One commenter stated that some providers may opt out of dispensing medications to Medicare patients due to concerns with both prospective and retrospective approaches. One commenter stated that there are benefits and drawbacks to both the retrospective and prospective approaches for stakeholders. This commenter noted that manufacturers have concerns about the potential for duplicate discounts if the MFP is offered prospectively and that retrospective payments offer better management of duplicate discounts; however, for dispensing entities, prospective payments provide more beneficial cash flow whereas retrospective payments require timely data and prompt payments.

A few commenters stated that effectuating the MFP as a retrospective rebate is the most operationally straightforward, efficient, and standardized approach to providing access to the MFP. One commenter recommended CMS finalize the retrospective approach to providing access to the MFP and plan for prospective options in future years. By contrast, one commenter raised significant operational concerns with the retrospective option, stating that it would require new systems and operational updates that could lead to challenges. In addition, many commenters stated that, if required by a manufacturer to purchase retrospectively, health centers would have to purchase the drugs at a higher price and operate at a loss until receiving the MFP refund retrospectively while incurring administrative burden to track MFP refunds from multiple manufacturers.

A few commenters stated that they do not support manufacturers providing dispensing entities with the MFP prospectively because it could lead to diversion, in which non-MFP-eligible beneficiaries receive access to the MFP. One commenter stated that prospective MFP access could lead to unintended consequences and disruptions for dispensing entities, manufacturers, the MTF, and CMS if it is implemented as early as 2026, and that CMS should plan for potential prospective options in later years of the program. One commenter preferred the prospective option and encouraged CMS to share additional details on parameters around this option. One commenter supported prospective access to the MFP to facilitate 340B nonduplication processes. A couple of commenters recommended CMS incentivize manufacturers to provide the MFP prospectively to reduce administrative burdens associated with claims processing. Many

commenters stated that all dispensing entities should have the opportunity to purchase selected drugs prospectively at the MFP, not at a manufacturer's discretion.

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 40.4.2 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 have to operate at a loss 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 describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns in their MFP effectuation plans.

Comment: Many commenters expressed concern about payers other than Medicare choosing to reimburse at the MFP of a selected drug. The commenters recommended CMS clarify which payers can reimburse at the MFP. One commenter stated that if private payers leverage MFPs to negotiate more competitive prices on selected drugs, they may be able to provide greater value for the patients they insure through lower out-of-pocket expenditures or lower insurance premiums that could be attributed to cost savings on drug expenditures. One commenter expressed concerns about the MFP expanding to apply beyond the Medicare market. The commenter recommended CMS specify in the agreement that the MFP not be lower than the ceiling price when a manufacturer shows that the MFP will be or has been used as a reference for setting pricing or payment limits outside of the Medicare market. The commenter alternatively recommended CMS specify that when there is a "non-trivial" amount of spillover of MFP pricing outside of the Medicare market, that this would constitute a "material change" to the agreement and trigger renegotiation of the MFP.

Response: CMS reiterates its response on pages 39 and 40 of the revised guidance for initial price applicability year 2026. The IRA directs CMS to negotiate an MFP for each selected drug for the Medicare program and requires the manufacturers of such drugs to make the MFP available to MFP-eligible individuals. As discussed in section 80 of this final guidance, for 2026 and 2027, Primary Manufacturers of selected drugs must provide access to an MFP-eligible individual, which 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 Medicare Advantage Prescription Drug Plan ("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, and for whom no PDE record is produced for the claim. The Negotiation Program does not regulate payment rates by payers outside of the Medicare program (e.g., in the commercial markets). CMS will publish the MFP for each selected drug, as required by law. CMS notes that Medicare already establishes and publishes payment rates for drugs under Part B using the Average Sales Price (ASP) methodology that may be used by other payers (such as state Medicaid programs), and Medicaid also publishes various pharmaceutical pricing benchmarks, such as the National Average Drug Acquisition Cost (NADAC) file and Federal Upper Limits (FULs) for multiple source drugs, that may be used by other payers. Renegotiation is outside of the scope of this final guidance.

Medicare Transaction Facilitator Data Facilitation (Section 40.4.1)

Comment: A few commenters stated that data requirements for privacy and security of data must be ensured throughout the MTF processes and are vital to the success of the program. A couple of commenters stated that they appreciate and support requiring the Primary Manufacturer to register with the MTF, sign privacy and security agreements, and maintain necessary functionalities to receive certain claim-level data elements from the MTF.

Response: CMS thanks these commenters for their feedback. As described in section 40.4.2.1 of this final guidance, in accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering and monitoring compliance with the Negotiation Program, Primary Manufacturer participation in the MTF DM is mandatory. All Primary Manufacturers will be required to register with the MTF DM and maintain the functionality necessary to receive certain claim-level data elements from the MTF DM. Each Primary Manufacturer will be required to sign privacy and security agreements with CMS and comply with privacy and security requirements to protect the data elements received from and transmitted to the MTF DM.

Comment: Many commenters recommended that CMS expand the list of claim-level data elements, which can be found on page 40 of the draft guidance for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027 titled "Table 2: MTF Claim-Level Data Elements," by adding additional elements that the MTF DM will provide to Primary Manufacturers. Examples of additional data elements requested include National Provider Identifier (NPI), encrypted/de-identified patient ID, drug description, Rx ID, billing code, dispensing pharmacy / provider name, billed amount, reimbursement amount, pharmacy

actual acquisition cost, wholesale invoice number, submission date, formulary code, covered and non-covered status indicator, bank identification number (BIN) / process control number (PCN) of the beneficiary's prescription drug insurance, and Medicare plan ID. Some of these commenters stated the need for the MTF DM to submit additional data elements to Primary Manufacturers for them to perform additional validation steps as to whether it was a claim for an MFP-eligible individual before making MFP refund payments to dispensing entities. Some commenters requested more data elements be added to assist with identifying potential 340B-eligible claims. Examples of additional data elements requested to support identification of these claims include mandatory 340B indicator/modifiers, 340B clearinghouse determination, 340B ceiling price (received from clearinghouse), provider NPI, 340B number and name of the covered entity, and encrypted/de-identified patient ID. A few commenters agreed with the data elements in Table 2 of the draft guidance and stated no changes should be made to the existing table with no additional data/information, beyond what was described in Table 2, shared with Primary Manufacturers. One commenter asked CMS to be more prescriptive on and clarify the purpose of each data element listed in Table 2 as they stated the purpose of several data elements are similar if not the same. They also suggested that CMS should work with manufacturers and other parties to refine the data elements list over time. One commenter supported the leveraging of existing Part D claims data.

Response: CMS appreciates the commenters' feedback. CMS carefully considered the suggestions for additional claim-level data, balancing the necessity of such information to verify the selected drug was dispensed to an MFP-eligible individual and for the transmission of such data to start the 14-day prompt MFP payment window against concerns from interested parties on providing superfluous data elements to Primary Manufacturers. Based on CMS' assessment, CMS agrees with commenters that limited additional information to support a Primary Manufacturer with identifying 340B-eligble claims is necessary, and CMS added two data elements ("Prescriber ID" and "Prescriber ID Qualifier modifier") to the list of data elements in Table 2. CMS believes these data elements could be useful to a Primary Manufacturer when identifying whether a prescription was written by a prescriber with a high percentage of claims originating from a 340B covered entity. As reiterated in the above response, each Primary Manufacturer will be required to sign privacy and security agreements with CMS and comply with privacy and security requirements to protect the data elements received from and transmitted to the MTF DM. CMS notes in section 40.4.5 of this final guidance that an NPI alone (whether a prescriber NPI or a hospital/provider NPI) 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.[25] CMS declines to accept other requests for the MTF DM to provide additional data elements because CMS believes these data elements are not necessary for a Primary Manufacturer to fulfill its statutory obligations. As stated in section 40.4.2.1 of the final guidance, the data elements to be provided to Primary Manufacturers will already have been dually verified by Part D plans and the CMS

[25] 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(a)(1) of the PHS Act regarding proper identification of 340B-eligible patients and covered outpatient drugs dispensed to such patients.

Drug Data Processing System (DDPS), so verification to validate an individual's MFP eligibility performed by the Primary Manufacturer prior to providing an MFP refund payment is unnecessary.

Comment: One commenter asked for clarification that the report of claim-level payment elements that the Primary Manufacturer sends to the MTF does not need to include additional discount amounts greater than what is required to effectuate the MFP, if applicable, and that such disclosures could lead to unintended consequences on availability of additional discounts from manufacturers.

Response: CMS thanks these commenters for their input. In response to the request for clarification, CMS confirms the Primary Manufacturer does not need to include information on additional discounts provided to the dispensing entity under the payment element "Amount of Payment Sent as the MFP Refund."

Comment: One commenter stated that manufacturers currently have practices around standard rebate payment, and that CMS should align the data elements sent by the MTF with existing standard practices to maintain consistency with how other rebate payments are made. Specific standards referenced by the commenter included a file to identify claims ineligible for payment, a file with total payments made by NDC and pharmacy, and a file that contains claims eligible for payment.

Response: CMS thanks this commenter for their recommendation and examples. As discussed in section 40.4.2.1, the data elements sent by the MTF DM to Primary Manufacturers will contain the minimum necessary information that verifies the selected drug was dispensed to an MFP-eligible individual. The MTF will send data elements that provide the minimum necessary information that verifies the individual was MFP-eligible.

Comment: A few commenters were concerned about DDPS "reject" claims not being passed along to the MTF DM for transmission to Primary Manufacturers. One commenter stated that currently, Part D sponsors adjudicate the claims, but pharmacies are fully reimbursed, and the Part D sponsor retains the responsibility for the claim.

Response: CMS thanks these commenters for their input. 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 dispensed to an MFP-eligible individual. In cases where DDPS edits would render the data elements listed in Table 2 of section 40.4.2.1 as incomplete, 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.

Comment: A few commenters recommended that CMS use a standard ERA X12 835 transaction format. One commenter indicated that a standard 835 format for MFP refund payments would reduce complications for the work of reconciliation vendors to reconcile Primary Manufacturer retrospective MFP refunds.

Response: CMS thanks this commenter for their recommendation and confirms that, if the Primary Manufacturer chooses to pass payment through the MTF PM, the MTF DM will make available an ERA that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act (HIPAA) for electronic payments and a remittance for payment made via paper check. If the Primary Manufacturer provides the MFP refund via electronic payment outside of the MTF PM, the Primary Manufacturer is required to make available an ERA that uses the X12 835 standard adopted under HIPAA. If the Primary Manufacturer provides the MFP refund via paper check outside of the MTF PM, the Primary Manufacturer is required to make available a remittance to the dispensing entity. CMS will provide more detail on user functionality within the MTF DM in forthcoming technical instructions.

Comment: One commenter suggested that CMS set up a taskforce with all interested parties to design and test the MTF. A couple of commenters requested that CMS provide a forum for manufacturer and dispensing entity engagement to identify operational solutions and implement the MFP effectuation process.

Response: CMS appreciates this commenter's recommendation for further engagement with interested parties. As mentioned above, to conduct market research on the availability and potential technical ability of health care related organizations to provide MTF services, on October 18, 2023, CMS issued a Request for Information (RFI) on the MTF for the Negotiation Program.[26] Since CMS announced it intended to engage with an MTF Contractor to facilitate the exchange of data between pharmaceutical supply chain entities to help effectuate access to the MFP in the June 2023 revised guidance for initial price applicability year 2026, CMS accepted and held 30 meetings with interested parties—including manufacturers, pharmacies, reconciliation entities, technology companies, standards organizations, and patient advocacy groups—on the development of policy related to and design features of the MTF. Additionally, after publishing draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS held three listening sessions on the MTF for pharmacies, drug manufacturers, plan/PBMs, and other supply chain entities. CMS used feedback from the RFI, meetings with interested parties, MTF listening sessions, and public comments on the draft guidance to inform policy outlining how CMS will engage with the MTF and the MTF design. CMS remains committed to ongoing engagement efforts with interested parties as CMS moves from the MTF design phase to the MTF development and testing phase.

Comment: Many commenters requested more information and details from CMS on how it will track and communicate claims adjustments, reversals, and PDE rejects to dispensing entities and Primary Manufacturers. A couple of commenters provided suggestions on how to offset payments made by a Primary Manufacturer if a claim is reversed, and one commenter suggested a claw back system (i.e., a system set up to allow money paid to a dispensing entity to be taken back by a Primary Manufacturer that paid the dispensing entity due to an event or circumstance such as a reversal or an overpayment of a claim). One commenter stated that a specific timeframe for addressing claim adjustments and reversals are unnecessary to ensure all parties are made whole. The commenter suggested in the case where a pharmacy submits and later reverses a claim within the same manufacturer batch, that each transaction should be included as

[26] See: https://sam.gov/opp/f9765a945b8b4aa08b263c7ccc53ae24/view.

separate line items in the remittance advice (i.e., 835), reflecting a positive amount as payment for the claim and a corresponding negative amount for the reversal for reconciliation purposes.

Response: CMS thanks commenters for their feedback. CMS understands the potential for a Primary Manufacturer to have transmitted the MFP refund within the 14-day prompt MFP payment window but subsequent changes to the status of the claim (e.g., reversals or adjustments) affect the amount of the MFP refund owed. To support prompt payment of MFP refunds while accommodating situations where the amount of the MFP refund owed for a claim subsequently changes, CMS plans to establish a credit/debit ledger system, administered by the MTF for payments passed through the MTF PM. This system will provide a mechanism that allows participating Primary Manufacturers to apply credits when the MFP-eligibility status, quantity dispensed, or other characteristics of a claim changes after transmission of the MFP refund payment through the MTF PM. These credits would be tracked on the NPI level such that they would be applied to future refunds owed to the dispensing entity. This credit/debit ledger system is described in further detail within sections 40.4.3.2 and 40.4.4.4 of this final guidance.

Comment: One commenter was concerned with relying on PDE records for validating claims and stated that a retroactive eligibility change may cause the pharmacy to not receive a refund if the patient received a drug but ultimately was not an MFP-eligible patient.

Response: CMS thanks the commenter for sharing their concern. In cases where a claim was subsequently found not to be MFP-eligible after an MFP refund was issued to the dispensing entity through the MTF PM, Primary Manufacturers that participate in the MTF PM can submit instructions for the MTF to apply a credit for previously paid refunds. Primary Manufacturers that do not participate in the MTF PM or who participate in the MTF PM but made payment for the claim to dispensing entities outside of the MTF PM will need to maintain their own accounting system to track such adjustments. See sections 40.4.3 and 40.4.4 in this final guidance for further information.

Comment: CMS received several comments on the frequency with which the MTF should transmit claim-level data elements to Primary Manufacturers. A few commenters suggested daily, a few commenters suggested every two weeks, and one commenter suggested quarterly. Commenters who suggested that CMS should consider less frequent data transmissions from the MTF stated this would reduce the burden on Primary Manufacturers to process the data elements received.

Response: CMS thanks these commenters for their input. CMS understands that dispensing entities typically have two-week payment cycles in which they must pay wholesalers for drug purchases. Since dispensing entities are reimbursed at or below the MFP plus dispensing fee by Part D plans, receiving timely refunds from Primary Manufacturers is important to make payments to wholesalers within these payment cycles. As such, CMS intends that the MTF DM will transmit claim-level data elements to Primary Manufacturers on a near-daily basis, subject to regular system downtime. The frequency of data transmission will operate based on the capabilities of DDPS, which will submit claims to the MTF DM daily Monday through Saturday.

Comment: One commenter recommended that CMS make the MTF payment facilitation component of the MTF mandatory for Primary Manufacturers and dispensing entities to avoid unintended consequences.

Response: CMS thanks this commenter for their input. As discussed in section 40.4.3 of this final guidance, the MTF PM will pass through retrospective payment from participating Primary Manufacturers to dispensing entities to help effectuate access to the MFP, unless the Primary Manufacturer and dispensing entity establish a mutually agreed-upon method for effectuating the MFP outside of the MTF PM. 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.

CMS understands the potential for complexity in paying the MFP refund if the Primary Manufacturer chooses not to pass payment through the MTF PM. To assist with MFP refund payment, CMS will require Primary Manufacturers to enroll in the MTF DM. In addition, CMS intends to also propose in future rulemaking to require Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM for purposes of data exchange. 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 ERAs or remittances, facilitating continued access to selected drugs that are covered Part D drugs, and ensuring accurate Part D claims information and payment.

In the MTF DM enrollment process, as discussed in section 40.4.2 of this final guidance, the MTF DM will collect banking information from dispensing entities. If a Primary Manufacturer chooses to pass payment through the MTF PM, the MTF PM will provide an avenue to make payment available to all dispensing entities enrolled in the MTF DM. Should the dispensing entity indicate its preference to receive payment through electronic transfer of funds, the MTF PM will pass through such payment from the participating Primary Manufacturer via an electronic fund transfer, and the MTF DM will create and make available to the dispensing entity an ERA. Should the dispensing entity indicate its preference to receive payment in the form of paper checks and the Primary Manufacturer elects to pass its payment through the MTF PM, the MTF PM will process such payment by issuing a paper check to the dispensing entity from the funds the Primary Manufacturer provided to the MTF PM, and the MTF DM will create and make available to the dispensing entity the remittance. Conversely, as discussed in section 90.2.1 of this final guidance, should a Primary Manufacturer choose not to pass payment through the MTF PM to process MFP refunds because it is not participating in the MTF PM, that Primary Manufacturer will be required to provide dispensing entities with an option to receive electronic transfer of funds and the associated ERA (e.g., a functional equivalent to the service offered by the MTF PM), and must also offer the ability to make MFP refunds available via paper check, along with the associated remittance, as a minimum requirement. Note that a Primary Manufacturer's participation in the MTF PM does not preclude dispensing entities and the Primary Manufacturer from reaching alternative arrangements for an approach to MFP effectuation for any given selected drug. That is, even if a Primary Manufacturer has chosen to

participate in the MTF PM, it may enter alternative arrangements with any subset of dispensing entities so long as both parties (i.e., the Primary Manufacturer and the applicable dispensing entity(s)) agree to the alternative approach. As described in section 90.2.1 of this final guidance, a Primary Manufacturer's MFP effectuation plan must indicate its MTF PM participation selection, its alternative approach to MFP effectuation should it elect not to utilize the MTF PM, and detail any alternative arrangements in place with dispensing entities; this plan must be kept up to date over time, with updates submitted in advance of any changes in approach.

Comment: Many commenters provided input on the 14-day prompt MFP payment window. Many commenters stated that the 14-day prompt MFP payment window is not enough time for manufacturers to process claims accurately and to thoroughly ensure compliance, with a few commenters recommending using timelines between 30 days and 45 days for the prompt payment to align with manufacturer payment timelines of other programs such as the Coverage Gap Discount Program (CGDP) and Medicaid Drug Rebate Program (MDRP). One commenter stated that the 14-day prompt MFP payment window is not mandated by statute. A couple of commenters stated that the 14-day prompt MFP payment window is too long for dispensing entities to be reimbursed and one commenter recommend a 7-day prompt MFP payment window. One commenter 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: 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 43 and 44 of the revised guidance for initial price applicability year 2026, 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 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 describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns 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, 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. In evaluating the impact of this policy, our

analysis of PDE record submissions shows that over 80% of PDE records are currently submitted within seven days of receipt from Part D plans. CMS intends to propose in future rulemaking to shorten the current 30-day window for plans to submit PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities.

Section 40.4 of this final guidance outlines that the prompt payment window will be a 14-day prompt MFP payment window to align with the timing requirement in the longstanding prompt pay rules in Part D. There are key differences between this program and other programs mentioned in comments that result in different payment timelines. The MDRP involves rebates paid to state Medicaid programs and CGDP involves payments to Part D plans within a prefunded program. The MFP involves payments to pharmacies and other dispensing entities that would have significant cashflow issues if not for a 14-day prompt MFP payment window.

The function of the MTF DM is to validate claims from MFP-eligible individuals to reduce data validation needs of Primary Manufacturers and ensure prompt MFP refund payment to dispensing entities. As discussed in section 40.4.2, to assist Primary Manufacturers with nonduplication of MFP-eligible claims and 340B claims within the 14-day prompt MFP payment window, data elements sent by the MTF will include prescriber identifiers. 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: One commenter stated that manufacturers need more than 14 days to verify that the quantity dispensed is correct.

Response: CMS believes that the 14-day prompt MFP payment window is sufficient for purposes of verifying quantity dispensed, as nearly all PDE records reflect the quantity dispensed of a claim for a single NDC-11. CMS notes that one instance in which the quantity dispensed may be populated accurately on a PDE record but would not reflect the actual quantity dispensed of the NDC-11 associated with the claim is a PDE record for a selected drug that was billed as a compound. Specifically, CMS understands that the PDE record for a selected drug that was billed as a compound would reflect the quantity dispensed of the compounded drug product as a whole and not the selected drug individually. To ensure the MFP availability obligation applies only to PDE records that accurately reflect the actual quantity dispensed of a selected drug, CMS has revised section 40.4.2.1 of this final guidance to clarify that, for operational reasons at this time for 2026 and 2027, MFP refunds will not be required for PDE records for selected drugs that were billed as compounds. Specifically, the claim-level data elements transmitted from the MTF to the Primary Manufacturer will exclude claim-level data elements from any PDE record with a compound code indicating the PDE record is for a compounded drug. For alignment, CMS has also revised sections 30.1.2, 30.2, 60.2.1, 60.3.2, and 60.5 of the final guidance to provide that, for initial price applicability year 2027, 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 rankings of negotiation-eligible drugs (section 30.2), the ceiling for the MFP (section 60.2.1), the Net Part D Plan

Payment and Beneficiary Liability of a therapeutic alternative(s) used to develop a starting point for the initial offer (section 60.3.2), and the application of the MFP across dosage forms and strengths (section 60.5). 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 part of a compounded drug, at which point such PDE records may be used to allow for inclusion in MFP effectuation. These operational changes may also facilitate the inclusion of PDE records for drug or biological products that are billed as a compound in CMS' determinations regarding potential qualifying single source drugs, qualifying single source drugs, and selected drugs in the respective drug selection and negotiation process calculations in future initial price applicability years.

Comment: A couple of commenters provided input on when the 14-day prompt MFP payment window should begin. One commenter stated that the start date of the 14-day prompt MFP payment window should begin on the day that the claim is adjudicated. A few commenters stated that CMS should clarify that if any adjustments are made to the claim-level data, the 14-day prompt MFP payment window would restart. One commenter stated that disputes should halt the 14-day prompt MFP payment window.

Response: CMS clarified in section 40.4 of this final guidance that the 14-day prompt MFP payment window will begin when the MTF DM sends claim-level data elements to the Primary Manufacturer, which are listed in Table 2 of section 40.4.2 of this final guidance. Starting the 14-day prompt MFP payment window when the MTF DM sends data elements to the Primary Manufacturer allows CMS to include 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. Adjustments made to claims after data elements have been sent to the Primary Manufacturer do not change the 14-day prompt MFP payment window for the original claim. That is, the Primary Manufacturer still must transmit payment of an amount that provides access to the MFP for the original claim within 14 days, while any adjustments to that claim can be reconciled within the MTF's crediting functionality if the MFP refund is passed through the MTF PM. Shifting the 14-day prompt MFP payment window due to adjustments in real time would create confusion with multiple timeframes for which to account. For adjustments to the claim during the 14-day prompt MFP payment window when the Primary Manufacturer has not yet transmitted the MFP refund, the Primary Manufacturer may pay the MFP refund based on the adjusted claim amount. For subsequent reversals or adjustments to claims, the MTF credit/debit ledger system will allow Primary Manufacturers participating in the MTF PM to claim credit for payments facilitated by the MTF PM based on the adjustments that will be sent as data elements from the MTF DM. Primary Manufacturers that do not participate in the MTF PM, or that participate in the MTF PM but establish with a dispensing entity a mutually agreed-upon method for effectuating the MFP outside of the MTF PM, will need to track and apply credits and debits for subsequent reversals or adjustments to claims paid outside of the MTF PM. The 14-day prompt MFP payment window will not be tolled for a claim in dispute. For payments facilitated by the MTF PM, resolution of a dispute that leads to a reversal or adjustment of the MFP refund will be addressed through the credit/debit ledger system. For payments made outside the MTF PM (either because

the Primary Manufacturer elects not to participate in the MTF PM, or because the Primary Manufacturer participates in the MTF PM but it and a dispensing entity establish a mutually agreed-upon method for effectuating the MFP outside of the MTF PM), the Primary Manufacturer and dispensing entity would be responsible for agreeing upon a method to account for the resolution of a dispute that leads to a reversal or adjustment of the MFP refund.

Comment: A couple of commenters stated that Primary Manufacturers should make MFP refund payments to pharmacies either daily or weekly.

Response: CMS thanks these commenters for their recommendations. CMS intends that the MTF PM will have the ability to receive payments from participating Primary Manufacturers and to distribute these payments to dispensing entities on a near-daily basis, subject to regular system downtime.

Comment: Many commenters shared their views on whether CMS should shorten the current 30-day window for plans to submit PDE records to seven days. Some commenters supported a seven-day window, one commenter supported a window that is less than seven days, one commenter supported a two-day window, and a few commenters supported a one-day window. A few commenters recommended that CMS not change the PDE reporting period. Many commenters also provided detailed views on the logistical and operational impacts of shortening the current 30-day window for plans to submit PDE records. These comments raised technical questions related to DDPS operations, file transmission timelines, and other related matters. These commenters provided perspectives on potential operational burden, costs, and risks of a shortened PDE submission timeline.

Response: CMS thanks these commenters for their input on this topic. In future rulemaking, CMS intends to propose to shorten the current 30-day window for plans to submit PDE records for selected drugs to seven days to ensure dispensing entities receive timely payment of MFP refunds. While the 14-day prompt MFP payment window aligns with the timing requirements for Part D plan sponsors in the longstanding prompt pay rules in Part D, 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.

While CMS appreciates the feedback on logistical and operational impacts of shortening the PDE submission window, these comments are outside the scope of this final guidance and will not be addressed. As part of CMS' assessment of a change to the PDE reporting timeline, CMS is considering the input provided on the draft guidance related to this topic. CMS intends to address this policy in future rulemaking and will further solicit comment on this policy at that time.

Comment: Many commenters provided their views on the 340B claim indicator data element (as voluntarily reported by dispensing entity). Many commenters stated that CMS should make the indicator mandatory, and a few commenters stated that CMS should include a mandatory 340B

claim indicator and a mandatory non-340B claim indicator to declare the 340B status of every claim. Some commenters stated their support for a voluntary 340B claim indicator. One commenter stated that CMS should prohibit the claw back of funds from a dispensing entity to the manufacturer of previously paid MFP refunds for purposes of nonduplication of the MFP and 340B ceiling price because preventing claw backs will provide incentives for dispensing entities and manufacturers to develop effective means to make dispensing entities whole without involving contract pharmacies and that any adjustments or resolution(s) related to a 340B claim should be handled through the dispute resolution process that is currently in place, as appropriate. One commenter stated that is imperative that CMS provide for an enforceable claw back mechanism by which manufacturers can readily recover the MFP should a covered entity receive a lower 340B price on the same unit after the payment of the MFP refund.

Response: CMS is not mandating that dispensing entities add a 340B claim indicator to claims at this time. The 340B claim indicator data element passes through information on the 340B status of a claim that the dispensing entity voluntarily provides. Neither CMS nor the MTF DM will verify that a claim was or was not billed as a 340B-eligible drug. CMS understands that the 340B determination may not be apparent to the dispensing entity at the point-of-sale. As described in section 40.4.5 of this final guidance, CMS and the MTF DM will not assume responsibility for deduplicating discounts between the 340B ceiling price and MFP. If claims are found to be 340B-eligible after MFP refunds are paid, the MTF will have a credit/debit ledger system through which a Primary Manufacturer using the MTF PM can request credit for an MFP refund that was previously paid through the MTF PM, as described in section 40.4.3.2 of this final guidance.

Comment: One commenter recommended that CMS batch the claims sent from the MTF to Primary Manufacturers consistent with the practices of the CGDP because the 14-day prompt MFP payment window may be too burdensome on a Primary Manufacturer.

Response: CMS appreciates this commenter's input. A key function of the MTF is to ensure that dispensing entities receive retrospective reimbursements as quickly as possible for dispensing selected drugs to MFP-eligible individuals. The 14-day prompt MFP payment window is an essential element of ensuring timely access to the MFP for dispensing entities. As such, CMS elects to maintain the policy outlined in this final guidance.

Nonduplication with the 340B Ceiling Price (Section 40.4.2 and 90.2)

Comment: Many commenters expressed opposition to the 340B nonduplication approach that CMS described in the draft guidance stating that it creates operational challenges and risks for supply chain entities. A couple commenters cited high volumes of Medicaid rebate-340B duplicate discounts as evidence that the potential for MFP-340B duplication is not merely a theoretical concern. A few commenters argued that 340B covered entities have no incentive to voluntarily identify 340B claims and allowing 340B covered entities to voluntarily disclose 340B-eligibility places manufacturers in an inequitable position and means covered entities would be able to demand both the 340B discount and the MFP. One commenter stated that manufacturers do not have the financial means to carry millions of dollars in excess payments that will likely result from MFP-340B duplicate discounts.

Many commenters asserted that aspects of the 340B replenishment model[27] used by the majority of covered entities run directly counter to CMS' suggested approach for MFP effectuation. First, point-of-sale identification of 340B claims is incompatible with this model, and a few commenters raised concerns that nonduplication with the 340B ceiling price will therefore not be possible within the 14-day prompt MFP payment window. Second, replenishment orders reflect units dispensed from a neutral inventory to many individuals with public or private insurance and can occur months post-dispense. For these reasons, commenters claimed Primary Manufacturers alone are unable to identify 340B units dispensed to MFP-eligible individuals and thereby prevent duplicate discounts. Many commenters asked how 340B claim identification would occur during the 14-day prompt MFP payment window through the MTF process if the dispensing entity purchased the selected drug prospectively at the MFP. One commenter stated that it cannot conceive of a process where there could be retrospective access to the MFP but prospective access to the 340B price and asked CMS to finalize an approach that ensures prospective access to the MFP and the 340B ceiling price, acknowledging that covered entities would need to maintain separate physical or virtual inventories for selected drugs. One commenter expressed concern that the MFP will unintentionally affect 340B-generated program revenue for AIDS Drug Assistance Programs (ADAPs) and impact the ability of the program to serve patients.

Response: CMS thanks these commenters for sharing their perspectives and acknowledges the concerns expressed. As explained in the draft guidance and in 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 deduplicating 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.

CMS notes that, for selected drugs in 2026, MFPs have been published and 340B prices are made available prior to the beginning of each quarter to covered entities and manufacturers in Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs Information System (OPAIS). 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. CMS is exploring the feasibility of

[27] Covered entities and their contract pharmacies can use a replenishment model in which they do not need to maintain a separate physical inventory for 340B-eligible drugs. Rather than maintain a physical inventory, they maintain a virtual inventory and a contract pharmacy can receive a replacement product, paid by the covered entity, after a full package size of the product has been dispensed to 340B-eligible patients.

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.

Further, CMS notes that, if the MFP for a selected drug is lower than the 340B ceiling price for a given quarter, section 1193(d)(1) of the Act would be inapplicable and the Primary Manufacturer should not claim the section 1193(d)(1) exception for any MFP-eligible claims for such selected drug for such quarter, since MFP-eligible claims for that selected drug for that quarter would categorically not be eligible for the section 1193(d)(1) exception.

CMS disagrees that there is no incentive for covered entities to voluntarily identify 340B claims, as the 340B ceiling price may be lower than the MFP and thus covered entities would be incentivized to identify claims to receive the 340B discount at the time of purchase. CMS also reiterates that a Primary Manufacturer may provide access to the MFP prospectively or retrospectively; at this time, CMS is not mandating a particular process to provide access to the MFP. Primary Manufacturers that make the MFP available to dispensing entities prospectively should work with dispensing entities and other supply chain entities to effectuate nonduplication of the MFP and 340B ceiling price. In response to concerns that nonduplication with the 340B ceiling price will not be possible within the 14-day prompt MFP payment window, CMS directs commenters to CMS' discussion of the credit/debit ledger system, which will be available to Primary Manufacturers participating in the MTF PM for payments made through the MTF PM, described in section 40.4.3.3 of this final guidance. CMS expects this system to allow Primary Manufacturers and dispensing entities to accrue credits and debits for claims retroactively identified as 340B-eligible but for which the Primary Manufacturer transmitted an MFP refund to make the MFP available during the 14-day prompt MFP payment window. Regarding concerns related to ADAPs, CMS reiterates a Primary Manufacturer's continued responsibility to comply with statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to offer the 340B ceiling price to eligible entities.

Comment: Many 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. Commenters explained that 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, essentially transitioning 340B purchases to a retrospective rebate model, which has never been authorized by HRSA outside of a very narrow exception for ADAPs. A couple of commenters urged CMS to emphasize to Primary Manufacturers 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 and urged CMS to avoid final guidance that enables retrospective payment of the 340B discount. One commenter urged CMS to develop a workable means for covered entities to continue purchasing at the 340B price, or alternatively, require Primary Manufacturers to sell drugs prospectively at MFP. In contrast, another commenter recommended that CMS clarify that manufacturers can choose to make the MFP the "default payment." Specifically, in coordination with HRSA, CMS could require covered entities to access the 340B price via a rebate, wherein manufacturers could initially

provide the MFP to covered entities for MFP-eligible claims and then later reimburse covered entities for any difference owed between the MFP and 340B ceiling price as a rebate.

Response: CMS appreciates commenters' input but will not require Primary Manufacturers to only sell drugs prospectively at the MFP. As stated in section 40.4 of this final guidance, a Primary Manufacturer must provide access to the MFP either prospectively or retrospectively at this time as CMS continues to monitor this policy. 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. 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). As stated above, 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. Additionally, dispensing entities have the ability to 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: Many commenters asserted that, under the nonduplication approach described by CMS in the draft guidance, Primary Manufacturers would likely mandate 340B claims data submission from covered entities. Many commenters strongly opposed CMS allowing for such mandates and stated that, at minimum, CMS should evaluate and regulate the data requirements imposed by Primary Manufacturers on covered entities. Commenters cited several challenges that interested parties would face absent CMS guidelines and criteria for Primary Manufacturers' nonduplication plans. These challenges included covered entities needing to navigate a wide variety of Primary Manufacturer methodologies, Primary Manufacturers needing to obtain data from numerous covered entities and covered entities needing to comply with Primary Manufacturers' submission requirements in order to access 340B pricing, and CMS facing barriers in monitoring and ensuring manufacturer compliance amidst multiple nonduplication methodologies. One commenter recommended that CMS and HRSA jointly require that covered entities submit 340B-eligible claims to manufacturers for MFP-eligible drugs, and another commenter asked that CMS at minimum clarify that a 340B covered entity will forfeit its right to the MFP if it does not participate in a manufacturer's reasonable process to address

nonduplication of the MFP and 340B ceiling price. One commenter said that it would be critical that manufacturers are given flexibility to develop and utilize their own processes to comply with section 1193(d) of the Act.

Response: CMS thanks commenters for their input. CMS will not prescribe a specific nonduplication approach that Primary Manufacturers must follow or impose parameters on a Primary Manufacturer's nonduplication plan, provided the Primary Manufacturer transmits payment of an amount that provides access to the MFP within the 14-day prompt MFP payment window and complies with the requirements under section 1193(d) of the Act, which enable the manufacturer to honor 340B discount obligations to covered entities through a 340B discount. Primary Manufacturers' nonduplication plans must be consistent with 340B statutory requirements.

As stated in the response above, CMS continues to encourage manufacturers to work in good faith with dispensing entities, covered entities and their 340B 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. CMS is exploring the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs, to identify claims eligible under section 1193(d)(1) of the Act into MTF processes in the future. CMS reiterates that nothing in this final guidance modifies a manufacturer's statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to offer 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. As noted above, manufacturers must offer the lower of the MFP or 340B ceiling price for the selected drug to eligible entities to comply with their obligations under section 1193(d) of the Act and section 340B(a)(1) of the PHS Act, respectively. CMS further encourages these industry partners to coordinate processes that minimize burden on all affected parties. At this time, the Primary Manufacturer maintains responsibility for nonduplication of the MFP and 340B ceiling price for the selected drug. The Primary Manufacturer must include this process for nonduplication in the plan it submits for making the MFP available, and CMS directs readers to the discussion in section 90.2.1 of this final guidance of how it will assess risk for Primary Manufacturer compliance to make the MFP consistently available. CMS reiterates that if the Primary Manufacturer does not have information to verify that a selected drug is subject to the exception under section 1193(d)(1) of the Act, the Primary Manufacturer is required 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.

Comment: Many commenters recommended approaches that CMS should take to deduplicate the 340B price and the MFP. Many commenters recommended that CMS require the use of claims modifiers for 340B claims, 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 a 340B and non-340B modifier. A couple of commenters said that, under a modifier approach, it will also be necessary for any 340B replenishment order of a selected drug to be accompanied by data linking the replenishment unit to the dispensed unit and showing whether the MFP or 340B price has already been provided on the dispensed unit. In

contrast, many commenters 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 the overwhelming majority of pharmacies as part of the 340B Program. These commenters 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 stated that it can take over 20 days after a 340B-eligible drug has been dispensed for a contract pharmacy using a replenishment model to receive drugs from the covered entity after those dispenses have been validated as 340B-eligible. One commenter referenced an analysis on the usage of 340B modifiers and remarked that 340B claim modifiers are not reliable, even when required. Another commenter acknowledged the difficulty for some dispensing entities to quickly identify 340B eligibility and encouraged CMS to continue to explore ways to improve identification of 340B claims at the point of sale while working with interested parties to address nonduplication in the interim. A couple commenters stated that the consensus in the pharmacy industry is that the N1 transaction is not feasible as it is not adopted by pharmacy information systems.[28] One commenter interpreted draft guidance as CMS stating that when the 340B price is lower than MFP, 340B entities append a modifier on the claim to identify the claim as 340B; the commenter pointed out that this approach is infeasible.

Many commenters recommended that CMS create—or work with stakeholders to 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. This "clearinghouse" would enable covered entities (or TPAs acting on their behalf) to retrospectively submit 340B claims data to the MTF, which would then withhold these claims from the claim-level data elements sent to Primary Manufacturers. Many 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 TPAs are an intrinsic element of the 340B process and urged CMS to integrate TPAs with the MTF to identify 340B claims without requiring new modifiers and stated that this integration would prevent Primary Manufacturers using nonduplication of the MFP and 340B ceiling price as a pretext for limiting or delaying payment to covered entities. A few commenters noted that this "clearinghouse" could also be used to remove units that covered entities identified as 340B eligible from the Part D Drug Inflation Rebate Program. One commenter stated that TPAs can identify 340B-eligible claims within 24 hours of prescription processing for inclusion in the PDE submission to DDPS, which would support the 14-day prompt MFP payment window. One commenter suggested that CMS work with HRSA to establish penalties for covered entities that do not submit claims data to the clearinghouse in the specified timeframe. Another commenter suggested that CMS create a conduit within the MTF to facilitate the direct transfer of 340B claims from covered entities to manufacturers, thereby relieving the MTF of the burden of matching and deduplicating claims. A few commenters requested that CMS work closely with covered entities and other affected parties to establish a process for nonduplication of the MFP and 340B ceiling price that is

[28] The National Council on Prescription Drug Program (NCPDP) allows for the use of an "N1" transaction to retrospectively identify drugs purchased under the 340B program. If it is determined that a 340B drug was dispensed after the claim has been adjudicated, then an N1 transaction can be submitted with the 420-DK submission. CMS understands that few pharmacies use this transaction. Consequently, CMS does not currently require a 340B indicator on the PDE record.

informed by stakeholder feedback, preserves existing 340B relationships, and includes oversight. A few commenters encouraged CMS to establish a nonduplication process but did not provide details on how CMS should go about this task.

Response: CMS thanks these commenters for their recommendations. In response to the recommendations for and against the use of a claim modifier for 340B claims, CMS acknowledges feedback from commenters that requiring such a modifier has the potential to pose operational challenges, increase administrative burden, and may not be accurate in many circumstances. 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 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.

Comment: A couple of commenters explained that, as a part of the MDRP, standard government price refiles can occur up to twelve quarters or three years after the date of dispensing, which could potentially impact 340B ceiling price due to rounding or other corrections. These commenters asked CMS to confirm that the 340B price at time of dispense is used for purposes of determining the lower of the MFP or 340B ceiling price and that recalculating the discount amounts (using the lower of MFP or 340B ceiling price) based on these government pricing refiles is not required when there is a change in 340B ceiling price.

Response: CMS understands that post-dispense adjustments to the 340B ceiling price may occur due to revisions to manufacturer reporting of Annual Manufacturer Price (AMP) under the MDRP; these revisions can occur up to 36 months from the month in which the data were due.[29] Under section 1193(d) of the Act, the Primary Manufacturer is not required to make the MFP available for a 340B-eligible claim if the 340B ceiling price is lower than the MFP, but the Primary Manufacturer is required to provide access to the MFP for such a claim if the MFP is lower than the 340B ceiling price. Within the 14-day prompt MFP payment window, the Primary Manufacturer must either indicate to the MTF DM that it is not providing access to the MFP because 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 it must transmit payment of an amount that provides access to the MFP because it has not determined that the exception under section 1193(d)(1) of the Act applies. Therefore, CMS will use the MFP and 340B ceiling price that were in effect on the date that the selected drug was dispensed to determine whether a Primary Manufacturer has met its obligations under section 1193(d) of the Act. CMS notes that nothing in this response should be interpreted to modify a manufacturer's existing AMP reporting obligations nor its obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities.

[29] 42 C.F.R. § 447.510(d)(3)

Comment: In response to CMS' statement in section 40.4.2 of the draft guidance that a Primary Manufacturer should use the payment elements described in section 40.4.1 of the draft guidance to indicate when it "reasonably believes" claim-level data elements for a selected drug are subject to the exception under section 1193(d)(1) of the Act, a couple of commenters requested that CMS clarify the definition of what constitutes "reasonable belief," and one commenter asked CMS to clarify the documentation requirements for 340B eligibility. A couple of these commenters also stated that the Primary Manufacturer should be required to share thorough documentation of 340B eligibility with the reporting of payment elements to the MTF, rather than only sharing such documentation upon request from CMS. One commenter expressed concern that a manufacturer might use a hospital's NPI to treat all MFP-eligible outpatient claims as 340B-eligible, even if they are not.

Response: CMS expects that a Primary Manufacturer reporting a "reasonable belief" that a selected drug is subject to the exception under section 1193(d)(1) of the Act will have documented evidence that the 340B ceiling price is lower than the MFP and that the claim for the selected drug is 340B eligible. CMS clarifies in section 90.2 of this final guidance that to comply with this data submission requirement at the time a Primary Manufacturer submits the section 1193(d)(1) exception code to the MTF, the Primary Manufacturer must have documentation that a claim is 340B eligible and the 340B ceiling price for the claim is lower than the MFP for the particular claim for which the Primary Manufacturer is applying the exception. CMS reiterates that nothing in this final guidance modifies a manufacturer's statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to offer 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 also notes that an NPI alone (whether a prescriber NPI or a hospital/provider NPI) 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. CMS is not requiring the Primary Manufacturer to submit documentation that a 340B discount has been or will be offered for a claim when it submits the code indicating its method for determining the MFP Discount/Refund Amount to the MTF; however, CMS intends to conduct targeted audits to monitor that appropriate reporting of payment elements and the appropriate application of the exception under section 1193(d)(1) of the Act, and the Primary Manufacturer must maintain this documentation to share with CMS upon request. The determination of whether a Primary Manufacturer has complied with its statutory obligation to make MFP available is ultimately based on the facts and circumstances and the totality of evidence made available to CMS.

Comment: CMS received many comments requesting that the complaint and dispute process include issues related to 340B nonduplication. Some commenters recommended that, under the complaints process, CMS use enforcement discretion in instances where a Primary Manufacturer is acting in a timely manner to rectify errors made due to the 340B operational challenges associated with policies in the draft guidance. These commenters stated that CMS should consider holding harmless manufacturers that demonstrate a good faith effort to offer covered entities with the lesser of the MFP or the 340B ceiling price. A couple of commenters raised

concerns about the adequacy of the "HRSA ADR process" (CMS understands this as a reference to the HRSA 340B Administrative Dispute Resolution (ADR) process).

Response: CMS thanks these commenters for their feedback. 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 system 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 MTF refund had been processed (i.e., the manufacturer provided a duplicate discount), 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 on a claim that the Primary Manufacturer claimed was subject to section 1193(d)(1) of the Act based on the Primary Manufacturer's report of claim-level payment elements, in which case CMS will investigate to assess whether the Primary Manufacturer's report was accurate and whether an MFP refund was owed rather than the exception in section 1193(d)(1) of the Act applying. As part of that investigation, CMS will review the extent to which the Primary Manufacturer reasonably believed the reported claim-level payment elements were correct and whether the Primary Manufacturer has complied with its statutory obligation to offer the lesser of the MFP or the 340B ceiling price, including assessing the role that any operational barriers played in the Primary Manufacturer taking timely actions related to these claims. If CMS determines that the MFP should have been made available for the claim, CMS will give the Primary Manufacturer an opportunity to take corrective action to make the MFP available. Regarding the commenters' requests that manufacturers be held harmless in certain cases, CMS reiterates that the determination of whether a Primary Manufacturer has complied with its statutory obligation to make MFP available is ultimately based on the facts and circumstances and the totality of evidence made available to CMS.

Comments about the adequacy of the HRSA 340B ADR process are outside the scope of this guidance document.

Comment: A few commenters stated that the 14-day prompt MFP payment window should not start until a manufacturer receives all data necessary to ascertain whether the unit of selected drug claim is a 340B claim. One commenter expressed concerns with CMS requiring the Primary

Manufacturer to provide access to the MFP within the 14-day prompt MFP payment window if CMS does not mandate the provision of 340B data or start the 14-day prompt MFP payment window when a manufacturer receives all data necessary to ascertain whether the unit of selected drug claim is a 340B claim. Two commenters expressed concern that the 14-day prompt MFP payment window does not allow adequate time for processes to deduplicate the MFP and 340B ceiling price and recommended CMS extend the window. One commenter recommended CMS direct manufacturers and 340B covered entities to determine 340B eligibility for claims for selected drugs within the 14-day prompt MFP payment window. One commenter recommended that CMS clarify that the requirement for manufacturers to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price does not mean that manufacturers can delay providing access to the 340B ceiling price where applicable.

Response: Pursuant to section 40.4 of this final guidance, the MFP must be made available to the dispensing entity by transmitting payment of an amount that provides access to the MFP within 14 days of the MTF DM sending to the Primary Manufacturer claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual. The text and structure of section 1193 of the Act support the interpretation that CMS may require Primary Manufacturers to provide access to the MFP in cases where, at the end of the 14-day prompt MFP payment window, the Primary Manufacturer has not verified that the claim is a 340B-eligible claim (as defined in section 40.4.5 of this final guidance). Applying section 1193(d) of the Act, unless the Primary Manufacturer indicates on the report of claim-level payment elements that 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 within the 14-day prompt MFP payment window, the Primary Manufacturer is required to transmit payment of an amount that provides access to the MFP of a selected drug within the 14-day prompt MFP payment window. If a Primary Manufacturer verifies a claim is a 340B-eligible claim after transmitting an MFP refund through the MTF PM on the claim within the 14-day prompt MFP payment window, the Primary Manufacturer may use the credit/debit ledger system detailed 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 resolve the duplicate discount outside of the MTF's processes.

Comment: A few commenters recommended that CMS develop a clear process for manufacturers to promptly provide the difference between the MFP and 340B price when the manufacturer makes the MFP available for a claim and it is later determined that the claim is 340B-eligible, and the 340B ceiling price is lower than the MFP.

A few commenters stated that when a covered entity engages with a contract pharmacy, the MFP may be made available to the contract pharmacy and the 340B price may be made available to the covered entity. The commenters claimed that in instances where the manufacturer pays the MFP refund on a claim that it is later determined to be 340B-eligible and the 340B price is lower, the manufacturer paying the difference between the MFP and the 340B ceiling price to make an entity whole will only work if the MFP is made available to the covered entity, rather than the contract pharmacy, and the difference is made available to the covered entity.

A few commenters stated CMS should establish a process for a manufacturer to claw back from the covered entity or receive a credit for future MFP refund payments to the covered entity or

contract pharmacy if the manufacturer makes the MFP available during the 14-day prompt MFP payment window and it is later determined that the 340B price should be made available to the covered entity. The commenters stated that the process of a manufacturer making the difference between the MFP and the 340B price available to a covered entity after the MFP refund has been paid could not function within the existing model for wholesalers to replenish 340B stock to 340B covered entities. One commenter stated that if a manufacturer must make the difference between the MFP and the 340B price available to a covered entity, it could delay the length of time the covered entity must wait to receive access to the 340B price, resulting in cashflow issues, putting covered entities in the position of having to pursue additional reimbursement to which they are entitled, and significantly undermines covered entities' 340B programs.

Response: CMS declines to prescribe a process for Primary Manufacturer to make the difference between the MFP and 340B ceiling price available. CMS also declines to provide a claw back process under which the MTF would facilitate the Primary Manufacturer requesting the MFP refund back, necessitating a payment by the dispensing entity to the Primary Manufacturer. In circumstances where an MFP refund is paid through the MTF PM but the claim is later verified by the Primary Manufacturer through the 340B nonduplication process or other claim validation review, consistent with the Primary Manufacturer's MFP effectuation plan, as a 340B-eligible claim and the 340B ceiling price is lower than the MFP at the time of dispense, the Primary Manufacturer may use the credit/debit ledger system detailed 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 resolve the duplicate discount outside of the MTF's processes.

Comment: Some commenters stated that the lack of coordination between pharmacies' claim receivable systems and 340B inventory tracking systems would present significant challenges and fragmentation if manufacturers were able to claw back MFP refunds for a claim that is later determined to be a 340B claim and the 340B price is lower than the MFP. The commenters noted that this fragmentation between pharmacies' claims receivable systems and 340B inventory tracking systems could result in a negative financial impact to covered entities and contract pharmacies. A couple of commenters recommended that CMS prohibit manufacturers from clawing back MFP refunds that have been paid to covered entities or contract pharmacies to effectuate 340B nonduplication. The commenters stated that CMS prohibiting claw backs for this purpose would incentivize covered entities and manufacturers to develop processes to effectuate nonduplication without involving contract pharmacies.

One commenter stated that, because 340B claims cannot be definitively identified at the time of dispensing, manufacturers need to true-up or claw back MFP refunds paid on claims that are identified to be 340B claims and the 340B price is lower than the MFP. One commenter recommended CMS provide an enforceable claw back mechanism for scenarios in which a covered entity paid both the 340B ceiling price and MFP for the same unit of a selected drug. One commenter recommended the MTF facilitate the process to address any duplicate discounts between the MFP and 340B price, stating that the process should be modeled after 340B audits. The commenter noted that covered entities should refund manufacturers when there are duplicate discounts rather than manufacturers auditing covered entities because allowing manufacturers to individually audit covered entities will result in additional administrative and financial burdens that strain safety net providers.

Response: As stated in the above response, CMS declines to establish a CMS-enforced claw back process within the MTF under which the Primary Manufacturer could demand the dispensing entity pay back the MFP refund through a new transfer of funds from the dispensing entity to the Primary Manufacturer. In circumstances where an MFP refund is paid through the MTF PM, but the Primary Manufacturer later verifies through its 340B nonduplication process that the claim is a 340B claim and the 340B ceiling price is lower than the MFP at the time of dispense, the Primary Manufacturer may use the credit/debit ledger system detailed 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 resolve the duplicate discount outside of the MTF's processes.

Comment: One commenter stated that the retrospective MFP refund process could lead covered entities that have not received the 340B ceiling price on selected drugs where applicable from manufacturers to use HRSA's 340B ADR claiming an overcharge. The commenter noted that these instances could inundate HRSA's ADR process with requests for administrative review, which could in turn lead to uncertainty for covered entities, manufacturers, and the government. One commenter recommended that CMS reconsider the approach of deferring certain 340B and MFP disputes to the HRSA ADR process as this commenter asserted that the process is biased against manufacturers.

One commenter stated that the HRSA ADR process is appropriate to use when the 340B price is not made available to a covered entity by a manufacturer. The commenter also noted that the lack of a clear timing requirement for the Primary Manufacturer to pay the difference between the MFP and 340B price where appropriate to a dispensing entity could lead to increased HRSA ADR complaints.

A couple of commenters recommended CMS work with and financially support HRSA to ensure manufacturers are not subject to duplicate discounts of the 340B ceiling price and the MFP. One commenter stated that CMS and HRSA should act within their authority to facilitate and enforce nonduplication. A couple of commenters recommended that CMS and HRSA issue additional guidance regarding how to prevent duplication of the 340B price and the MFP.

Response: CMS appreciates the feedback and is committed to working with HRSA throughout implementation of the Negotiation Program. 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 work with HRSA and 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 deduplicating between the 340B ceiling price and the MFP.

Comment: Many commenters asserted that section 1193(d)(1) of the Act assigns CMS, as administrator of the Negotiation Program, a duty to ensure manufacturers are not subject to

providing both the 340B price and the MFP on the same unit of selected drug. One commenter asserted that it would be arbitrary and capricious for CMS to finalize a policy under which a manufacturer is required to pay an MFP refund by the end of a prompt MFP payment window, or risk a civil monetary penalty, where the manufacturer does not have the data necessary to determine whether the unit is not subject to the 340B price. Many commenters stated that sections 1193 and 1196 of the Act require CMS to administer and ensure compliance with the Negotiation Program, including the effectuation of the MFP, and 340B nonduplication is a core component of effectuation of the MFP because the MFP is not required to be made available if the 340B ceiling price is lower than the MFP. A couple of commenters asserted that CMS has the authority to implement the 340B nonduplication requirement and the obligation to help facilitate statutory intent.

One commenter asserted that CMS failed to meet its statutory obligation to ensure that 340B covered entities can procure drugs at the lower of the 340B ceiling price or the MFP. Another commenter stated that there is no language in the IRA's 340B nonduplication provisions suggesting that manufacturers have authority to create their own nonduplication methodologies. The commenter asserted that allowing manufacturers to develop their own processes for nonduplication could drastically alter how hospitals participate in 340B and result in an "implied repeal" of the 340B program, which is generally disfavored by courts.

Response: While the statute does not expressly foreclose a role for CMS in facilitating deduplication, section 1193(d) of the Act does not expressly require CMS to deduplicate the two discounts. The text of section 1193(d)(1) of the Act provides an exception from the obligation to provide access to the MFP to enable the Primary Manufacturer of a selected drug to comply with any obligations they may separately have to offer 340B discounts on selected drug claims. However, section 1193(d)(2) of the Act imposes a requirement on a Primary Manufacturer of a selected drug to provide access to the MFP in a nonduplicated amount to the 340B ceiling price including in cases where the selected drug claim is 340B-eligible, and the MFP is below the 340B ceiling price. CMS reiterates 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 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.

Comment: A few commenters stated that the draft guidance prohibits the use of the 340B discount when the MFP is lower than the 340B price, which requires hospitals to float more up-front drug costs. The commenters argued that prohibiting the use of the 340B discount for Medicare-eligible beneficiaries could disrupt hospitals' longstanding practices and affect virtual inventory systems. The comments stated that covered entities should be able to use the 340B price for all 340B-eligible patients, as permitted under section the 340B of the PHS Act.

Response: CMS appreciates the feedback. 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 offer 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.

Retrospective Refund Amount to Effectuate the MFP (Section 40.4.3)

Comment: Many commenters supported the use of WAC to calculate the SDRA. One commenter suggested CMS clarify that WAC on the date of dispensing is based on the date of service of the Part D claim and to specify the effective and termination dates for WAC. This same commenter suggested CMS specify the pharmaceutical pricing database compendia used as the source for WAC. Some commenters stated that WAC is not an accurate proxy for calculating the SDRA and recommended CMS use an alternative metric or method for determining the SDRA that more closely reflects acquisition costs. A few commenters suggested various alternative pricing metrics to WAC, such as NADAC, ASP, Federal supply schedule, and annual non-Federal average manufacturer prices. One commenter stated NADAC would be an inappropriate metric to calculate the SDRA since it may reduce or eliminate profit margins for pharmacies.

Response: CMS appreciates commenters' support for the use of WAC to calculate the SDRA and feedback regarding alternative metrics or methods. CMS clarifies in section 40.4.1 of this final guidance 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 to make the MFP available. CMS will provide accurate and timely updates to WAC in the calculation of the SDRA and will engage with the MTF Contractor as needed for support.

Comment: A couple of commenters expressed concerns that manufacturers may alter WAC such that it would affect the profits of dispensing entities. For example, one commenter expressed concern that manufacturers would decrease WAC below acquisition costs such that dispensing entity profits would decrease. Another commenter expressed concern that manufacturers may raise WAC above acquisition costs such that dispensing entity profits would increase.

Response: CMS acknowledges commenters' concerns regarding the possible manipulation of WAC by manufacturers. CMS will monitor the effects of the Negotiation Program on the pharmaceutical industry generally and encourages dispensing entities to utilize the complaint process to report if the MFP was not made available. CMS also reiterates that provision of the SDRA claim-level data element, which will be calculated by using the selected drug's WAC, is intended to provide an additional data point that might assist the Primary Manufacturer in calculating the MFP refund. 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.

Comment: Commenters provided various perspectives on the pricing metric used to determine the MFP refund amount. Some commenters recommended CMS clarify that the pricing metric used to determine MFP refund amounts cannot exceed WAC. One commenter recommended CMS clarify that the pricing metric used to determine MFP refund amounts cannot be lower than WAC. Some commenters recommended CMS use the lesser of WAC or an alternative metric, such as acquisition cost, when determining the refund amount. One commenter recommended CMS clarify that manufacturers may provide refund amounts based on acquisition cost rather than WAC. One commenter stated that dispensing entities may have costs exceeding WAC in certain situations, such as when a drug is in shortage and a dispensing entity must use a secondary wholesaler, and recommended CMS ensure access to a refund amount reflective of higher acquisition costs. Another commenter stated situations in which dispensing entities' acquisitions costs are above WAC are rare and recommended CMS also use the SDRA in these instances to prevent dispensing entities from having to report actual acquisition costs. One commenter recommended that CMS allow manufacturers to cap the payment provided to dispensing entities for amounts other than the SDRA, such as limiting payments to acquisition costs, excluding distributor fees. Some commenters expressed concern about providing a refund amount based on acquisition cost since acquisition cost is highly variable and only known by dispensing entities. One commenter recommended CMS prohibit manufacturers from requiring pharmacies to provide their acquisition costs as these are highly variable and contain sensitive and proprietary information. A few commenters recommended CMS clarify that a refund amount other than the SDRA is only required in limited circumstances, such as when a dispensing entity notifies a manufacturer that acquisition costs exceed WAC, when a manufacturer and dispensing entity have a contract price agreement for an amount below WAC, or when manufacturers have charged dispensing entities above WAC. One commenter expressed concern that manufacturers may exclude distributors charging dispensing entities above WAC from their network, resulting in decreased patient access to selected drugs. A couple of commenters stated the statute requires manufacturers to provide access to no more than the MFP.

Response: CMS thanks commenters for their feedback. Section 1193(a) of the Act requires the Primary Manufacturer to provide access to the MFP to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed a selected drug during a price applicability period. Section 40.4 of this final guidance permits the Primary Manufacturer to make the MFP available through a retrospective refund for the difference

between the dispensing entity's acquisition cost for the selected drug and the MFP. Accordingly, the Primary Manufacturer might provide access to the MFP to the dispensing entity by paying an MFP refund equal to the difference between the dispensing entity's actual acquisition cost for the selected drug, as described in section 40.4.1 of this final guidance, and the MFP. However, based on feedback from interested parties, CMS recognizes the significant operational challenges that manufacturers and dispensing entities may face in calculating a retrospective refund amount based on real-time actual acquisition cost, including concerns related to the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates between parties. Therefore, as stated in section 40.4.1 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 quantity dispensed) as part of the transmitted claim-level data elements. Based on feedback and comments provided by interested parties, CMS believes that using WAC as the standardized pricing metric to calculate the SDRA is sufficiently representative of most dispensing entities' acquisition costs to generally enable the Primary Manufacturer to meet its statutory obligation to make the MFP available via a retrospective refund payment equal to the SDRA.

However, CMS acknowledges that the SDRA may not be universally appropriate or sufficient to effectuate the MFP. Under the statute, the obligation to calculate and pay an MFP refund amount that ensures 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 and can document some other amount is appropriate to make the MFP available (e.g., the dispensing entity purchased the selected drug at a cost above WAC). CMS encourages Primary Manufacturers and dispensing entities to work together to establish an MFP refund amount using the SDRA or the dispensing entity's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available prior to the issuance of MFP refund payments between the interested parties. CMS recommends Primary Manufacturers and dispensing entities remediate MFP refund payment issues with each other directly. If remediation between the parties cannot be reached, Primary Manufacturers and dispensing entities may utilize the complaints process within the complaint and dispute system, as described further in section 90.2.2 of this final guidance, to report that the MFP was not made available.

Comment: A few commenters recommended CMS clarify that acquisition costs do not include wholesaler or distributor fees. Some commenters expressed concern that acquisition costs may include fees or markups from other parties within the pharmaceutical supply chain that manufacturers should not be responsible for paying. Some commenters were concerned that allowing manufacturers to pay such fees as part of acquisition cost may incentivize others in the supply chain to inflate prices or fees to increase profit, and a few commenters suggested CMS implement safeguards to protect against and monitor such gaming opportunities. One commenter mentioned requiring manufacturers to pay such fees may challenge the Fifth Amendment's prohibition against taking without just compensation. A few commenters mentioned doing so would exceed a manufacturer's statutory obligations.

Response: CMS appreciates the feedback regarding supply chain fees and acquisition costs. As described in section 40.4.1 of this final guidance, CMS intends to consider further the issue of determining actual acquisition cost and may address it in future guidance.

Comment: Some commenters expressed concern about the administrative and financial burden of using a payment amount other than the SDRA, which would require separate payment amounts and contracts between multiple manufacturers and dispensing entities, and some commenters recommended CMS require the use of WAC in calculating the MFP refund amount. A couple of commenters stated that mandating the use of WAC as the standardized pricing metric would protect pharmacies against receiving refund amounts that do not effectuate the MFP. A couple of commenters recommended CMS consider manufacturers to have met their obligation to make the MFP available if they offer the SDRA.

Response: CMS acknowledges commenters' concerns regarding a refund amount other than the SDRA. As discussed above, based on feedback and comments from interested parties, CMS believes the SDRA, as calculated using WAC, offers a reliable refund amount for both Primary Manufacturers and dispensing entities that agree to use such a standardized pricing metric, and we expect manufacturers and dispensing entities will generally find it advantageous to use the SDRA. However, as stated in section 40.4.1 of this final guidance, CMS acknowledges the SDRA may not apply universally and may not be sufficient to make the MFP available to the dispensing entity consistent with the Primary Manufacturer's obligation under section 1193(a)(3) of the Act in some circumstances. The Primary Manufacturer is ultimately responsible under the statute for establishing and paying the appropriate MFP refund amount to ensure access to the MFP.

Comment: A few commenters asked CMS to provide a safe harbor to a manufacturer that makes a good faith effort to make the MFP available. One commenter expressed concern that without a safe harbor, manufacturers may be at legal risk for both overpaying and underpaying dispensing entities. A few commenters requested CMS clarify the process for manufacturers and dispensing entities to agree to a pricing metric other than WAC and a refund amount other than the SDRA, such as documentation requirements for a dispensing entity requesting an alternative refund amount or reporting acquisition costs higher than WAC, what alternative pricing metrics are acceptable, how dispensing entities will be notified if a manufacturer chooses to use a metric other than WAC, and whether dispensing entities may appeal this decision. One commenter recommended CMS clarify that the determination of another refund amount should not be imposed by one party but rather result from a negotiation between manufacturers and dispensing entities.

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, including to account for perceived legal risks associated with use of SDRA in particular circumstances. CMS encourages Primary Manufacturers and dispensing entities to work together to establish an MFP refund amount using the SDRA or the dispensing entity's actual acquisition

cost or an adjusted standardized pricing metric that ensures the MFP has been made available. 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 reached, 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, regarding reports that the MFP was not made available. As part of the complaints process, parties may submit supporting documentation to CMS, such as invoice information detailing acquisition costs above WAC.

MTF Payment Facilitation (Section 40.4.4)

Comment: In response to the solicitation of feedback on the presented payment options in section 40.4.4 of the draft guidance, CMS received many recommendations from commenters supporting the selection of "Option 2: MTF Pass Through of Primary Manufacturer Funds to Dispensing Entities" ("Option 2") to support the effectuation of MFP refund payments between interested parties. Interested parties commented that Option 2 would be invaluable in streamlining the MFP refund payment process and would represent an operationally straightforward solution in support of a single platform for transmitting a high volume of refund payments in an efficient, standard, and predictable manner. Commenters noted concerns with "Option 1: MTF Collects and Shares Banking Information to Facilitate Private Transactions" ("Option 1"), such as compressed timelines for implementation of a new market solution that does not currently exist, variability in manufacturer selection of MFP refund payment issuance mechanisms, variability in dispensing entities' receipt of payment, security concerns, and general fragmentation to the current pharmaceutical supply chain. A couple of commenters did not prefer either of the two options and provided alternate solutions for how a payment exchange process might be effectuated including chargebacks and independent commercial solutions.

Response: CMS appreciates the robust feedback provided from interested parties on their preferred payment options. After publication of the draft guidance, CMS received feedback from many interested parties urging the establishment of a payment facilitation mechanism that would create standardization, predictability, and reduced burden for all parties. Interested parties commented that drug manufacturers do not typically provide payments directly to dispensing entities and that a direct means does not currently exist to allow for the exchange of MFP refund payments between parties. In response to feedback from interested parties, including comments received on draft guidance, CMS will move forward with establishing voluntary payment facilitation through the MTF PM and involve the MTF Contractor in the development and implementation of the MTF PM. The MTF PM builds on the approach described as Option 2 in the draft guidance. CMS elaborates on the functionality of how the MTF PM will operate in section 40.4.3 of this final guidance. 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.

Comment: CMS received many comments related to the collection and sharing of banking information, outlining the support and operational efficiency gained by interested parties if such

information was collected and shared. One commenter expressed concerns with cybersecurity and the sharing of sensitive information between numerous parties. A couple of commenters recommended that CMS automatically collect and share banking information from dispensing entities that elect not to participate in the MTF PM with manufacturers to prevent manufacturers that elect to make the MFP available via the MTF PM from having to independently collect banking details to effectuate MFP refund payments outside of the MTF with respect to such dispensing entities. Some commenters stated that, in addition to implementing Option 2 as described in section 40.4.4 of the draft guidance, CMS should also collect and share dispensing entities' banking information to allow for validation of accurate depositing into the dispensing entities' account by manufacturers and to support MFP refund payments required to be made outside of the MTF PM.

Response: CMS thanks these commenters for their recommendations. CMS understands that bank account information is a necessary condition for issuing accurate ERAs or remittances to reconcile an open claim transaction and to confirm that MFP refund payment was successful as described in section 40.4.2 of this final guidance. CMS has consistently heard from interested parties that without an ERA or remittance, MFP refund payments may be rejected and, in these scenarios, dispensing entities would not have a means to reconcile received payments against outstanding MFP-eligible claims. CMS intends to require the collection of banking information from dispensing entities as a mandatory element of enrollment in the MTF DM; enrollment details are further outlined in section 40.4.2 of this final guidance. CMS clarified in this final guidance that the collection and sharing of banking information collected during enrollment is required to establish an accurate ERA or remittance for Primary Manufacturer MFP refund payments and is a required element of a dispensing entity's enrollment in the MTF DM. CMS believes that the collecting and sharing of dispensing entities' bank account information with Primary Manufacturers to establish an ERA or remittance based on industry standards addresses interested parties' concerns related to the lack of an established channel to support MFP refund payments made outside of the MTF PM. CMS expects to develop more details on how dispensing entities' bank account information will be provided to Primary Manufacturers and what safeguards will be required to ensure protections of both parties, including requirements and liabilities related to data sharing and breach in MTF agreements.

Comment: Many commenters provided feedback on voluntary participation in the MTF PM, as described in section 40.4.4 of the draft guidance, and provided recommendations on which aspects of the MTF PM they would like to see clarified in this final guidance. Some commenters suggested that participation in the MTF PM should be mandatory for all manufacturers and dispensing entities. Commenters cited as a rationale for mandatory participation of dispensing entities the challenges manufacturers would encounter with having to establish payment mechanisms for the potentially many dispensing entities that elect not to participate in the MTF PM. A few commenters raised operational challenges and concerns with having to operate multiple MFP effectuation processes if there is not a single, standardized payment flow for dispensing entities to receive payments and cited concerns with restrictions in access to selected drugs as a response imposed by manufacturers. Some commenters recommended that, when a manufacturer elects to provide access to the MFP through the MTF PM, all dispensing entities

should be required to receive funds through the MTF PM and expressed concerns with dispensing entities placing requirements on manufacturers resulting in a fragmented and unstable payment market where manufacturers would be required to develop different payment solutions to accede to a dispensing entity's terms to avoid Negotiation Program penalties. Some commenters also suggested that if a manufacturer elects to provide the MFP refund through the MTF PM, then the manufacturer should not be subject to compliance actions for dispensing entities that elect not to receive payments from the MTF PM, based on the theory that manufacturers participating in the MTF PM have made good faith efforts and should not be liable if a dispensing entity refuses to accept this form of payment. One commenter noted that manufacturers and dispensing entities should be required to participate in the MTF PM, but that only the manufacturer should then have the option to opt out if so desired.

Response: CMS thanks these commenters for their input. Section 1193(a)(3)(A) of the Act makes it the sole responsibility of the Primary Manufacturer to provide access to the MFP for its selected drug to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drugs. The statute does not specify one particular mechanism by which Primary Manufacturers must provide access to the MFP, nor does it provide CMS with an express role to support manufacturer effectuation of the MFP, but it does require in section 1193(a)(5) of the Act that "the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program." CMS acknowledges that currently a means to facilitate direct payments between manufacturers and dispensing entities does not exist, so CMS will engage the MTF Contractor to establish a voluntary MTF PM that will provide MFP payment facilitation functionality for participating Primary Manufacturers. Participation in the MTF PM is not sufficient in and of itself for Primary Manufacturers to fulfill their statutory obligation in making the MFP available. CMS expects that many Primary Manufacturers will elect to participate in the MTF PM given the many requests from interested parties requesting such functionality; however, Primary Manufacturers remain free to establish their own payment processes outside of the MTF PM if they choose to do so in order to meet their statutory obligations to provide access to the MFP.

Under Option 2 in the draft guidance, it was contemplated that the MTF PM's payment facilitation functionality would be available only if both the Primary Manufacturer and the dispensing entity opt into the MTF PM. Upon review of comments from interested parties and further consideration of the nature of the MTF PM, CMS recognizes that the original concept of the MTF PM as a two-party platform requiring the dispensing entity's "participation" was inconsistent with the MTF PM's intended ministerial role as a mechanism through which Primary Manufacturers could transmit MFP refund payments to be passed through to dispensing entities. 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 a means by which MFP refund payments can be passed through to dispensing entities at the Primary Manufacturer's election. Accordingly, CMS clarifies in section 40.4.3.3 of this final guidance that 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 discussed in sections 40.4.2.2 and 40.4.3.1 of this final guidance, upon enrollment in the MTF DM, the dispensing entity will indicate 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 checks. If the Primary Manufacturer participates in the MTF PM and elects to send an MFP refund payment for the dispensing entity to 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). 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. 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.

Regardless of whether the MFP refund payment is passed through the MTF PM or made outside of the MTF PM, CMS understands that the collection of dispensing entity banking information is essential to the accurate establishment of an ERA or remittance and therefore will be a required element of dispensing entity enrollment in the MTF DM. Whenever payment by the Primary Manufacturer 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. In addition, CMS believes that the collection and sharing of dispensing entities' banking information with Primary Manufacturers will assist the Primary Manufacturer in transmitting MFP refund payment to a dispensing entity outside of the MTF PM and in generating the ERA or remittance. CMS outlines in this final guidance that the MTF will collect dispensing entity banking information as part of enrollment in the MTF DM and will share that information with Primary Manufacturers to account for instances in which the MFP refund is not paid through the MTF PM to enable development by the Primary Manufacturer of an accurate ERA or remittance for dispensing entities. The determination of whether a Primary Manufacturer has complied with its statutory obligation to make MFP available is ultimately based on the facts and circumstances and the totality of evidence made available to CMS.

Comment: Many commenters expressed interest in CMS further defining the establishment of a system for the handling of claims that are reversed or that require an adjustment to a previously paid MFP refund amount. Some commenters provided recommendations on how manufacturers should be notified by the MTF when a reversal or adjustment occurs on a claim, additional justification codes, the benefits of using established models for handling a reversal, and concerns regarding liabilities if manufacturers are not allowed to perform proper validation of adjusted or reversed claims. A couple of commenters noted how reversals and adjustments might be reflected on an ERA, including the corresponding transaction lines that should be included. A few commenters provided feedback related to how payments should be handled in a reconciliation process, including requesting clarification related to timelines and the type of contractor CMS should consider engaging to provide a reconciliation service. Lastly, some commenters noted their preference for a credit and reconciliation process where the credit would be netted out from future payments when a reversal or adjustment is identified.

Response: CMS thanks these commenters for their input. CMS agrees that a reliable and accurate credit and adjustment process is necessary for the communication of MFP-eligible claim reversals and claim adjustments to the Primary Manufacturer, regardless of whether the Primary Manufacturer participates in the MTF PM, and reconciliation of MFP refund payments passed from the Primary Manufacturer to the dispensing entity through the MTF PM on claims that are later reversed or adjusted. 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. The MTF will not maintain 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. 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 paid claim requires an adjustment and the corresponding adjusted payment amount as determined by the Primary Manufacturer in provision of MFP access. In both pathways, a credit 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. For payments not passed through the MTF PM, section 40.4.4 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 Primary Manufacturers that elect not to participate in the MTF PM or with respect to claims paid outside of the MTF PM for Primary Manufacturers that participate in the MTF PM but make payment to a dispensing entity outside of the MTF PM. 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: CMS received a few process-related comments specific to how Primary Manufacturers that elect to participate in the MTF PM should be required to make MFP refund payments outside of the MTF PM to dispensing entities if those payments cannot be facilitated through the MTF PM because a dispensing entity has elected not to participate in the MTF PM. A couple of commenters suggested that the 14-day prompt pay requirements not apply to MFP refunds that must be paid outside of the MTF PM to dispensing entities that elect not to receive MFP refund payments from the MTF PM where the manufacturer has elected to participate, citing delays with collecting banking information and, if banking information is not available, potentially being required to issue and mail paper checks to dispensing entities, which adds additional time and burden to the manufacturer's payment process. Additionally, a couple of commenters also stated that it should be sufficient for Primary Manufacturers participating in the MTF PM to provide a single approach for effectuating the MFP outside of the MTF PM for

dispensing entities that do not participate in the MTF PM in their MFP effectuation plans, as described in section 90.2.1 of the draft guidance.

Response: CMS thanks these commenters for sharing their perspectives and acknowledges the concerns expressed. CMS reiterates that participation in the MTF PM is voluntary for Primary Manufacturers, as outlined in sections 40.4.3 and 40.4.4 of this final guidance. It is ultimately the Primary Manufacturer's responsibility to provide access to the MFP to a dispensing entity, as required by section 1193(a)(3) of the Act. In the event the Primary Manufacturer elects to fulfill that responsibility by participating in the MTF PM, the MTF PM will provide an avenue to process payments to all dispensing entities enrolled in the MTF DM, either via an electronic transfer of funds or by issuing a paper check from the funds the Primary Manufacturer provides to the MTF PM. The MTF PM will pass through the Primary Manufacturer's MFP refund payment in accordance with the dispensing entity's selected payment method preference (i.e., electronic transfer of funds or paper check). As clarified in section 40.4.3.3 of this final guidance, upon further consideration, 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. In the event the Primary Manufacturer elects to fulfill its responsibility for MFP effectuation outside of the MTF PM, the Primary Manufacturer is obligated to establish an approach that makes MFP available to all applicable dispensing entities by transmitting payments of an amount that provides access to the MFP within the 14-day prompt MFP payment window, whether through a combination of electronic transfer of funds, paper checks, or any alternative arrangement that may be agreed upon by the Primary Manufacturer and applicable dispensing entities.

As described in section 40.4.2.2 of this final guidance, in future rulemaking, CMS intends to propose requiring Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM. To meet standards in the creation of an accurate ERA or remittance, a dispensing entity enrolling in the MTF DM will be required to provide up-to-date banking information as part of the dispensing entities' terms of enrollment. This banking information will be shared with Primary Manufacturers to establish accurate ERAs or remittances for MFP refund payments made outside of the MTF PM. For Primary Manufacturers participating in the MTF PM, payment to dispensing entities that indicate a preference for payment by paper check will be issued by paper check by the MTF PM on the Primary Manufacturer's behalf. For Primary Manufacturers not participating in the MTF PM or that are participating but have a mutually agreed-upon process with a dispensing entity for payment outside of the MTF PM, the Primary Manufacturer might use the banking information to provide Automated Clearing House (ACH) payment, where allowable by the dispensing entity, or might issue paper checks to the address collected during enrollment for a dispensing entity that does not allow receipt of payment from any of the options described above.

If the Primary Manufacturer submits payment to the MTF PM for pass through to dispensing entities, CMS reiterates that the passed through MFP refund payment will be issued by paper check by the MTF PM to dispensing entities that indicate a preference for payment by paper check. If a Primary Manufacturer elects to establish its own payment facilitation method and

decline the use of the MTF PM, then the Primary Manufacturer's MFP effectuation plan is required to account for dispensing entities that elect to receive electronic transfer of funds and dispensing entities that do not. As discussed in section 40.4.2 of this final guidance, the MTF DM will include the dispensing entity's selected payment method preference among the claim-level data elements transmitted to the Primary Manufacturer. For dispensing entities that have indicated their preference to receive electronic transfer of funds, the Primary Manufacturer is required to provide an electronic reimbursement mechanism, and 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 were provided as a reimbursement mechanism. The determination of whether a Primary Manufacturer has complied with its statutory obligation to make MFP available is ultimately based on the facts and circumstances and the totality of evidence made available to CMS.

Comment: CMS received a few comments from interested parties requesting clarification that participation in the MTF PM should not preclude parties from establishing contractual arrangements outside of the MTF. A few commenters requested that CMS clarify that Primary Manufacturers will still be allowed to participate in the MTF PM if they have contractually established pricing or rebate amounts with dispensing entities, and that they should not be excluded from being allowed to participate in the MTF PM and provide MFP refunds using their contracted prices with dispensing entities as opposed to the SDRA. One commenter noted that CMS should clarify whether a dispensing entity may elect to participate in the MTF PM for some or all drugs.

Response: CMS thanks the commenters for their input. In response to comments related to the establishment of contractual MFP refund amounts agreed upon by parties, CMS reiterates that the MTF DM's provision of the SDRA claim-level data element is intended only to provide an additional data point that might assist the Primary Manufacturer in calculating the MFP refund. The Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP. The Primary Manufacturer is free to pay through the MTF PM an MFP refund different from the SDRA, including refund amounts that the Primary Manufacturer has established contractually with the dispensing entity. If the Primary Manufacturer makes an MFP refund payment that is based on a measure other than the SDRA provided in the claim-level data elements (e.g., the dispensing entity's actual acquisition cost), the Primary Manufacturer can indicate this using Table 5, Justification Code 2 as described in section 40.4.3 of this final guidance. If the dispensing entity believes that access to the MFP has not been made available, the dispensing entity is encouraged to use the complaint process within the complaint and dispute system to remediate access to the MFP if efforts to resolve directly with the manufacturer have failed.

In response to the comment related to dispensing entities participating in the MTF PM for some drugs and not others, CMS clarified in section 40.4.3.3 of this final guidance that the MTF PM does not require an affirmative election of participation by dispensing entities since the MTF PM will serve only as a mechanism to pass through MFP refund payments paid by participating Primary Manufacturers to dispensing entities. However, this does not preclude a dispensing

entity from reaching an outside agreement with the participating Primary Manufacturer for a separate arrangement to pay MFP refunds outside the MTF PM.

Comment: CMS received a few comments with requests for clarification that a manufacturer cannot be held liable if the MTF PM payment facilitation process fails through no fault of the Primary Manufacturer, such as due to technical failures outside of the control of the manufacturer, if an MFP refund payment is not transmitted, or if a related error in transmission occurs because of erroneous banking information.

Response: CMS thanks these commenters for their questions. CMS has added language to section 100.1 of final guidance noting that CMS will take into consideration technical failures related to transmission of payments outside of the Primary Manufacturer's control as well other factors for consideration as evidenced by the Primacy Manufacturer in the Primary Manufacturer's response to CMS' Notice of Potential Noncompliance.

Comment: CMS received many comments requesting that CMS "prefund" MTF PM payment accounts to facilitate efficient and timely payments to dispensing entities. This system would entail the Medicare program advancing payment to dispensing entities to effectuate the MFP and Primary Manufacturers reimbursing the Medicare program at a later date. A couple of commenters provided discussion related to the authorities that they believe require CMS to pre-fund the MFP payments itself and stated that CMS has authority to require that Primary Manufacturers pre-fund the MTF payment accounts to enable the MTF PM to issue MFP refund payments to dispensing entities more quickly. Some commenters requested that CMS establish an approach to MFP refund payment modeled after CGDP, or an aligned model, where CMS prefunds the MTF payment accounts. A few commenters expressed that, in the absence of prefunded MTF payment accounts, dispensing entities are essentially being given the responsibility to fund or "float" the Negotiation Program until MFP refunds are paid and that this would result in additional financial burden to dispensing entities that would have to operate at a cashflow deficit while they await receipt of MFP refund payments. One commenter noted the financial challenges of operating at a loss while dispensing entities wait for resolution on an MFP refund payment.

Response: CMS appreciates this feedback. 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. 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 intends to propose in future rulemaking

to shorten the current 30-day window for plans to submit 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 will ask 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. CMS intends to continue to work with interested parties to establish a reliable, predictable, and efficient MTF payment model.

Comment: CMS received many comments related to the operation, function, and implementation of the MTF PM. A few commenters suggested that CMS must ensure that no fees or costs are passed to interested parties participating in the MTF. One commenter noted that the cost of administrative fees should not be shifted from manufacturers to dispensing entities in the provision of access to the MFP for selected drugs. Many commenters shared recommendations related to the functionality of the MTF and features or functions that they would like to see from the module. A few of those commenters noted specifications for the way that the interface could work, including descriptions of what accessibility features a portal could have, and the available information that could be accessed depending on the interested party. A few commenters noted different specifications and functions that a contracted TPA might perform, or features that a TPA should have experience with, such as claims and financial functionality, and recommended that a selected contractor should be independent of interested parties to avoid conflicts of interest. CMS also received other general recommendations from a few commenters related to the establishment of Electronic Data Exchange (EDI) connectivity, collection of delivery detail for ERA transmission, change control process for when dispensing entity ownership changes, frequency of billing and payment cycles, and securities and fraud.

Response: CMS appreciates the commenters' recommendations on how the operational components of the MTF PM might operate. As stated in section 40.4.3 of this final guidance, neither Primary Manufacturers nor dispensing entities shall have to pay any fees to utilize the MTF PM as CMS will bear the cost of operationalizing the MTF PM. As outlined in section 40.4.3, regardless of whether the MFP refund is facilitated 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. CMS intends to contract 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.

Comment: One commenter requested that CMS utilize Option 2 for the MTF PM set forth in section 40.4.4 of the draft guidance and require Primary Manufacturers to submit their Table 4 data to the MTF DM within one day of receiving Table 2.

Response: CMS thanks the commenter for their feedback. After receiving public comments and feedback, CMS will engage an MTF Contractor to facilitate the transfer of MFP refund payments between participating Primary Manufacturers and dispensing entities, as generally contemplated by Option 2 in section 40.4.4 of the draft guidance. CMS declines to require Primary Manufacturers to submit their claim-level payment elements (see Table 4 of section 40.4.3.1 and Table 6 of section 40.4.4.2 of this final guidance) on a daily basis but reiterates that Primary Manufacturers are responsible for prompt return of their claim-level payment elements to ensure compliance with the 14-day prompt MFP payment window.

Medicare Transaction Facilitator Dispensing Entity Participation Requirements (Section 40.4.5)

Comment: Many commenters urged CMS to make MTF payment facilitation mandatory for both manufacturers and dispensing entities; they did not support voluntary participation for either manufacturers or dispensing entities. A couple of commenters requested that the decision to participate in the MTF PM by the dispensing entities be required to be effective for the full year before changing their decision. A few commenters recommended that CMS mandate dispensing entities to utilize the manufacturer's preferred payment method.

Response: CMS thanks commenters for their input. While registration in the MTF DM is mandatory for Primary Manufacturers, CMS intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM. As discussed in section 40.4.2 of this final guidance, participation in the MTF PM will be voluntary for Primary Manufacturers. As discussed above, CMS clarifies in section 40.4.3.3 of this final guidance that the MTF PM does 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. Upon review of comments from interested parties and further consideration of the nature of the MTF PM, CMS recognizes that the original concept of the MTF PM as a two-party platform requiring the dispensing entity's "participation" was inconsistent with the MTF PM's intended ministerial role as a mechanism through which Primary Manufacturers could transmit MFP refund payments to be passed through to dispensing entities. 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 a means by which MFP refund payments can be passed through to dispensing entities at the Primary Manufacturer's election. As described in section 40.4.3.3 of this final guidance, at the time of enrollment into the MTF DM, the dispensing entity will have the opportunity to indicate its preference 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 may indicate its preference to receive payment issued in the form of a check, if

such type of payment is preferred by the dispensing entity. If the Primary Manufacturer participates in the MTF PM and elects to send an MFP refund payment for the dispensing entity to 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). 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 the MTF PM.

Comment: A couple of commenters provided suggestions for functionality that the MTF could provide for dispensing entities. Suggestions include an easy sign-up process, management of bank account information and pharmacy credentials, collection of primary and secondary contact information, and ability to determine status of manufacturer payments on the claim-level.

Response: CMS thanks these commenters for their suggestions. CMS refers to section 40.4.2.2 of the final guidance for discussion on MTF DM functionality and section 40.4.3 of the final guidance for discussion on MTF PM functionality. CMS intends to provide further information on dispensing entity enrollment in the MTF DM at a later date.

Comment: A couple of commenters expressed support for the creation and delivery of ERA files by the MTF. They suggested that the ERA and payment be provided at the same time, and that the ERA utilize existing provider, payer, and banking system registration processes. One commenter suggested ERA files be made available to pharmacies via the MTF portal.

Response: CMS thanks these commenters for their input. CMS clarified in section 40.4.3 that, for MFP refund payments made through the MTF PM by Primary Manufacturers participating in the MTF PM to dispensing entities, the MTF DM will produce ERAs or remittances for efficient operations. Specifically, for electronic transactions facilitated through the MTF PM, ERA transactions created by the MTF DM will be made available in a timely manner after the MTF PM facilitates payment. For these transactions, the MTF DM will strive to align making the ERA available as close to the same time as possible with transmission of MFP refunds. For transactions involving a Primary Manufacturer participating in the MTF PM and a dispensing entity that elects not to receive electronic transfer of funds where MFP refund payment is instead facilitated through the MTF PM via the MTF PM issuing paper checks, remittances created by the MTF DM will be made available in a timely manner after the MTF PM issues the paper check.

For transactions involving a Primary Manufacturer that makes payment outside of the MTF PM, the Primary Manufacturer will provide the remittance transaction to the dispensing entity, using an ERA that uses the X12 835 standard adopted under HIPAA for electronic payments. CMS has clarified in section 40.4.4 that, for transactions involving a Primary Manufacturer that chooses not to pass payment through the MTF PM, the MTF DM will not create nor make available ERA or remittance files to the dispensing entity, and CMS will require that the Primary Manufacturer send ERAs or remittances to the dispensing entity directly. As part of the dispensing entity's

enrollment into the MTF DM, dispensing entities will be required to designate where payment and ERAs or remittances should be delivered.

Termination of the Agreement (Section 40.6)

Comment: One commenter recommended that CMS maintain voluntary participation for Negotiation Program participants. One commenter expressed support for the requirement of an attestation within the Agreement termination notification by the Primary Manufacturer that the manufacturer does not intend to enter into future Medicare or Medicaid program agreements or seek Medicare coverage of its drugs, because the commenter stated that attestation to these terms ensures accountability.

Response: CMS thanks commenters for their feedback.

Negotiation Factors (Section 50)

Comment: A few commenters supported CMS' efforts to revise data collection processes and information collected based on lessons learned.

Response: CMS thanks commenters for their feedback.

Comment: A few commenters requested clarification regarding how optional information submitted by the public related to section 1194(e)(2) of the Act will be used in determining the MFP so that respondents can better prepare and ensure their qualitative and quantitative information is relevant. A few commenters suggested providing educational information to help the public understand the Negotiation Program and prepare responses to address the optional request for information related to factors that are described in section 1194(e)(2) of the Act. One commenter asked that CMS provide advanced notice of the data elements that are valuable to the negotiation process. The same commenter requested that CMS publicize the ICR on multiple channels so the public is aware of the data submission opportunity.

Response: Section 50.2 of this final guidance describes what evidence CMS considers under section 1192(e)(2) of the Act and how CMS considers such evidence. CMS also refers commenters to the Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act ICR (CMS-10849, OMB 0938-1452), hereinafter referred to as the "Negotiation Data Elements and Drug Price Negotiation Process ICR," which CMS will publish for a 30-day public comment period during Fall 2024, for the specific instructions and questions that CMS proposes to collect regarding the optional request for information related to factors that are described in section 1194(e)(2) of the Act.

Comment: A couple of commenters raised concerns with the breadth and volume of information requested. A few commenters requested that CMS permit manufacturers to submit data based on their reasonable assumptions of the data elements required along with a justification of such assumptions when interpreting the applicable IRA statutory requirements and to provide voluntary explanations of information the manufacturer deems appropriate. One commenter

requested that CMS allow manufacturers to submit information the manufacturer believes is relevant and aligns with the specified requirements of the Negotiation Program. Another commenter stated that permitting Primary Manufacturers to make assumptions may result in the Primary Manufacturer choosing assumptions that are strategic to the negotiations and suggested CMS providing more structure would be beneficial.

Response: Consistent with CMS' response on page 86 of the revised guidance for initial price applicability year 2026, CMS consulted with subject matter experts and federal agencies regarding the terms defined in this guidance and solicited feedback from subject matter experts and federal agencies regarding any updates to such terms adopted in this final guidance. As already discussed herein, CMS engaged (and continues to engage) with interested parties through various platforms since the enactment of the IRA in August 2022. CMS considered recommendations and suggestions regarding the definitions included in Appendix A of this guidance, which serve as the basis for the information to be collected under section 1194(e) of the Act. 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 Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452). For example, in the ICR form, CMS instructs the Primary Manufacturer of the selected drug to explain the methodology used to calculate certain costs reported to CMS (e.g., Question 7 related to unit production and distribution cost and Question 10 related to prior Federal financial support). Otherwise, CMS believes it is important that data submissions reflect the application of consistent standards and definitions to permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted. As such, data submitted in response to this final guidance must be based on consistent definitions and scope, as reflected in Appendix A of this final guidance. CMS appreciates the resources required to meet these submission requirements. CMS also directs commenters to the Negotiation Data Elements and Drug Price Negotiation Process ICR.

Comment: A couple of commenters raised concerns regarding the clarity of submitter affiliations and potential bias. One commenter suggested that CMS should require submitters to clearly disclose sources of information and funding. One commenter praised CMS' commitment to transparency for the Negotiation Program.

Response: CMS thanks commenters for raising these concerns. CMS directs commenters to Section I of the Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452), which includes a request to identify the type of individual responding (e.g., patient, trade association, researcher, etc.) and if the individual has a relationship to the manufacturer of a selected drug or therapeutic alternative.

Comment: One commenter recommended CMS clarify that Primary Manufacturers are only obligated to report restatements to government price calculations during the negotiation period. This commenter stated that without clarity in the final guidance, Primary Manufacturers could face the obligation to provide ongoing restatements to government price reporting, creating unnecessary operational burdens.

Response: CMS thanks this commenter for their feedback. 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 and Drug Price Negotiation Process ICR Form (CMS-10849, OMB 0938-1452). Primary Manufacturers must submit to CMS updates to the Primary Manufacturer's data submitted under sections 1193(a)(4)(A) and 1194(e)(1) if the data was restated due to requirements of the government entity that initially receives and oversees processing of such data. At this time, CMS is not specifying an end date for the Primary Manufacturer's obligation to submit to CMS updates to the Primary Manufacturer's data submitted under sections 1193(a)(4)(A) and 1194(e)(1) due to restatements to government pricing data.

Comment: A couple of commenters stated that the manufacturer-specific data elements do not accurately portray the cost of innovation and are not reflective of the realities of bringing a selected drug to patients, as complexities of the U.S. drug channel, patient access, and other costs are not captured. One commenter recommended that to the extent possible, CMS account for such additional measures by providing an opportunity to submit a more complete view of the drug development and delivery process.

Response: CMS thanks these commenters for their feedback. CMS is required to consider the manufacturer-specific data described in section 1194(e)(1) of the Act, including research and development (R&D) costs of the Primary Manufacturer for the selected drug, current unit costs of production and distribution of the selected drug, and prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug, among other costs. CMS believes that for the purposes of the Negotiation Program, the definitions of these costs, as described in Appendix A of this final guidance, are sufficiently broad to capture the range of expenses a Primary Manufacturer and as applicable, a Secondary Manufacturer, may incur in bringing a selected drug to patients. As such, CMS declines to add costs related to distribution channel complexities or patient access to the manufacturer-specific data elements described in section 50.1 and Appendix A of this final guidance. Consistent with CMS' response on page 56 and 57 of the revised guidance for initial price applicability year 2026, there is flexibility for CMS to use these manufacturer-specific factors to inform offers for the MFP in such a way as to recognize the unique characteristics of a selected drug.

Comment: A few commenters supported CMS' approach to group questions together by potential respondent type. One commenter suggested a pilot and test approach to this method. A couple of commenters suggested multiple methods of submission, including either using a format best suited to the expertise, or in the case of patients, providing mail-in and call-in options with materials translated into commonly spoken languages in the United States. Another commenter raised concerns about how the grouping would be understood to impact the overall assessment of information received by CMS. Some commenters stated that the ICR for initial price applicability year 2026 was too technical and complex for patients, patient organizations, and caregivers. Commenters recommended simplifying the ICR to make it more patient friendly. One commenter said word limits were a barrier for respondents. Another commenter 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.

Response: Section 50.2 of this final guidance describes what evidence CMS considers under section 1192(e)(2) of the Act and how CMS considers such evidence. CMS declines to adopt a pilot approach for the methodology on grouping questions at this point in time. CMS considered providing test questions to the public for feedback in advance of the data collection process; however, CMS is not able to accommodate the time and operational support needed to facilitate a test process at this time. CMS provides for multiple rounds of public review and comment of the proposed Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452) and Negotiation Program guidance, which allow for opportunities for the public to comment on CMS' proposals. CMS also welcomes additional feedback from interested parties during the upcoming 30-day comment period this Fall, including input on grouping questions, among other topics. Further, consistent with the information provided on page 10 of the revised guidance for initial price applicability year 2026, CMS continues to receive feedback on the implementation of the Negotiation Program, including related to information collections, from interested parties. CMS also directs interested parties to the response provided on pages 121 of this final guidance related to comments received regarding commenters' desire for a continuous cycle of patient engagement.

In response to public feedback received about the process used to access the questions, the structural presentation of the questions within the CMS webpage, and the readability of the questions, CMS made significant revisions to the organization of the questions and the text used for the question prompts for the collection of information for initial price applicability year 2027. For example, CMS grouped questions together that more closely align to a respondent's areas of expertise and for easier navigation by respondents. CMS also sought input from the CMS Office of Minority Health and the CMS Office of Strategic Operations and Regulatory Affairs for expertise regarding the complexity of information requested whilst ensuring that the ICR meets the requirements of the Paperwork Reduction Act of 1995. CMS directs commenters to the Negotiation Data Elements and Drug Price Negotiation Process ICR Form for examples of specific language used to present patient-focused questions for initial price applicability year 2027, which CMS believes are presented in a patient-friendly manner. CMS will take the suggestions regarding translations and alternative collection methods into consideration for future initial price applicability years. Notably, CMS provides comprehensive interpretation services of written materials and notices through the tollfree hotlines for Medicare and the Health Insurance Marketplace®. These options include translation into languages other than English, free auxiliary aids, and information provided in accessible formats (including Braille, large print, data/audio files, and more). As explained in more detail in response to comments received on section 60.4 of this final guidance, 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).[30]

Comment: Some commenters urged CMS not to use any metrics of cost-effectiveness or clinical effectiveness because the metric and/or the underlying data or assumptions used to develop the metric may be discriminatory. Some commenters supported CMS' decision not to use Quality-

[30] See: https://www.cms.gov/about-cms/web-policies-important-links/accessibility-compliance.

Adjusted Life Years (QALYs) when assessing section 1194(e)(2) factors. Some commenters stated that CMS should adopt a full prohibition on the use of QALYs and/or "similar measure[s]" under the relevant prohibition in the Patient Protection and Affordable Care Act and Section 504 of the Rehabilitation Act (29 U.S.C. 794).

Response: CMS appreciates these commenters' feedback and, consistent with our response on page 46 of the revised guidance for initial price applicability year 2026, reaffirms that QALYs will not be used in the Negotiation Program to adjust CMS offers. 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 the 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 for initial price applicability year 2027. 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) of the Act, or under section 1182(e) of the Act.

Comment: Regarding CMS' intent to use data that can be separated from the use of QALYs within a given study, a few commenters requested clarification on how CMS would separate such evidence from QALYs. A few commenters requested that CMS not consider any cost-effectiveness analyses. A couple of these noted that if CMS does consider cost-effectiveness analyses, this should be done as part of a broader, holistic approach to examining the information on the selected drug. Another commenter stated that CMS has not sought input on willingness-to-pay or cost-effectiveness thresholds from the public and therefore should not include cost-effectiveness studies in CMS' analyses. One commenter stated that cost-effectiveness data should be used only for an upward adjustment to the starting point when developing the initial offer. A couple of commenters supported the use of cost-effectiveness analyses.

Some commenters supported the use of comparative effectiveness research when considering section 1194(e)(2) factors when comparing the selected drug to its therapeutic alternative(s). A few commenters cautioned CMS to ensure comparative effectiveness research is not used in such a way that would value the lives of individuals who are elderly, disabled, or terminally ill as of lower value, consistent with section 1194(e)(2) of the Act. One commenter encouraged CMS not to rely solely on comparative effectiveness research when reviewing information on the selected drug and its therapeutic alternative(s).

Response: Consistent with the response on page 47 of the revised guidance for initial price applicability year 2026, CMS recognizes per section 1194(e)(2) of the Act that comparative clinical effectiveness research may not be used "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." CMS will not, per section 1182(e) of Title XI of the Act, use QALYs but may consider other content (e.g., clinical effectiveness, risks, harms) that is relevant and allowable under applicable law in studies that employ QALYs.

By doing so CMS may glean important insights into the outcomes associated with the drug under consideration. Factors in a study that do 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 terminally ill, such as demographic information, blood pressure, cardiovascular events, and mortality before and after starting a drug (drug A) vs. another drug (drug B) may provide important data to CMS about the clinical benefit of drug A when compared to drug B. Reviewing demographic information and outcomes, such as in this example, does not require CMS to review the results of the QALY calculation but may still provide important clinical information. This approach aligns with CMS' decision to not use QALYs in the Negotiation Program while also enabling CMS to review and consider relevant information. CMS will not exclusively use data from analyses examining cost-effectiveness to adjust the starting point upward or downward and agrees with commenters that information gleaned from such studies will serve as one component in a holistic review of the selected drug and its therapeutic alternative(s).

Comment: A few commenters expressed support for the inclusion of patient-centered outcomes in the negotiation process. Some commenters encouraged CMS to select outcomes preferred by patients when evaluating the benefit of the selected drug and its therapeutic alternative(s). One commenter stated that CMS should consider outcomes that are meaningful to physicians, such as improving the ability for a patient to control their condition, minimizing safety risks, or minimizing risk of drug resistance, in addition to outcomes that are meaningful to patients. A couple of commenters requested clarification on the types of outcomes that CMS would consider, and a few commenters suggested the inclusion of outcomes related to impacts on the health system, health equity, and society.

Response: CMS appreciates commenters' support for the inclusion of patient-centered outcomes in the draft guidance. The final guidance describes how CMS will consider certain patient-centered outcomes in addition to other outcomes when evaluating the benefit of the selected drug and therapeutic alternative(s). Consistent with CMS' response on page 48 of the revised guidance for initial price applicability year 2026, 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. CMS encourages patients and other interested parties to submit their perspective on outcomes that CMS should consider for each selected drug through the Negotiation Data Elements and Drug Price Negotiation Process ICR submission and in the patient-focused roundtable events and town hall, per revised section 60.4 of this final guidance. Additionally, CMS included a question in the clinician-focused section of the Negotiation Data Elements and Drug Price Negotiation Process ICR on outcomes for CMS to consider. CMS will consider and prioritize the information as described in section 50.2 of this final guidance.

Comment: A few commenters expressed support for the inclusion of patient input and patient experience data when reviewing the selected drug and its therapeutic alternative(s). Among these comments, a few of commenters urged CMS to include data sources such as patient registries and other real-world data sources. A couple of commenters stated that CMS should prioritize real-world evidence and evidence submitted by manufacturers and clinicians. A few commenters supported CMS' approach to reviewing and prioritizing data; one commenter asked CMS to

establish standards for what would be considered "good" quality data; a couple of commenters asked CMS to adopt established frameworks and standards for CMS' literature review and internal analysis to ensure methodological rigor and a patient-centered approach; and one commenter suggested requiring a statement on data quality for external data submissions. A couple of commenters stated that there may not be statistical significance due to sample size in studies that focus on small populations, such as special populations or the Medicare population; one commenter requested that evidence from these studies be considered of equal priority to evidence from larger studies; and a couple of commenters requested transparency around the types and sources of information CMS is considering. Another commenter supported the use of clinical guidelines but cautioned that guidelines are typically infrequently updated and often do not include patients in the development process.

Response: CMS appreciates commenters' support for the inclusion of patient input and patient experience data in the draft guidance and agrees with the importance of considering this information, including equity concerns, in the negotiation process. CMS agrees with commenters on the importance of applying relevant methods and principles to CMS' literature review and internal analyses to ensure appropriate methodological rigor and patient-centricity.

CMS will consider and prioritize the information as described in section 50.2 of this final guidance. More specifically, when reviewing the literature from the public and manufacturer submissions as well as literature from CMS' review, CMS will 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 appreciates the commenter's feedback on clinical guidelines and will consider these factors when reviewing clinical guidelines, along with the other evidence listed in section 50.2 of this final guidance.

CMS also encourages interested parties to submit analyses or studies leveraging data from sources such as patient registries and other real-world sources through the Negotiation Data Elements and Drug Price Negotiation Process ICR.

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

Comment: A few 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. A couple 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.

Response: CMS thanks these commenters for their feedback and suggestions. Consistent with our response on page 50 of the revised guidance for initial price applicability year 2026, this final guidance provides information about how CMS will use the days' supply field in PDE data to calculate 30-day equivalent supply using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) when calculating the ceiling (described in section 60.2 of this final guidance) and using the WAC ratio for initial price applicability year 2027 to apply the MFP across dosage forms and strengths (described in section 60.5 of this final guidance). For purposes of weighting across dosage forms and strengths, CMS believes that calculating a 30-day equivalent supply, using the days' supply field, is feasible for the high expenditure, single source drugs covered under Part D that might be selected for negotiation for initial price applicability year 2027. As we explain in section 60.5 of this final guidance, the policies described in this final guidance are for initial price applicability year 2027, and CMS may consider additional policies for future years of the Negotiation Program. While this final guidance also describes a suggestion of error process that a Primary Manufacturer can use if it believes CMS has made a mathematical error in its calculations, this process should not be used to suggest an alternative methodology for CMS to use in its calculations.

Limitations on Offer Amount (Section 60.2)

Comment: One commenter stated that the 30-day equivalent supply methodology to negotiate a single MFP, which is then converted to an as-applied MFP for each dosage form and strength, should not be applied where the single ceiling is self-evident (meaning all NDCs of the selected drug share the same unit type, treatment regimen, and WAC per unit) as the use of this methodology in the ceiling calculation could distort the true ceiling due to potential inaccuracies in the days' supply field in the PDE. One commenter encouraged CMS to establish MFPs at the ceiling for selected drugs that address unmet needs or significantly advance patient care, as establishing higher MFPs for these drugs will help maintain investment in assets and clinical programs that address unmet needs not served by current drugs. Another commenter stated that they are unaware of private market negotiations in which purchasers start with a ceiling that cannot be exceeded for any reason (i.e., unmet medical needs, superiority over alternative treatments, new FDA-approved uses, or that are under development through ongoing clinical trials) and enforce a chosen price with penalties if not agreed to.

Response: CMS thanks these commenters for sharing their feedback. The Act provides details and a specific formula for the calculation of the ceiling for a selected drug, which is further described in section 60.2 of this final guidance. CMS interprets the language in section 1194(c)(1)(A) of the Act to mean 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 and for 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. Accordingly, CMS will calculate a single ceiling per 30-day equivalent supply across all dosage forms and strengths of the selected drug. CMS understands that Primary Manufacturers may engage in a variety of different negotiation processes with different payers and supply chain entities, but the agency sets forth in this final guidance a negotiation process that is consistent with the requirements of the Act with respect to selected drugs under the Negotiation Program.

Methodology for Developing an Initial Offer (Section 60.3)

Comment: A few commenters requested that CMS avoid considering off-label use when determining indications for the selected drug; a couple of commenters supported consideration of off-label use. A couple of commenters requested that CMS provide clarification on when off-label uses will be considered. One commenter noted that the draft guidance uses the word "may" when discussing CMS' consideration of off-label use, which the commenter asserted could lead to increased ambiguity and uncertainty. Another commenter requested clarification on whether CMS will consider off-label uses of the selected drug not covered by Medicare Part D and noted that the criteria for identifying off-label indications for the selected drug and therapeutic alternatives does not account for ultra-rare off-label use because such uses are not typically included in CMS-recognized compendia and therefore may not be covered by Part D. The same commenter also suggested that CMS revise the criteria for consideration of off-label use to allow for consideration of ultra-rare off-label uses supported by nationally recognized, evidence-based guidelines, even if the off-label use is not also included in CMS-recognized compendia. One commenter suggested that CMS include indications with low utilization that address high unmet medical need to maintain investment in research and development, for example investment in pediatric oncology indications. One commenter requested clarification for how manufacturers may provide evidence related to off-label uses not included in evidence-based guidelines.

Response: CMS appreciates commenters' feedback on the consideration of off-label use when identifying indications for the selected drug. CMS encourages all interested parties, including but not limited to clinicians, patients, caregivers, manufacturers, and researchers, to provide information about off-label use(s) through the Negotiation Data Elements and Drug Price Negotiation Process ICR. CMS will consider information submitted through the Negotiation Data Elements and Drug Price Negotiation Process ICR when developing the initial offer. CMS' policy is intended to describe the criteria that must be met for CMS to consider an off-label use of a selected drug. Should an off-label use be included in both nationally recognized, evidence-based guidelines and CMS-recognized compendia under Medicare Part D, then that off-label use may be included in CMS' analysis of the selected drug. The requirement that off-label use be included in CMS-recognized compendia is consistent with Medicare Part D coverage requirements for a medically accepted indication of a drug. Section 1860D-2(e)(4) of the Act defines "medically-accepted indication," in part by reference to section 1927(k)(6) of the Act, as any use of a covered Part D drug which is approved under the FD&C Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act.[31]

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 prior to the initial offer deadline. 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 any off-label use(s) with CMS.

[31] For further information, see section 10.6 of the Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements. Available at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.

Comment: Some 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). Some commenters urged CMS to limit the selection of therapeutic alternatives to the same pharmacologic class. Among these, a couple of commenters requested that human immunodeficiency virus (HIV) drugs be considered an exception, and that CMS look across other drug classes for clinically appropriate therapeutic alternatives or use the HHS Guidelines[32] A1 recommendations for Single Treatment Regimens. A few commenters asked CMS to also limit consideration of therapeutic alternatives to drugs with the same or similar dosing requirements, mechanism of action, or treatment modality. One commenter stated therapeutic alternatives should be chosen if they represent the standard of care for treatment of a given indication. One commenter recommended CMS include nonpharmacologic therapeutic alternatives that are included in clinical guidelines. A couple of commenters recommended that CMS consider real world data when selecting a therapeutic alternative for conditions such as cancer and HIV for which patients may be prescribed a treatment that is not included in the literature or does not have a therapeutic alternative. One commenter suggested that CMS preserve the approach described in the initial price applicability year 2026 revised guidance to use the most clinically comparable therapeutic alternative rather than potentially using a subset of clinically comparable therapeutic alternatives. 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.[33]

Response: CMS appreciates commenters' feedback regarding the selection of a therapeutic alternative(s) for the selected drug. Consistent with the response provided on pages 54-55 of the revised guidance for initial price applicability year 2026 and as described in section 60.3.1 of this final guidance, CMS will identify the therapeutic alternative(s) based on factors related to section 1194(e)(2) of the Act and consideration of various sources of evidence including clinical guidelines, peer-reviewed literature, CMS-recognized compendia, and data submitted by manufacturers and the public. CMS believes the framework described in this final guidance will allow CMS to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist, including those used in cancer and HIV treatment. Also, per section 60.3.1 of this final guidance, CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials, and therefore CMS will only consider therapeutic alternatives that are drugs or biological products covered under Part D or Part B. CMS also may consult with FDA in the process of identifying other approved therapies for the same indication and with health care providers, patients or patient organizations, and academic experts to ensure that the appropriate therapeutic alternative(s) are selected. 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 prior to the initial offer deadline. 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. CMS appreciates the suggested AHRQ resource for best practices in

[32] See: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new.
[33] Agency for Healthcare Research and Quality, "Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide." (Content last reviewed March 2021). See: https://effectivehealthcare.ahrq.gov/products/observational-cer-protocol.

observational comparative effectiveness research and intends to consider how this resource may be used in the Negotiation Program.

Comment: A couple of commenters opposed the inclusion of biosimilars and generic drugs as potential therapeutic alternatives stating this may undervalue the selected drug. A couple of commenters expressed support for including generic and biosimilar therapeutic alternatives.

Response: CMS appreciates commenters' feedback. CMS will consider generic and biosimilar therapeutic alternatives for the selected drug and use the appropriate price(s) (Net Part D Plan Payment and Beneficiary Liability, ASP, or MFP of the therapeutic alternative(s)) to determine a starting point for initial offer development, as described in sections 60.3.1 and 60.3.2 of this final guidance.

If a Primary Manufacturer disagrees with CMS' identification of a biosimilar or generic drug as an appropriate therapeutic alternative to the selected drug, the Primary Manufacturer will have multiple opportunities to share that feedback with CMS, as described in section 60.4 of this final guidance.

Comment: Some commenters requested that clinicians and patients and/or patient organizations be involved in the selection of the therapeutic alternative(s) for each selected drug to ensure patient preferences and experiences are included and to leverage the clinical expertise of clinicians who treat specific indications of the selected drug. One commenter stated that contributing to the ICR is not sufficient engagement of stakeholders and suggested that CMS solicit public comment on the selection of therapeutic alternatives. One commenter recommended that CMS seek input from health care advisor provider boards and suggested CMS provide more information on when FDA or other experts will be consulted and what criteria would be used to identify experts.

Response: CMS thanks these commenters for their input. CMS is committed to incorporating input from interested parties throughout the negotiation process. As described in section 60.3.1 of this final guidance, CMS may consult with FDA, clinicians, patients or patient organizations, and/or academic experts, to help inform the identification of appropriate therapeutic alternatives. CMS also 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 Negotiation Data Elements and Drug Price Negotiation Process ICR. CMS specifically added questions to this ICR to gather input on selection of the therapeutic alternative(s). CMS also encourages input from patients, patient advocacy organizations, caregivers, clinicians, and other interested parties through the patient-focused roundtable events and town hall meeting described in section 60.4 of this final guidance. CMS does not anticipate developing specific criteria for individuals or organizations that may provide information to avoid limiting the variety of individuals and organizations that may be interested and able to share their expertise during the negotiation process.

Comment: Some commenters requested that CMS engage manufacturers before and during the process of selecting a therapeutic alternative(s) for each selected drug. Among these commenters, a few suggested engaging manufacturers early in the selection process to provide

data and contribute information to identifying appropriate therapeutic alternatives. A few commenters requested that manufacturers have the opportunity to provide feedback on therapeutic alternative(s) selected, including the opportunity to object to the selected therapeutic alternative(s) and to submit additional information. One commenter requested that CMS provide a written justification sharing the therapeutic alternative(s) selected and the information used to make the selection. Another commenter suggested CMS establish a separate scoping process for manufacturers and other interested parties to contribute to selection of therapeutic alternatives.

Response: CMS appreciates commenters' suggestions related to the identification of therapeutic alternatives. CMS expects Primary Manufacturers and other interested parties to provide information, including suggestions for potential therapeutic alternatives for a selected drug, through the Negotiation Data Elements and Drug Price Negotiation Process ICR. In this ICR, CMS added a question requesting input on therapeutic alternatives for the selected drug to the manufacturer-focused section, the clinician-focused section, and the patient-focused section, though any interested party may contribute to any section of the ICR.

If a Primary Manufacturer disagrees with CMS' identification of a therapeutic alternative to the selected drug, the Primary Manufacturer will have multiple opportunities to share that feedback with CMS. As described in section 60.4 of this final guidance, the Primary Manufacturer will have the opportunity to meet with CMS prior to the initial offer deadline as well as opportunities to meet throughout the negotiation process, if applicable, to convey the Primary Manufacturer's perspective on CMS' identification of a therapeutic alternative(s) to the selected drug, among other potential points of discussion. For example, after issuing the initial offer and concise justification, CMS will reach out to the Primary Manufacturer of a selected drug and offer a negotiation meeting for both parties to meet and discuss the initial offer. This will enable CMS and Primary Manufacturers to engage in negotiation discussions sooner in the negotiation process, including with respect to the therapeutic alternative(s) identified by CMS as part of CMS' initial offer development.

Comment: A couple of commenters suggested that considering generics and biosimilars when determining a therapeutic alternative is incongruous with statute because drugs with a generic or biosimilar on the market are exempt from selection for the Negotiation Program. One commenter stated the consideration of generic and biosimilar therapeutic alternatives is counter to the framework established under the Drug Price Competition and Patent Term Restoration Act and the Biologics Price Competition and Innovation Act, though the commenter did not elaborate. One commenter stated that generic and biosimilar products should not be considered when selecting a therapeutic alternative(s) because CMS selects drugs for negotiation using a narrow definition of generic competition but would then use a more expansive set of generic and biosimilar products, which the commenter argued would represent "actual" competition, when negotiating the MFP.

Response: The process for identifying a selected drug as defined in section 1192 of the Act and further described in section 30 of this final guidance is distinct from the statutory requirement in section 1194(e)(2) of the Act to consider evidence related to therapeutic alternatives. Section 1192(e) of the Act directs CMS to exclude, from selection for negotiation, drugs for which CMS determines one or more generic or biosimilar products are approved or licensed, as applicable,

and marketed. By contrast, for any selected drug, section 1194(e)(2) of the Act directs CMS to consider various factors during negotiation including comparing a selected drug to therapeutic alternative(s) that provide an alternative treatment to the selected drug, which may include drugs that are available as generic or biosimilar products. The inclusion of generic and biosimilar products as possible therapeutic alternatives to a selected drug aligns with statutory obligations, including the statutory directive for CMS to use a consistent methodology and process to achieve the lowest MFP for each selected drug.

Comment: Some commenters requested more transparency regarding how CMS identifies therapeutic alternatives for each selected drug. Examples of opportunities for increased transparency that commenters provided included more detail on the methodology for selecting a therapeutic alternative, more information on how stakeholder information is used in the selection process, how real-world data is leveraged in the selection process, and providing the Primary Manufacturer with details on how CMS calculated the price of each therapeutic alternative.

Response: CMS thanks commenters for their input. CMS will identify a therapeutic alternative(s) for each indication of a selected drug in accordance with section 60.3.1 of this final guidance. As discussed in section 60.4 of this final guidance, CMS will offer to hold one meeting with the Primary Manufacturer of each selected drug prior to CMS' initial offer to allow the Primary Manufacturer to provide context for the section 1194(e) data submission, including information on potential therapeutic alternatives. CMS will also provide a concise justification, described in section 60.4.1 of this final guidance, which will include a description of the methodology that CMS used to determine the initial offer, which includes the identification of therapeutic alternatives. Federal laws, including the Trade Secrets Act and certain provisions of the Social Security Act, such as sections 1927(b)(3)(D) and 1847A(f)(2)(D), prohibit CMS from disclosing confidential and proprietary information including certain information related to the price of a therapeutic alternative.

Comment: A couple of commenters suggested that CMS should review the extent to which a selected drug represented a therapeutic advance at the time of the selected drug's approval rather than within the current market as described in section 60.3.3.1 of this final guidance. A couple of commenters requested that CMS review each selected drug and the negotiation factors over the lifecycle of the selected drug rather than at the time of negotiation.

Response: CMS appreciates commenters' suggestion that the extent to which a selected drug represents a therapeutic advance should be evaluated at the time of the selected drug's approval. Consistent with CMS' approach to reviewing the extent to which a selected drug fills an unmet medical need, manufacturer-submitted data, therapeutic alternative(s), and other considerations related to the section 1194(e) negotiation factors, CMS will evaluate the extent to which a selected drug represents a therapeutic advance, as clarified in this final guidance section 60.3.3.1, as of the time the section 1194(e)(2) data is submitted, which CMS believes is consistent with section 1194(e) of the Act.

Comment: A few commenters opposed using the price of a therapeutic alternative(s) as the basis for CMS' starting point for developing an initial offer. Among these commenters, a couple of commenters stated that this approach involves consideration of cost, which is not grounded in

statute; one commenter expressed concern about this policy because studies show that Part D prices are inflated compared to other public payers and prices paid in other countries. One commenter suggested CMS adopt a modified cost-plus approach that accounts for risk-adjusted R&D costs, therapeutic advancement, and the marginal cost of production and distribution, stating the starting point policy uses prices set in the system that are too high and does not incentivize manufacturers to lower their prices. A couple of commenters supported using the price of a therapeutic alternative as the starting point for initial offer development.

Response: CMS appreciates commenter feedback. CMS disagrees that the approach to determining a starting point for development of the initial offer is not grounded in statute. As described in section 60.3.2 of this final guidance, section 1194(e)(2)(A) of the Act directs CMS to consider both the extent to which a selected drug represents a therapeutic advance compared to its therapeutic alternative(s) and the cost of such existing therapeutic alternative(s). CMS considered several alternative options for what price should be used as the starting point for developing the initial offer including the unit cost of production and distribution for the selected drug, the ceiling, a domestic reference price (e.g., the Federal Supply Schedule (FSS) price), or a "fair profit" price based on whether R&D costs have been recouped and margin on unit cost of production and distribution. CMS determined using Net Part D Plan Payment and Beneficiary Liability, ASPs, or MFPs of therapeutic alternatives would be consistent with the Act and enable 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, and then make adjustments based on the additional section 1194(e) factors. 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.

CMS understands concerns that using the Medicare price(s) of a therapeutic alternative(s) that is grounded in PDE data for the selected drug may result in a higher starting point. However, in section 60.3.2 of this final guidance, CMS notes that using Net Part D Plan Payment and Beneficiary Liability, ASPs, or MFPs of therapeutic alternatives enables CMS to determine a starting point within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition. As described in section 60.3 of this final guidance, the starting point will be adjusted based first on section 1194(e)(2) factors and then based on manufacturer-specific data elements submitted in accordance with section 1194(e)(1) of the Act, generating an initial offer that incorporates the negotiation factors described in section 1194(e) of the Act, based on information provided by manufacturers, patients, clinicians, and other interested parties.

Comment: One commenter suggested CMS consider lower priced therapeutic alternatives when determining the starting point for CMS' development of the initial offer.

Response: CMS appreciates this commenter's input. As described in section 60.3.1 of this final guidance, CMS will identify the therapeutic alternative(s) based on clinical appropriateness and consideration of various sources of evidence including clinical guidelines, peer-reviewed literature, CMS-recognized compendia, and data submitted by manufacturers and the public. While prices of potential therapeutic alternatives will not be used in identifying therapeutic

alternative(s), CMS notes that the framework described in section 60.3.1 may result in CMS identifying a potential therapeutic alternative with a lower price. The therapeutic alternative(s) identified will then be used to determine a starting point for developing the initial offer as described in section 60.3.2 of this final guidance.

Comment: One commenter noted that CMS does not provide information on an alternative methodology that CMS would use to calculate 30-day equivalent supply for Part B therapeutic alternatives and requested additional detail.

Response: As described in section 60.3.2 of this final guidance, while CMS generally intends to use the same methodology for calculating a 30-day equivalent supply of a therapeutic alternative that is used to calculate a 30-day equivalent supply of the selected drug (used in the ceiling and application of MFP calculations), there may be instances in which CMS may need to use an alternative methodology to ensure an appropriate comparison. Such an alternative methodology would be specific to the circumstances of the therapeutic alternative in question; CMS may, but is not required to, apply a single alternative approach. For example, because Part B claims data do not contain a "days' supply" field similar to PDE data, CMS may use an alternative methodology to calculate the price per 30-day equivalent supply for the therapeutic alternative(s) covered under Part B.

Comment: A couple of commenters expressed concern regarding CMS' intent to use the lower of FSS[34] or Big Four price[35] as a starting point for developing the initial offer for a selected drug with no therapeutic alternative(s) or for selected drugs with therapeutic alternative(s) with Net Part D Plan Payment and Beneficiary Liability, MFP, and/or ASP greater than the statutory ceiling. One commenter was concerned that if CMS uses these prices, manufacturers may be less willing to provide price concessions to FSS or Big Four customers. One commenter stated that the FSS and Big Four prices are not meant to be pricing benchmarks and that these prices do not reflect the full cost of the drug, nor costs incurred across the supply chain.

Response: CMS thanks these commenters for their remarks. Per section 60.3.2 of this final guidance, CMS will use the lower of the FSS or Big Four prices in situations where the selected drug has no therapeutic alternative(s) or the price of the therapeutic alternative(s) exceeds the ceiling. As discussed on page 55 of the revised guidance for initial price applicability year 2026, CMS believes use of FSS/Big Four prices are appropriate in these situations, as these prices are publicly available and are reflective of prices available to other federal payers. Manufacturers can provide additional information and context on the FSS/Big Four prices as needed during the negotiation process. CMS also notes that the use of the FSS/Big Four prices, as needed, is

[34] 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.

[35] 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 section 8126 of title 38 of the U.S. Code. See: https://www.cbo.gov/publication/57007.

specifically for the purpose of determining a starting point, which will be adjusted based on the negotiation factors listed in section 1194(e) of the Act in development of CMS' initial offer.

Comment: Some commenters opposed the removal of CGDP payments in addition to Direct and Indirect Remuneration (DIR) from Total Gross Covered Drug Cost (TGCDC) when determining the starting point for developing the initial offer. A couple of commenters supported the removal of CGDP payments in addition to DIR from TGCDC when determining a starting point for 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 and another expressing concern that using the MFP as a starting point ties one manufacturer's negotiation to another. One commenter opposed the use of Part D net prices as a starting point for the initial offer.

Response: CMS thanks commenters for their feedback. As discussed in section 60.3.2 of this final guidance, removing 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 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.[36]

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 and the MFP is lower than the Net Part D Payment and Beneficiary Liability also aligns with CMS' intent for the starting point to reflect the amount paid by the plan and beneficiary for a therapeutic alternative. CMS disagrees with the commenter's assertion that this approach should be avoided because it ties one manufacturer's negotiation to another. The starting point is one step in the initial offer development process and will be adjusted based on section 1194(e) factors as discussed in section 60.3 of this final guidance. This policy is also aligned with the statutory directive in section 1194(e)(2)(A) of the Act to consider the costs of therapeutic alternatives, which for selected drugs may include the MFP. Additionally, after the initial offer, the Primary Manufacturer has an opportunity to provide a statutory written counteroffer, and then engage in further negotiations with CMS to reach agreement on a potential MFP. This process 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 a portion of those therapeutic alternatives was a selected drug). Finally, this policy promotes coherence across different years of the Negotiation Program when MFPs for multiple drugs may be in effect and those drugs may be therapeutic alternatives to selected drugs under negotiation.

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[36] Manufacturer Discount Program Final Guidance, pg. 20. See: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.

Comment: One commenter requested that CMS clarify how net prices across multiple indications and therapeutic alternatives, as applicable, will be weighted when determining the starting point. Another commenter stated that CMS suggests it will use a volume-weighted approach to arrive at the starting point and requested clarification as to whether this approach will also apply across multiple indications within the active moiety or active ingredient and, if so, raised a concern that this would undervalue a drug with multiple approved uses. One commenter requested additional information about how pricing will be calculated across dosage, form, and strength for therapeutic alternatives.

Response: CMS thanks commenters for their feedback. In section 60.3.2 of this final guidance, CMS states that if there are multiple therapeutic alternatives, CMS will consider the range of Net Part D Plan Payment and Beneficiary Liability, MFP(s) for initial price applicability year 2026 selected drugs, and/or ASPs, including the prices of generic and biosimilar therapeutic alternatives, as well as the utilization of each therapeutic alternative relative to the selected drug, to determine the starting point within that range. As part of its consideration of the utilization of therapeutic alternatives, CMS may consider the utilization of therapeutic alternative(s) across multiple indications or other patterns of use for the therapeutic alternative(s) or the selected drug. CMS also notes that this step is a part of the initial offer development process and the starting point will be adjusted based on section 1194(e) factors, as discussed in section 60.3 of this final guidance.

Comment: A couple of commenters requested clarification on how CMS intends to evaluate pending and approved patent applications and FDA exclusivities, applications, and approvals to adjust the preliminary price for selected drug. One commenter requested an upward adjustment for a selected drug with unexpired patents or exclusivities provided by the FD&C Act or PHS Act.

Response: CMS thanks these commenters for their input. Section 1194(e)(1)(D) directs CMS to consider data on approved patents and exclusivities in its determination of offers and counteroffers. Consistent with CMS' discussion on page 60 of the revised guidance for initial price applicability year 2026, CMS believes that information on patents and FDA exclusivities will support CMS' consideration of manufacturer-specific data and 1194(e)(2) factors described in section 60 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 meets 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 condition; 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 condition.

Comment: Many commenters requested additional detail on how negotiation factors would be weighted when adjusting the starting point to develop the initial offer. Some commenters asked CMS to emphasize factors important to patients, such as unmet medical need and clinical value.

A few commenters suggested that CMS weigh section 1194(e)(2) factors more than manufacturer-specific data. Similarly, some commenters urged CMS to place less weight on manufacturer-specific data. Of these commenters, a couple suggested applying a proportional adjustment for prior Federal financial support and one commenter requested that CMS consider the investment of both the manufacturer's R&D and federal financial support as well as the returns on both manufacturer and federal investments. One commenter requested that minimal weight be placed on adjustments related to the recoupment of R&D costs and asked that CMS specify the starting point would not be adjusted downward based on such data. One commenter requested that CMS only count a fraction of global net revenue toward the recoupment of R&D costs. A couple of commenters expressed support for CMS' approach of using section 1194(e)(2) factors to adjust the starting point followed by adjustments, as appropriate, based on manufacturer-specific data.

One commenter suggested that CMS apply a therapeutic advancement multiplier, based on the magnitude and certainty of net clinical benefit accounting for negotiation factors, to risk-adjusted R&D costs for drugs that represent a therapeutic advance. One commenter suggested adding a "premium" to selected drugs with new indications that address an unmet medical need. One commenter recommended emphasizing the elements of value outlined in the ISPOR Value Flower.[37]

Many commenters requested additional detail on how evidence would be evaluated and prioritized, stating additional transparency is needed ensure reproducibility, public accountability, standardized processes, and to support future research.

Response: CMS appreciates commenters' feedback and recognizes the importance of balancing transparency and confidentiality in the negotiation process. Consistent with CMS' response on page 57 of the revised guidance for initial price applicability year 2026, 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. Regarding therapeutic advance, CMS will determine the extent to which a selected drug represents a therapeutic advance by examining improvements in outcomes for the selected drug compared to its therapeutic alternative(s) and will consider the costs of such therapeutic alternative(s) as described in section 60.3.3.1 of this final guidance. CMS also included considerations for how evidence will be prioritized in section 50.2 of this final guidance as well as 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.

[37] Lakdawalla, D et. Al. "Defining Elements of Value in Health Care – A Health Economics Approach: An IPSOR Special Task Force Report" (2018). See: https://www.valueinhealthjournal.com/article/S1098-3015(17)33892-5/fulltext.

Comment: One commenter stated that CMS should refine the methodology used to develop the initial offer through notice-and-comment rulemaking, including how the section 1194(e) factors will be weighted.

Response: CMS thanks this commenter for their input. 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.

Comment: A few commenters recommended CMS adopt principles or frameworks from external organizations to incorporate patient-focused information into CMS' analysis, including the National Health Council Rubric to Capture the Patient Voice[38] and resources from ISPOR, the Innovation and Value Institute (IVI), and PhRMA.

Response: CMS appreciates commenters' recommendations for resources to reference when incorporating patient-focused information into its assessment, such as the information CMS will collect from public engagement events and patient and caregiver submissions to the Negotiation Data Elements and Drug Price Negotiation Process ICR into the negotiation process. CMS intends to review these resources to help ensure patient-focused information is incorporated into CMS' analysis.

Comment: A few commenters suggested changes to the definition of unmet medical need, including expanding the definition to include dosing regimens, route of administration, reduction in side effects, and decreases in treatment period; 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 cost to patient, patient preferences (route of administration, convenience, satisfaction, etc.), hope for better quality of life or survival until newer therapies are available, reduction in caregiver burden, equitable access, and access to new innovations; and adopting a "whole health" approach to include the collective impact of physical, behavioral, spiritual, and socioeconomic factors on one's health when considering unmet medical need.

One commenter requested clarification on whether unmet medical need would be assessed differently within specific populations. A few of commenters requested that CMS more clearly define the factors or measures considered when determining unmet medical need. One commenter recommended that CMS consider unmet medical need from initial approval of the selected drug through the time of assessment. One commenter supported CMS' consideration of unmet medical need.

Response: CMS appreciates commenters' feedback. 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

[38] See: https://nationalhealthcouncil.org/wp-content/uploads/2019/12/NHC_Patient_Engagement_Rubric.pdf.

reference to section 1194(e)(2)(D) of the Act and FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics." Consistent with CMS' response on page 56 of the revised guidance for initial price applicability year 2026, CMS will consider any updates concerning unmet medical need that may be issued by FDA. 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. CMS encourages patients and other interested parties to submit their perspective on the extent to which a selected drug meets an unmet medical need through the Negotiation Data Elements and Drug Price Negotiation Process ICR and in the public engagement events described in section 60.4 of this final guidance.

Comment: One commenter suggested that CMS seek input from stakeholders on specific aspects of unmet medical need, such as the impact on families and communities as well as infrastructure needs for screening and treatments. One commenter recommended providing additional context around unmet medical need and using quantitative inputs to consider unmet medical need, if possible, such as life expectancy estimates or measures that value the quality of life during life extension equally, such as the equal value life-year (evLY).

Response: CMS appreciates commenters' input. CMS is interested in input from patients, caregivers, and other interested parties on the extent to which a selected drug addresses an unmet medical need and the context and impact on patients and caregivers. CMS encourages patients and other interested parties to submit their perspective on the extent to which a selected drug meets an unmet medical need through the Negotiation Data Elements and Drug Price Negotiation Process ICR and in the patient-focused roundtable events and town hall meeting described in section 60.4 of this final guidance. Regarding the use of life expectancy estimates, CMS states in section 50.2 of this final guidance that CMS will review and consider cost-effectiveness measures and studies that use such measures for initial price applicability year 2027. However, measures will not be used if the measure is prohibited under section 1194(e)(2) of the Act, or under section 1182(e) of the Act.

Comment: A few commenters recommended CMS consider equity throughout the offer development and negotiation process, including consideration of measures that address disparities in drug access and affordability, and consideration of how the negotiation process impacts existing disparities. Additionally, commenters recommended CMS review potential sources of bias in the evidence and analysis of studies used in the assessment of the selected drug. One commenter supported CMS' expanded focus on health equity.

Response: CMS thanks these commenters for their feedback. Health equity is the first pillar of the CMS Strategic Plan, which builds health equity into the core functions of CMS, including the Negotiation Program. As noted in section 60.3.3.1 of this final guidance, CMS will consider the effects of the selected drug and its therapeutic alternative(s) on specific populations and, in doing so, CMS will evaluate health outcomes for specific populations, including through an access and equity lens. CMS is considering additional approaches to include an equity perspective in the negotiation process. CMS encourages patients and other interested parties to submit information on equity considerations for a selected drug through the Negotiation Data Elements and Drug

Price Negotiation Process ICR and during the public engagement events described in section 60.4 of this final guidance.

Comment: A few commenters suggested additional considerations for when CMS is developing the initial offer, such as diagnostic testing strategies, heterogeneity of treatment effects, patient and caregiver preferences, treatment efficiency, benefit to society and the health care system, and cost offsets such as conditions averted.

Response: CMS thanks commenters for their suggestions. 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. 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.

Comment: Some commenters recommended that CMS establish the MFP at the ceiling for all or a subset of selected drugs. Recommendations included establishing the MFP at the ceiling for drugs under patent protection; small molecule drugs approved less than 13 years prior; drugs subject to a value-based purchasing agreement and the multiple Best Prices reporting option; drugs that have provided therapeutic advancements, filled an unmet need, or otherwise demonstrated significant patient or societal benefit; vaccines recommended by the Advisory Committee on Immunization Practices; drugs with a ceiling equal to the drug's net price; oncology drugs rating 1 or 2A per the National and Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium; and all drugs for the first several years of the Negotiation Program. A few commenters also suggested accepting manufacturer data demonstrating a price at which patient access could be at risk and adopting such price as the MFP. One commenter stated such price should be adopted as MFP if it were higher than the ceiling for the selected drug; one commenter stated such price should be adopted as MFP if it were lower than the ceiling for the selected drug. One commenter stated that CMS should specify that the negotiation process will not result in an MFP below ceiling if the selected drug is subject to a value-based purchasing agreement and the manufacturer elects the multiple Best Price reporting option under MDRP.

Response: CMS appreciates commenters' input. 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 section 1194(e) of the Act. The methodology described in section 60.3 of this final guidance adheres to CMS' statutory obligation to review the statutory factors, including manufacturer-submitted data, and negotiate for the lowest MFP possible.

Comment: A few commenters recommended using an established framework for evaluating evidence related to a selected drug and its therapeutic alternative(s). Commenters suggested Multi-Criteria Decision Analysis, the Institute for Clinical and Economic Review (ICER) Value Assessment Framework, the ISPOR Good Practices process for report preparation, resources from IVI, PhRMA, and the National Health Council, and a cost-consequence model. One

commenter suggested a cost-effectiveness approach with CMS-generated, non-biased cost effectiveness targets to be adjusted based on negotiation factors. One commenter stated that CMS should use industry data to estimate total health value created by a selected drug and the distribution of such value between social value and private value. One commenter suggested CMS use external organizations for evidence synthesis or technology assessment only if those organizations meet standards for independence, patient-centered methods, methodological rigor, and transparency; the commenter also stated these standards should apply to CMS' internal analysis as well. One commenter requested that CMS specify whether the purpose of negotiating an MFP is "value" or "cost reduction" as these objectives will affect the methods used in evidence generation. One commenter requested CMS publish its decision-making framework for determining the MFP and issue results using the framework at different points in the negotiation process, including in the explanation of the MFP.

Response: CMS appreciates these suggestions for evaluating evidence related to a selected drug and its therapeutic alternatives as part of CMS' initial offer development. As noted in the final guidance, CMS will take a qualitative approach when reviewing information related to the section 1194(e)(2) factors for a selected drug and will consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality. As described on page 58 of the revised guidance for initial price applicability year 2026, CMS can preserve flexibility in negotiation by employing a qualitative approach to information review rather than a more formulaic quantitative approach, and this flexibility includes the ability to consider nuanced differences between different drugs that might not be captured in a more thoroughly pre-specified quantitative approach. Section 50.2 of this final guidance describes how CMS will consider the information submitted by manufacturers and the public, as well as information gathered through CMS internal analysis, and section 60.3 of this final guidance provides the method and process by which CMS will develop an initial offer. Section 60.4 of this final guidance further describes how CMS will engage in negotiations with participating Primary Manufacturers. The information provided in this final guidance is intended to describe CMS' decision-making framework for negotiating the MFP.

Comment: A couple of commenters suggested that CMS provide the methodology used to develop initial offers to manufacturers to facilitate manufacturer feedback. One commenter requested that CMS share a report of data robustness.

Response: Per section 1194(b)(2) of the Act and section 60.4.1 this final guidance, CMS will provide each manufacturer of a selected drug with an initial offer and a concise justification based on the factors used to develop the initial offer. As stated in section 60.4.1 of this final guidance, the justification will include a qualitative description of the factors from section 1194(e) of the Act and a description of the methodology that CMS used to determine the initial offer. As described in section 60.4 of this final guidance, CMS revised the timing of the negotiation meetings such that the first negotiation meeting occurs earlier in the negotiation process (after CMS issues the initial offer but prior to the deadline for the Primary Manufacturer's statutory written counteroffer). This adjustment in timing will allow for more discussion on CMS' development of the initial offer. CMS declines to share a separate report of data robustness outside of information otherwise to be provided to each Primary Manufacturer but intends to publish an explanation of the MFP consistent with section 1195(a)(2) of the Act.

Negotiation Process (Section 60.4)[39]

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, 2025 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. The commenters also said that not allowing new data submission until the negotiation meetings could result in an inefficient process. Another commenter suggested submissions be permitted after patient listening sessions, as there may be gaps identified during the sessions that can be filled by additional research. This commenter stated that while they understand this timing may not allow for the data to be incorporated into CMS' initial offer, it may be useful during later stages of the negotiation process. A couple of commenters suggested that interested parties should be allowed to submit new section 1194(e) data after the March 1, 2025 initial price applicability year 2027 deadline when there is good cause.

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, 2025 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, 2025, 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) information after the March 1, 2025 deadline. First, CMS will invite the Primary Manufacturer of each selected drug to a meeting after the March 1, 2025 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 2025. 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, 2025 data submission.

[39] CMS notes that the section 60.4 section and subsections referenced in this document have been updated to reflect the reorganization adopted in final guidance. No comments were received on the topics covered in subsections 60.4.3 and 60.4.6 of this final guidance, so there are no comment and response sections for these subsections.

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 speakers 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) data that has been identified since the March 1, 2025 deadline. These events will occur in Spring 2025 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, 2025 for initial price applicability year 2027. 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, 2025 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. 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: A few commenters suggested options for engaging clinicians in the negotiation process, including ad hoc consultations or a standing committee or panel of experts. One commenter recommended that CMS consult with clinical experts and leaders of appropriate medical specialty societies at key milestones during the negotiation process. The commenter noted that providers can offer real-world experience and insight into selected drugs and inform therapeutic alternatives, unmet need, impact on specific subpopulations, and formulary access

considerations. Another commenter requested transparency into how CMS evaluated disease areas, consulted with clinical experts (including the names and credentials of these experts), and analyzed data.

Response: The initial price applicability year 2027 negotiation process provides multiple opportunities for clinicians to share input. Clinicians are encouraged to submit information on section 1194(e)(2) factors that will be considered during negotiation via the Negotiation Data Elements and Drug Price Negotiation Process ICR. CMS will publish this ICR for a 30-day public comment period during Fall 2024 for the specific questions and instructions that CMS proposes to collect regarding the optional request for information related to factors that are described in section 1194(e)(2) of the Act and be available for data submission in early 2025. This ICR includes a section on clinical-focused experience, and CMS encourages clinicians to submit information for this section and any other relevant sections.

As described in section 60.4.1 of this final guidance, clinicians will also be encouraged to provide input through the town hall meeting as part of CMS' public engagement efforts. This town hall meeting will complement patient-focused roundtable events with patients, caregivers, and patient advocacy organizations. While the patient-focused roundtable events will be combined by condition when appropriate (instead of one session per selected drug), the town hall meeting will be an opportunity for clinicians, as well as researchers, manufacturers, and members of the public, to share input on any of the selected drugs. The town hall meeting will be livestreamed for the public. CMS will provide more information about these input opportunities at a future date. As described in section 50.2 of this final guidance, CMS may also consult subject matter and clinical experts when considering available evidence about alternative treatments to a selected drug.

Comment: One commenter requested that CMS provide manufacturers visibility into input received from other parties when developing the initial offer. The commenter requested a summary of feedback for each selected drug and requested insight into meeting minutes, meetings with other parties, and written commentary used when developing the initial offer. Another commenter suggested that CMS issue a confidential report to manufacturers alongside the initial offer and concise justification. This confidential report would make manufacturers aware of section 1194(e)(2) data submitted by other interested parties and allow manufacturers to use that information in counteroffers, if applicable, and in future data submissions.

Response: Consistent with CMS' response on page 63 of the revised guidance for initial price applicability year 2026, 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 for initial price applicability year 2027that 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 public explanation of the MFP no later than March 1,

2026. As part of this public 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 public explanation.

Comment: Some commenters asked that CMS' concise justification of its initial offer be meaningful and explain how CMS arrived at the offer. Commenters mentioned that the justification should include 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. One commenter stated that without a meaningful justification from CMS in the initial offer, manufacturers cannot provide a meaningful justification in a statutory written counteroffer. One commenter asked that CMS issue a template for the initial offer concise justification in the final guidance.

Response: CMS thanks these commenters for their feedback and will consider the recommendation to include the information suggested by commenters when developing initial offers and concise justifications for selected drugs. Consistent with CMS' response on page 63 of the revised guidance for initial price applicability year 2026, 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 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. CMS does not plan on issuing a template for the initial offer or the concise justification but will release redacted information regarding the initial offer with the MFP explanation no later than March 1, 2026.

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. 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 suggested CMS develop a methodology for incorporating clinical and patient-focused metrics into the evaluation of selected drugs and therapeutic alternatives during the negotiation process. The commenter recommended incorporating this methodology into the concise justification for the initial offer. Another commenter encouraged CMS to include how patient input was considered when evaluating unmet need, treatment alternatives, and clinical benefit.

Response: As stated above, the concise justification will include information that helps the Primary Manufacturer understand the range of evidence and other information submitted pursuant to section 1194(e) of the Act, including clinical and patient-focused information, that CMS found compelling in developing its initial offer.

Comment: One commenter asked CMS to commit to responding to counteroffers within 30 days of receipt. The commenter also recommended CMS give manufacturers at least 30 days to review and comment on CMS' response to counteroffers and asked CMS to consider these comments in the negotiation process to further transparency and fairness and help minimize any misunderstanding or gap in information.

Response: Section 60.4.3 of this final guidance affirms that CMS will provide a written response to the manufacturer's statutory written counteroffer, if applicable, within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later.

Consistent with CMS' response on page 64 of the revised guidance for initial price applicability year 2026, CMS declines to update this final guidance for initial price applicability year 2027 to allow manufacturers 30 days to review and comment on CMS' response to counteroffers. If a manufacturer's statutory written counteroffer is rejected, further optional negotiation meetings with the Primary Manufacturer and CMS will span from approximately August 1, 2025, to September 30, 2025. This period exceeds 30 days and will give Primary Manufacturers the opportunity to comment on CMS' response to the statutory written counteroffer in negotiation meetings. Additionally, as described in section 60.4.5 of this final guidance, CMS and the Primary Manufacturer may 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 one week before final offers are due to be sent by CMS (October 15, 2025), whichever is earlier. This additional price exchange functionality in the CMS HPMS will include an optional text field to enable either party to include and consider 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.

If applicable, CMS will issue a "Notification of Final Maximum Fair Price Offer" no later than October 15, 2025, and require Primary Manufacturers to respond to this final offer by October 31, 2025. Although this turnaround is less than 30 days, it will come at the end of approximately five months of negotiations (June 2025-October 2025) where there will have been ample opportunity for the Primary Manufacturer to review the initial offer, respond in writing via a statutory written counteroffer, and consider the discussions that occurred within the context of up to three negotiation meetings. As described in section 60.4.5 of this final guidance, Primary Manufacturers and CMS will also be able to exchange proposed MFPs after the Primary Manufacturer's statutory written counteroffer is rejected, if applicable, until one week before final offers are due or when an MFP is agreed upon, whichever is earlier, in the CMS HPMS via the additional price exchange functionality.

Public Engagement Events (Section 60.4.1)

Comment: A couple of commenters suggested CMS work with FDA and other organizations with experience conducting patient engagement sessions. These commenters noted that FDA could help identify strategies and best practices for CMS to employ to accomplish the goals of patient-focused events, citing FDA's Patient-Focused Drug Development meetings as a model for CMS to follow.

Response: CMS appreciates this suggestion to work with FDA and others that have experience engaging with patients. CMS notes that it has consulted with FDA regarding its Patient-Focused Drug Development meetings, as well as reviewed FDA's "Patient-Focused Drug Development: Collecting Comprehensive and Representative Patient Input" guidance, to draw from FDA's principles and strategies for such engagement. CMS will continue to consult with FDA as CMS develops its patient-focused roundtable events for initial price applicability year 2027 and considers additional enhancements for future years. CMS is also consulting with other federal government offices and may consider consulting external organizations with experience obtaining input from patients, beneficiaries, caregivers, patient advocacy organizations, and other interested parties.

Comment: Many commenters stated they appreciated CMS' interest in holding patient-focused events that promote discussion instead of events that are listen-only. A couple of commenters noted that CMS' lack of dialogue during the initial price applicability year 2026 events made it unclear if CMS staff were in attendance. Commenters suggested CMS consider using event formats, such as focus groups and roundtable discussions, that encourage dialogue among participants and with CMS to foster more meaningful engagement and input from participants. One commenter recommended CMS hold panel discussions or town hall meetings. One commenter suggested CMS hold focus groups in addition to listening sessions. Additionally, a couple of commenters recommended that CMS use a neutral, independent moderator to facilitate engagement at patient-focused events. Some commenters also supported CMS asking clarifying questions of speakers. Further, a couple of commenters suggested CMS staff turn on their cameras and be shown on screen during virtual events, even if they are unable to communicate with participants, to help speakers feel like they are engaging with others and to foster a sense of interaction. Finally, one commenter encouraged CMS to engage with subject-matter experts in

academia and patient communities to develop decision guidelines to determine the type of format for a given event.

Response: CMS thanks commenters for this feedback. In this final guidance, CMS notes that it intends to host up to 15 patient-focused roundtable events that will feature a discussion-based format instead of a listen-only format. CMS agrees with commenters that a discussion-based format may foster more meaningful engagement and input from participants; therefore, CMS will host discussion-based, patient-focused roundtable events to try to elicit more participation and sharing among patients, patient advocacy organizations, and caregivers. In addition to these patient-focused roundtable events, CMS will host one town hall meeting (for which CMS will encourage participation from clinicians, although any interested parties may register to participate) during which CMS will have the opportunity to ask follow-up questions of participants. CMS representatives will be present at the patient-focused roundtable events and the town hall meeting to engage with participants and ask clarifying questions. CMS will engage a moderator to facilitate discussion at both types of engagement events. CMS may consider the suggestion to engage with subject matter experts to develop decision guidelines on event format for future initial price applicability years.

Comment: Some commenters stated they want patient-focused events to be public and livestreamed. One of these commenters recommended CMS host both livestreamed and non-livestreamed events and noted that livestreamed events with multiple stakeholder types allows participants to contribute as equals and to directly impact the perspectives of other participants and that small-group private events allow for more focused, candid discussions. Another commenter felt summaries and redacted transcripts should be only supplements, not replacements, to public events. A few commenters recommended non-livestreamed patient-focused events. A couple of commenters added that if events are not livestreamed, CMS should make a summary report available after the patient-focused events. Additionally, some commenters stated that CMS should hold in-person events and virtual events, and a couple of these commenters suggested CMS make them hybrid events. Regardless of format, some commenters stated that CMS should hold patient-focused events with fewer participants than in initial price applicability year 2026.

Response: CMS thanks commenters for providing feedback on whether public engagement events should be livestreamed or non-livestreamed. As described in section 60.4.1 of this final guidance, the patient-focused roundtable events will be aggregated by condition when appropriate and will not be livestreamed. These roundtable events will include fewer participants than events for initial price applicability year 2026 and will be limited to patients, patient advocacy organizations, and caregivers. Because these roundtable events will not be livestreamed, CMS will publish a redacted transcript after all of the public engagement events have ended. 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,[40] as well as omit identifying information for patient advocacy organization representatives and family members/caregivers.

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

In addition to these smaller, non-livestreamed events, CMS will host one larger town hall meeting, focused on the clinical considerations related to the selected drugs. CMS encourages practicing clinicians and researchers to register to participate (although other interested parties also may register to participate). This town hall meeting will be livestreamed. CMS will make a redacted transcript publicly available for the town hall meeting after the meeting concludes. For initial price applicability year 2027, patient-focused roundtable events and the town hall meeting will only be held virtually; however, CMS recognizes the benefits and value of sharing information about experiences with a disease or condition via an in-person format and will take this feedback under consideration for future initial price applicability years.

Comment: A few commenters recommended CMS continue to organize patient-focused events by selected drug. A couple of commenters want them to be organized by condition(s)/disease(s), noting that this organization would allow CMS to contextualize selected drugs, therapeutic alternatives, and other medications and their interactions in ways that are beneficial to patients, providers, pharmacists, and caregivers. A few commenters suggested CMS organize patient-focused events by stakeholder type, which they said would encourage more participation and enable participants to provide substantive input. One commenter suggested they be organized by indication and by the type of stakeholder included in the event, stating that by focusing on indications, patients would be able to provide feedback on the product's value for patients in specific situations. One commenter wrote that as the number of selected drugs increases, CMS should hold patient-focused meetings by therapeutic area. Finally, one commenter expressed concern that CMS did not capture the value of selected drugs and therapeutic alternatives by organizing patient-focused events for initial price applicability year 2026 by drug class and also stated that combining events by disease or condition would fail to recognize heterogeneity in treatment effects.

Response: CMS thanks commenters for providing input on whether and how to combine 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 2027, which will be combined by condition when appropriate. CMS notes that these events will include only patients, patient advocacy organizations, and caregivers. Additionally, for initial price applicability year 2027, CMS will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register to participate. Finally, CMS notes that for initial price applicability year 2026 CMS organized patient-focused events by selected drug, not by drug class, as one commenter stated.

Comment: In addition to including patients in patient-focused events, some commenters recommended CMS include clinicians and some other commenters recommended CMS include caregivers. A few commenters also suggested patient advocates or disease groups be included in the events. Some commenters noted that if CMS includes interested parties other than patients, CMS should promote them as "stakeholder" events rather than patient-focused events. Additionally, one commenter said rather than limiting the patient-focused events to patients being treated with the selected drug, CMS should include patients living with the disease(s)/condition(s) because it is likely that such patients will receive the selected drug as treatment in the future. Additionally, one commenter suggested CMS conduct separate meetings

with guideline-specific entities to get an understanding of how written guidelines translate into clinical practice. Finally, one commenter said CMS should provide guidance on the types of patients or providers it wants to hear from during patient-focused events.

Response: CMS thanks commenters for this input. As described in section 60.4.1 of this final guidance, CMS will host up to 15 patient-focused roundtable events, organized by condition when appropriate, that will include patients, patient advocacy organizations, and caregivers. CMS also communicated in this guidance that, in addition to the patient-focused roundtable events described above, CMS will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register to participate. CMS believes including perspectives from clinicians in a town hall meeting will help concentrate discussion around the clinical benefit of the selected drugs as compared to therapeutic alternatives, the extent to which the selected drugs address unmet medical need, and how the selected drugs impact specific populations. Finally, CMS welcomes comments and feedback from patients living with the condition(s) treated by the selected drug (not only patients taking the selected drug), caregivers caring for an individual who has experience taking the selected drug or its therapeutic alternative(s), and clinicians with experience with the selected drug, the condition(s) it is used to treat, and other treatments used for that condition(s).

Comment: Many commenters recommended that CMS diversify the methods for patients and other interested parties to provide information to CMS, beyond participating in patient-focused events. These commenters stated increasing the methods for patients and other interested parties to engage with CMS would accommodate individuals who may be unable, for a variety of reasons, to participate in real time, as well as allow them to contribute in a non-livestreamed manner. For example, the National Health Council's "Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement" report found that individuals may have work or personal responsibilities or lack access to stable and affordable Internet that may prevent them from participating at the scheduled day and time.[41] Similarly, some commenters recommended CMS vary the times of day that patient-focused events are held to accommodate individuals who may not be able to attend during business hours. Additionally, the report noted that some patients lack the confidence or ability to speak clearly in a public setting or to a government entity, while other would-be participants may be concerned about speaking publicly about their condition for fear of discrimination by employers or others. One commenter expressed concern that the voices of some individuals may have been left out because of the event format for initial price applicability year 2026, stating that the format created language, logistical, and technological barriers. Another commenter suggested that diversifying the methods for patient engagement may mitigate such barriers and encourage more participation. Many commenters suggested CMS accept recorded comments, written statements, mail-in forms, and emails, as well as conduct phone and/or online surveys. One commenter suggested CMS consider hosting informal discussions with patients directly affected by the drugs identified for negotiation. A few commenters specifically cited patient privacy as a reason to offer an option for individuals to privately share information about their experiences. One commenter noted that CMS should offer more than one type of format for patient-focused events. Additionally, a

[41] National Health Council, "Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement," March 2024.

couple of commenters suggested that CMS offer the option of audio-only events. A few commenters also said CMS should allow participants to submit limited data and other information after the patient-focused events end.

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 that will be organized by condition when appropriate. CMS believes hosting such events in a non-livestreamed venue that includes only patients, patient advocacy organizations, and caregivers will encourage engagement and help mitigate barriers, such as the concern about speaking in a public setting, that may prevent some individuals from participating. For initial price applicability year 2027, CMS also will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register to participate. For both the patient-focused roundtable events and the town hall meeting, CMS will select speakers through an intentional process, rather than random selection, to help ensure diverse representation of viewpoints. CMS will release redacted transcripts after all the events have ended. The town hall meeting will be livestreamed, and CMS will also release a redacted transcript after the meeting concludes. Further, CMS will strive to vary the times of day it hosts patient-focused roundtable events and notes that this also may help increase participation. CMS intends to announce, if feasible, the dates and times of the patient-focused roundtable events when it publishes the selected drug list for initial price applicability year 2027.

In addition, patients, patient advocacy organizations, and caregivers and others such as clinicians, researchers, and the public at large, may submit written comments via the Negotiation Data Elements and Drug Price Negotiation Process ICR. This ICR will be available for patients and others to submit their information in early 2025. CMS revised this ICR for initial price applicability year 2027 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 academic experts, 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: Some commenters noted that participants were stopped from speaking when their time elapsed during the initial price applicability year 2026 patient-focused listening sessions. They encouraged CMS to allow more time for participants to share their comments, suggesting CMS increase the amount of time from three minutes to five minutes. A few commenters noted there was no way for participants to monitor the time and encouraged CMS to include a timer on the screen for virtual events to help participants manage the pacing of their comments.

Response: CMS thanks commenters for these suggestions. CMS agrees that each participant should have more time to speak than the three minutes allotted in the initial price applicability

year 2026 patient-focused events so that participants may share more information. CMS notes that the smaller patient-focused roundtable events for initial price applicability year 2027 may provide additional time for speaking because each event will have fewer participants and the informal format will encourage discussion among participants. Additionally, CMS will explore technology to include a timer on the screen to help speakers track their allotted speaking time. CMS will provide more information about the event logistics and technology at a future date.

Comment: A few commenters were concerned with CMS' recruitment for the patient-focused events for initial price applicability year 2026, noting that a limited number of speakers applied or were chosen to participate, including speakers who represented Medicare or Medicaid beneficiaries and individuals from underrepresented communities. Citing the National Health Council's "Amplifying the Patient Voice: Roundtable and Recommendations" report[42], one commenter wrote that patients and other stakeholders, such as caregivers, family members, providers, and patients who formerly used a selected drug, were not aware of the patient-focused events for initial price applicability year 2026 or how to participate in them. One commenter noted that CMS relied on patient advocacy organizations to recruit participants. Many commenters generally recommended CMS recruit and engage speakers with diverse backgrounds and perspectives. A few of these commenters specifically mentioned CMS should ensure representation from underrepresented and historically underserved populations, and one commenter advocated for including Medicare beneficiaries. A few commenters recommended CMS work with the CMS Office of Minority Health and minority-focused advocacy organizations to conduct outreach to underrepresented individuals. Some commenters felt CMS generally should improve outreach efforts to recruit a variety of participants for patient-focused events. A few of these commenters suggested CMS work with patient advocacy organizations, senior-focused community organizations, manufacturers, and other third parties to target specific demographics for patient-focused events. One commenter said CMS should use its regional offices and their ties to local communities to ensure appropriate patient engagement across different demographic groups. For example, this commenter suggested CMS use regional patient summits or health care provider meetings to engage with community organizations. A couple of commenters recommended CMS build long-term partnerships by identifying therapeutic areas likely to be impacted by selected drugs (e.g., oncology, lung, cardiovascular, diabetes) and proactively engage with key stakeholder groups that represent patients impacted by these diseases. Additionally, one commenter noted that when identifying stakeholder audiences, CMS should distinguish between a patient (i.e., an individual living with a disease or condition) or patient advocate (i.e., an individual or organization representing those living with a disease or condition) and a consumer (i.e., an individual or organization other than a caregiver, not living with a disease or condition) or consumer advocate (i.e., an individual or organization representing those not living with a disease or condition). One commenter suggested CMS use mail outreach to recruit participants for patient-focused events because CMS' website can be difficult to navigate for Medicare beneficiaries and patients. This commenter also noted that CMS should improve participation by increasing the visibility for the dates of patient-focused events for initial price applicability year 2027 and beyond. Finally, one commenter said CMS should improve its screening of participants, noting that at least one speaker in a patient-focused

[42] See: https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf.

event for initial price applicability year 2026 shared information not directly related to the patient experience or the selected drug, condition(s) it treats, or other treatments.

Response: CMS thanks commenters for this feedback and these recommendations about patient-focused event recruitment. CMS agrees with commenters that increased participation generally and among underrepresented populations and people with Medicare specifically would help ensure diverse perspectives are communicated and heard during patient-focused roundtable events. As such, CMS intends to announce the dates for all patient-focused roundtable events when it publishes the selected drug list for initial price applicability year 2027 (i.e., by February 1, 2025). CMS conducted outreach to patient advocacy organizations, disease groups, and other consumer associations regarding patient-focused listening sessions for initial price applicability year 2026 and will continue to publicize and promote the patient-focused roundtable events for initial price applicability year 2027. Additionally, CMS has worked with the CMS Office of Minority Health in redesigning the patient-focused roundtable events for initial price applicability year 2027 and to help increase participation among underrepresented populations. Going forward, CMS intends to continue to communicate and work with the CMS Office of Minority Health in redesigning patient-focused events and to help increase participation among underrepresented populations. CMS will consider using regional offices to increase awareness of patient-focused roundtable events among regional community organizations. CMS also appreciates the comment about clarifying the types of intended participants, and CMS may consider differentiating between patients, patient advocacy organizations, and caregivers in forthcoming materials about patient-focused roundtable events. CMS does not intend to communicate about patient-focused roundtable events via mail at this time but may consider this medium for future initial price applicability years. CMS also acknowledges the commenter's remark about the difficulty beneficiaries and patients may have navigating CMS' website and will consider making information about patient-focused roundtable events more prominent on CMS' IRA website.[43] Lastly, CMS will use an intentional process to select, rather than randomly select, speakers with the goal of ensuring that a diverse set of interested parties can share their experiences and information. CMS will consider releasing more information on this intentional selection process in the future.

Comment: A couple of commenters suggested CMS compensate patients and caregivers to acknowledge their time and expertise when they participate in patient-focused events.

Response: CMS is committed to collaborating with and engaging the public in the policy-making 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 patient-focused roundtable events.

Comment: A few commenters were disappointed in CMS' registration process to participate in patient-focused events for initial price applicability year 2026, stating that the process was lengthy and complicated, which made it difficult for patients to sign up to participate. These commenters recommended CMS streamline and simplify the registration process to make it easier for patients to register. Relatedly, a couple of commenters said the different formats (i.e.,

[43] See: https://www.cms.gov/inflation-reduction-act-and-medicare.

Word and PDF) of the forms CMS requested were difficult to download, complete, and submit—in other words, these commenters said the format of the forms were "not patient friendly." One commenter also suggested CMS use patient-friendly language in the registration materials and forms. Additionally, one commenter said the registration required participants to submit too much personal health information and recommended CMS limit personal health information to only necessary information; while some commenters also suggested CMS waive the HIPAA Privacy Rule requirements altogether, if legally permissible.

Response: CMS thanks commenters for this feedback on the registration process. For initial price applicability year 2027, CMS will simplify the registration process for all interested parties to sign up to participate in the patient-focused roundtable events. This includes minimizing the amount of individually identifiable health information required to be submitted, if applicable, and reconsidering the format in which participants must submit their registration and any related forms. More information on the registration process will be forthcoming. Because the Medicare Fee-for-Service program is a health plan, it must comply with the privacy requirements of the HIPAA Privacy Rule.

Comment: Some participants expressed concern about CMS' management of conflict-of-interest disclosures for initial price applicability year 2026 patient-focused events. A few commenters noted that the reporting process lacked standardization, which led to inconsistent conflict-of-interest interpretation and disclosures. For example, a couple of commenters noted that CMS required participants to report funding from drug manufacturers as possible conflicts of interest but were not required to report funding from other parties, such as payers and pharmaceutical benefit managers. One commenter stated that this may have confused event listeners about participants' potential conflicts of interest. Another commenter wrote that CMS treated funding from patient advocacy organizations in the same manner as funding from drug manufacturers, which the commenter believed unfairly stereotyped patient advocacy organizations. A few commenters underscored the importance of reporting all conflicts—both the existence and nature of such conflicts. A couple of commenters pointed out that for patient-focused events held for initial price applicability year 2026, it seemed that participants appeared to represent organizations financially supported by drug manufacturers and some participants failed to disclose conflicts of interest. One commenter also flagged that for those participants in the initial price applicability year 2026 patient-focused events who did report conflicts, CMS did not provide information on the nature of those conflicts. Finally, one commenter stated that because members of the public are not accustomed to reporting conflicts of interest and were unclear as to whether and how reported conflicts would be communicated, they may have been deterred from reporting any conflicts of interest.

Some commenters offered recommendations for how to improve conflict-of-interest reporting for initial price applicability year 2027. A few commenters recommended CMS require participants to report all potential conflicts of interest, and that CMS should publish those disclosures. One commenter also encouraged CMS to make such disclosures a prerequisite for participating in patient-focused events. A couple of other commenters suggested CMS go further—with one commenter saying CMS should scrutinize publicly available information related to reported conflicts of interest and another commenter recommending CMS describe how a disclosure or nondisclosure affects or does not affect patient testimony and why disclosures are needed.

Finally, one commenter recommended CMS present disclosures in a less direct manner; for example, the commenter said CMS could include a link on the website associated with the listening session.

Response: CMS welcomes this feedback. To promote transparency in the relationships between participants and interested parties, CMS agrees with commenters that it is important for all participants to report potential conflicts of interest, including the existence and nature of the conflict. As such, for initial price applicability year 2027, CMS will revise the conflict-of-interest disclosure request and require potential speakers in the patient-focused roundtable events and the town hall meeting to include information about the existence and nature of conflicts of interest. This approach aims to promote transparency during the patient-focused roundtable events and the town hall meeting. CMS also agrees that members of the public likely are not accustomed to reporting potential conflicts. Therefore, CMS also will revise the conflict-of-interest disclosure request to more clearly and plainly describe the type of conflict information speakers need to submit to participate in patient-focused roundtable events and the town hall meeting. More information about patient-focused roundtable events and the town hall meeting, including conflict-of-interest reporting, is forthcoming. CMS does not intend to implement additional conflict-of-interest requirements beyond revising the conflicts-of-interest disclosure request.

Comment: A few commenters recommended CMS offer tools and resources to ensure that patient-focused listening sessions and associated materials are accessible to all participants. Suggestions from these commenters included: using plain language for patient-focused materials; providing Spanish-language listening sessions or real-time translation services; providing accommodations for individuals with disabilities and language or other barriers; and proactively soliciting requests for accommodations. One commenter also wrote that participants may need additional time to process questions in advance of patient-focused events. Some commenters recommended CMS create an ombudsman designated to engage with patients and disability communities. Finally, one commenter referred CMS to the DOJ's recent final regulation regarding web and mobile application accessibility for people with disabilities under Title II of the ADA and urged CMS' compliance.[44]

Response: CMS appreciates this input. CMS is committed to providing educational materials to patients, including informational materials about patient-focused roundtable events. As done for initial price applicability year 2026, CMS will ask potential speakers if they require Spanish-language translation or American Sign Language interpretation services for individuals with disabilities during the registration process for initial price applicability year 2027. CMS provided a Spanish-language line for all the initial price applicability year 2026 patient-focused listening sessions. For initial price applicability year 2027, CMS will again provide a Spanish-language line for public engagement events. 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.[45] 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

[44] See https://www.ada.gov/assets/pdfs/web-rule.pdf.
[45] See 45 C.F.R. § 85.51.

of, program or activity conducted by the agency.[46] CMS is aware of the DOJ's final regulation regarding web and mobile app accessibility, and notes that the rule is specific to State and local governments. However, as previously mentioned, 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.[47]

Comment: A few commenters supported CMS' concern for the privacy of patient-focused event participants and its plan to redact names and other identifying information. These commenters noted that redacting names and identifying information may help to reduce barriers to participation. One commenter suggested that de-identification could be CMS' default for certain public forums or available upon request (e.g., an option to select when participants register or present).

Response: CMS thanks commenters for their support. CMS provides in this final guidance that it will share a redacted transcript for each patient-focused roundtable event and for the town hall meeting after all of the events have concluded. 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,[48] as well as omit identifying information for patient advocacy organization representatives and family members/caregivers.

Comment: A few commenters recommended CMS generally increase transparency into the patient-focused events process. For example, one commenter said CMS should share redacted transcripts in a timelier manner for initial price applicability year 2027 than it did for initial price applicability year 2026. Another commenter suggested that CMS record the events to allow stakeholders to review what was said.

Response: CMS thanks commenters for their feedback. CMS believes that all interested parties should have a transparent understanding of the process. As such, CMS will post redacted transcripts for all patient-focused events, including the patient-focused roundtable events and the town hall meeting. 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 HIPAA Privacy Rule is thorough and takes time. Therefore, CMS will post redacted transcripts as soon as practicable after all public engagement events have concluded. Finally, CMS declines to publish recordings of the patient-focused roundtable events or for the town hall meeting for initial price applicability year 2027.

Comment: Many commenters felt that before hosting patient-focused events, CMS should communicate about the type of information it seeks from patients to help participants prepare for

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[46] *Id.* at § 85.51(a)(1).
[47] See: https://www.cms.gov/about-cms/web-policies-important-links/accessibility-compliance.
[48] See: 45 C.F.R. 164.514(b)(2); https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#safeharborguidance.

these events and provide relevant information to CMS. Some commenters offered specific suggestions for the types of information CMS could seek from participants of patient-focused events. For example, a few commenters suggested CMS seek input on the benefits and impacts of selected drug(s), those benefits and impacts on subpopulations, how a selected drug meets unmet medical needs, and therapeutic alternatives. A couple of commenters encouraged CMS to tailor questions by participant type (e.g., patients and caregivers, patient advocates, and clinicians); while a different commenter recommended CMS develop a process to tailor questions to each therapeutic area, selected drug, or patient group. Another commenter broadly recommended that CMS develop a set of standardized questions that would be most relevant to CMS. One commenter suggested CMS work with patient organizations, manufacturers, and other interested parties to develop topics or questions that would be most productive to solicit patient perspectives. Another commenter encouraged CMS to ask which outcomes are most important to patients and how their preferences may vary across different diseases and patient groups. Moreover, some commenters recommended that CMS establish and communicate the goals and desired outcomes of the patient-focused events, noting that doing so may give participants a clear understanding of CMS' expectations, may build trust, and may increase participation. Additionally, one commenter encouraged CMS to be as specific as possible about the logistics of patient-focused events, including the event format, time limit for speakers, and types of follow-up questions CMS may ask. Finally, some commenters said CMS could communicate the type of information described above via educational webinars held before patient-focused events.

Response: CMS recognizes that providing additional information about the type of information CMS seeks would help event participants prepare and focus their comments. CMS also thanks commenters for their feedback regarding providing transparency around the goals and desired outcomes for public engagement events. CMS believes that all interested parties should have a transparent understanding of the process and rationale used during negotiation process. As such, for initial price applicability year 2026, CMS provided speakers with the following optional discussion topics: patients' day-to-day experiences living with the condition(s) treated by the selected drug, including how the experience may differ for different patient populations as well as patient caregivers and families; how the selected drug impacts patients, including benefits and side effects, as compared to the therapeutic alternative(s), and which outcomes matter most to patients with the condition(s) treated by the selected drug; patient experiences of access, adherence, and affordability of the selected drug as compared to therapeutic alternative(s); and any other information about the selected drug, the condition(s) it is used to treat, and other treatments used for that condition(s) that the speaker believes is important.[49] CMS will also consider providing information in writing and/or via a webinar to help participants prepare to speak at patient-focused roundtable events. In addition to the topics listed above, CMS clarified in this final guidance how it will use input shared during public engagement events, which CMS believes will further help speakers prepare their remarks. Specifically, CMS stated it will use shared information 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.

[49] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation/2026-policy-and-public-input.

Comment: Many commenters expressed concern that patients and patient advocacy organizations did not have clear understanding of how qualitative information collected from patients during initial price applicability year 2026 would be used for the Negotiation Program. These commenters recommended CMS communicate about how it will consider and implement patient, beneficiary, and provider feedback for initial price applicability year 2027, stating that such information would help participants tailor the information they provide to CMS. For example, many commenters suggested CMS explain in plain language how CMS is using, analyzing, and incorporating patient-, beneficiary-, and clinician-shared information into the negotiation process, such as in drug reviews, drug selection, and negotiating the MFP. Additionally, one commenter suggested CMS should clarify how information from different subpopulations may be considered, noting that different therapeutic alternatives may be available to different patient populations. Finally, one commenter encouraged CMS to share information about its expectations for lower costs for patients and how patients can realize savings as a result of negotiations.

Response: CMS recognizes commenters' desire to understand how information shared at public engagement events may be used to help inform negotiations. CMS believes that all interested parties should have a transparent understanding of the process and rationale used during the negotiation process. As required by section 1195(a)(1) of the Act, for initial price applicability year 2027, CMS will publish the public explanation of the MFP for each selected drug no later than March 1, 2026. The public explanation will include a narrative explanation of the negotiation process that occurred with each 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. Further, CMS clarified in this final guidance how it will use input shared during public engagement 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. Additionally, CMS is committed to providing accessible educational materials to patients and beneficiaries—as well as the pharmacies, mail-order services, and other dispensing entities that serve them—about the MFPs for selected drugs and how they can report a violation if they do not believe that they were able to access the MFP for a selected drug.

Comment: Some commenters recommended CMS clarify how speakers will be selected for patient-focused events. One commenter noted that for initial price applicability year 2026, CMS stated that 20 speakers would be selected for each session, but some sessions had fewer than the maximum allotted speakers. The commenter noted that CMS did not provide an explanation regarding the size of sessions (e.g., whether the size of the sessions was due to limited response or a decision by CMS).

Response: CMS thanks commenters for this feedback. For initial price applicability year 2026, CMS used a process to randomly select speakers from among the individuals who registered for the opportunity to speak. For some sessions in initial price applicability year 2026, fewer than 20 participants with in-scope input registered to speak, which meant these sessions did not include the maximum allotted speakers. Because CMS is changing the format of patient-focused

roundtable events for initial price applicability year 2027 (i.e., CMS will host patient-focused roundtable events that include only patients, patient advocacy organizations, and caregivers and one town hall meeting), CMS will adjust how it selects speakers for these events. For each of these types of events, CMS will use an intentional process to select speakers, rather than randomly selecting speakers, with the goal of ensuring that a diverse set of interested parties have the opportunity to share their experiences and information. CMS will consider releasing more information on this intentional selection process in the future.

Comments: Some commenters want CMS to create a systematic, continuous approach to patient engagement whereby engagement occurs throughout the negotiation process and goes beyond hosting listening sessions and seeking written comments. For example, one commenter said CMS should regularly convene meetings with patient organizations and other interested parties to brief them on the negotiation process, hear feedback and concerns about access to treatments, and provide a means to resolve and address those concerns. Another commenter suggested CMS work with an advisory group of experts representing individuals with chronic conditions and disabilities to develop a formal process for ongoing engagement. Additionally, a couple of commenters suggested CMS dedicate funds to support patient engagement and education about MFP and the result of negotiations.

Response: CMS recognizes commenters' desire for a continuous cycle of patient engagement. Public feedback has been instrumental in implementing the IRA thus far, and CMS will continue this engagement as it moves forward. Since the enactment of the IRA in August 2022, CMS has engaged with interested parties through various platforms, including small- and large-group meetings, written materials, and emails via the IRA mailbox (IRARebateandNegotiation@cms.hhs.gov). CMS hosted 10 listening sessions from October 20, 2023 to November 15, 2023, offering the public an opportunity to provide patient-focused input relevant to each selected drug, including information related to clinical benefit of a selected drug as compared to its therapeutic alternative(s), how a selected drug addresses unmet medical need, and how a selected drug impacts specific populations, among other topics. Between September 2022 and June 2024, CMS held more than 250 meetings with interested parties representing the views of consumer and patient organizations, health care providers, health plans, PBMs, pharmaceutical and biotechnology manufacturers, pharmacies, researchers and academic experts, and wholesalers. CMS leadership participated in 83 speaking engagements on IRA implementation hosted by interested parties.

In addition to meetings with interested parties on specific issues, CMS has held monthly calls, as needed, open to all pharmaceutical and biotechnology manufacturers since December 2022. During these monthly calls, CMS staff provide an overview of recent IRA activities and take questions from manufacturer participants. In 2023 and to date in 2024, CMS held quarterly strategic calls with trade associations, health plans, pharmacies, patient groups, and others.

Finally, CMS does not believe continuous patient engagement in the manner suggested by commenters is feasible at this time, but the agency believes it has conducted significant engagement and plans to continue to engage with patients in the future, including in its public engagement events for initial price applicability year 2027.

Negotiation Meetings and Additional Written Offers (Section 60.4.2, 60.4.4, and 60.4.5)

Comment: A few commenters recommended CMS provide the opportunity for additional written offers during the negotiation process and a few of these commenters stated that these offers should not replace a negotiation meeting. A couple of commenters recommended CMS update its latest offer after each negotiation meeting. A couple of commenters suggested that CMS provide justifications for all offer and counteroffer responses and not just initial offers. One commenter recommended CMS provide written materials to accompany each offer.

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 62 of revised guidance for initial price applicability year 2026, 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 one week before final offers are due, whichever is earlier. This opportunity for additional written offers during the negotiation process will not replace a negotiation meeting, and 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.

Comment: A few commenters recommended that CMS allow negotiation meetings to happen throughout the negotiation period (i.e., between the publication of the selected drug list through the conclusion of negotiations), and not just in the situation when a Primary Manufacturer's statutory written counteroffer is rejected. A couple of commenters suggested specific periods during the negotiation process where CMS should hold meetings with Primary Manufacturers of selected drugs, such as after drug selection, prior to the initial offer, and after the initial offer.

Response: CMS recognizes commenters' interest in having meetings throughout the negotiation period. 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 2027. Additionally, as described in section 60.4.2 of this final guidance, CMS is revising the timing of the optional negotiation meetings such that 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 sooner in the process and at different intervals throughout the negotiation period.

Comment: Some commenters stated that limiting negotiation meetings to a maximum of three meetings is restrictive and recommended that CMS allow for more exchanges throughout the negotiation period. Some commenters disagreed that the statutory requirements for initial price applicability year 2027 present challenges to conducting up to three negotiation meetings. A few commenters recommended CMS continue to hold at least three negotiation meetings.

Response: The statutory negotiation period for initial price applicability year 2027 starts on February 1, 2025 and concludes November 1, 2025, which is a total of nine months. After the March 1, 2025 deadline for Primary Manufacturers to submit section 1194(e) data and before CMS' June 1, 2025 deadline to issue initial offers, CMS will hold one optional meeting with the Primary Manufacturer of each selected drug to discuss the section 1194(e) data submission. As described in section 60.4.2 of this final guidance, CMS will host a first negotiation meeting after an initial offer is issued and before a Primary Manufacturer must submit a written response, by July 1, 2025 if an initial offer is sent on June 1, 2025. If an MFP is not agreed upon following CMS' response to the Primary Manufacturer's statutory written counteroffer, if applicable, CMS will offer up to two more negotiation meetings before issuing a final offer, if applicable, by October 15, 2025. This totals up to four optional meetings per selected drug. CMS believes that additional meetings during the negotiation period are not feasible due to time constraints.

As mentioned in the responses to the comments above 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 one week before final offers are due, whichever is earlier. CMS believes these revisions to the negotiation process provide more opportunities for exchanges between CMS and Primary Manufacturers throughout the negotiation period.

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

Comment: A couple commenters provided views regarding the application of the MFP across dosage forms and strengths. One commenter stated that section 60 of the draft guidance 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 read is not consistent with statute as statute requires only that the manufacturer offer the MFP across different dosage forms and strengths of a qualified single source drug. One commenter agreed with CMS' approach to applying the MFP

across different dosage forms and strengths, stating that they believed it would incentivize manufacturers to launch new products that improve patients' experience or care.

Response: CMS appreciates commenters' feedback. 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 are clear, and these statutory provisions 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.

Comment: One commenter suggested basing the application of MFP across dosage forms and strengths on something close to transaction price such as Medicare net price, rather than WAC, to construct the relative price weights. They suggested that CMS would not be revealing any individual product net prices because aggregation would be done applying ratios.

Response: CMS appreciates this commenter's suggestion. For initial price applicability year 2027, CMS will continue to use the WAC ratio to apply the MFP across dosage forms and strengths of a selected drug and will monitor changes to WAC relative to other pricing data, as well as shifts in utilization across dosage forms and strengths. CMS appreciates the commenter's recommendation to use Medicare net price but is concerned that using Medicare net prices in place of WAC could potentially disclose proprietary data. CMS recognizes that there may be other ways to apply the MFP to dosage forms and strengths and will continue to monitor whether this policy and approach 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 2027 and CMS may consider additional or different policies for future years of the Negotiation Program.

Comment: A couple commenters gave feedback regarding the application of the MFP to a new drug product or biological product included in a selected drug that is approved or licensed under a new NDA or BLA that is aggregated with the selected drug. One commenter disagreed with CMS applying the MFP to these new drug products or biological products with the same active moiety / active ingredient and NDA / BLA holder as the selected drug. They stated that this will undercut the value of selected drugs with multiple indications and / or ongoing clinical

development programs. The same commenter stated that the statutory language of the IRA specifies that the approval of a new indication would constitute a "material change" and thus trigger renegotiation, and that CMS has yet to release guidance on program implementation of the renegotiation process. One commenter requested more details on how CMS will identify a comparable drug to the new drug product or biological product and similarly, for cases without a comparable drug, how the imputation of the average units per 30-day equivalent supply will be implemented. This commenter also suggested assigning the existing weighted average price for a period of at least one year to the new drug product or biological product. That would be followed by a rescaling (re-weighting using net prices). They stated that a related question is how long the new product should be on the market to ensure the market has adjusted to it and adequate data exists prior to the re-weighting calculations being made.

Response: CMS appreciates the feedback from these commenters. Consistent with CMS' process for identifying a qualifying single source drug as described in section 30.1 of this final guidance, if the Primary Manufacturer for a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient as the selected drug, CMS will include such NDCs, 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. Similarly, after the drug is selected, 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, CMS will include such NDCs, 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. The statute does not contemplate renegotiation until 2028, therefore renegotiation is outside of the scope of this final guidance.

As described in section 60.5.1 of this final guidance, CMS will determine whether there is an existing, comparable NDC to which the MFP for the selected drug has been applied and, if so, will use the quotient of total quantity dispensed to 30-day equivalent supply (adjusted as necessary to reflect dosing 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. 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 a comparable NDC does not exist, CMS will impute the quotient of total quantity dispensed to 30-day equivalent supply using sources such as FDA-approved label and other sources associated with the NDC that lacks sufficient PDE and/or WAC data, but will use a WAC ratio of 1.0 to apply the MFP to the new NDC. CMS acknowledges the commenter's concerns and suggestion that the application of the MFP across dosage forms and strengths be re-weighted for new drug products or biological products using net prices by a rescaling. CMS intends to address, in future guidance, how the MFP application could be adjusted by updating the quotient of total quantity dispensed to 30-day equivalent supply based on observed PDE data for existing NDCs that lacked sufficient WAC or PDE data in calendar year 2024 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 that launched after the initial calculation of WAC ratios. CMS will solicit comment on this policy and would appreciate any suggested criteria or comments at that time.

Publication of the MFP (Section 60.6)

Comment: One commenter commended CMS' commitment to providing transparency into how the MFP was determined, which includes publishing relevant data and information in the explanations of MFP. The same commenter also expressed support for CMS updating MFPs as needed on an annual basis.

Response: CMS thanks the commenter for their feedback.

Comment: One commenter recommended that CMS solicit comments from stakeholders on the MFP explanations after they are published.

Response: CMS does not intend to provide a public comment period after explanations of MFP are 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 asked that CMS detail specific information in the explanations of MFP. These elements include therapeutic alternatives by indication and information on how they were selected, data and analysis used, benefits and impacts considered, stakeholders and government agencies consulted and how their input was used, sources for information used in negotiation, and details on how information influenced the MFP. A few commenters requested CMS discuss in the MFP explanations how input from the patient listening sessions and patient-submitted data was used in negotiations.

Response: CMS thanks these commenters for their feedback. Consistent with our response on page 67 of the revised guidance for initial price applicability year 2026, as required under section 1195(a)(1) of the Act, CMS will publish the public explanation of the MFP for all selected drugs where there is an agreed-upon MFP for initial price applicability year 2027 no later than March 1, 2026. The public 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 thanks commenters for their recommendation to include how patient-focused input was used in negotiations in the MFP explanations and will further consider this suggestion. As discussed in section 60.4.1 of this final guidance, CMS will use this information 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: A few commenters recommended that CMS allow manufacturers to review the explanation for the MFP before it is published so that manufacturers can provide comment. One commenter stated a draft explanation was required to ensure the explanation was succinct and simple, did not contain confidential or proprietary information, and aligned with processes followed by other agencies. One commenter requested CMS respond to these comments. One commenter requested manufacturers be able to approve an explanation for the MFP before it is published.

Response: Consistent with our response on 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 public 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. 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.

Comment: One commenter recommended CMS issue a template for the explanation of the MFP in advance and allow public comment to ensure the template meets transparency expectations.

Response: CMS does not intend to publish a template for the explanation of the MFP ahead of its publication. CMS believes the information it has provided about the content of these explanations in section 60.6 of this final guidance provides sufficient insight.

Comment: A couple of commenters recommended CMS include in public education materials for Medicare enrollees information about the MFP and what the enrollees should expect at the point of sale, including information about where to direct questions.

Response: As described in section 60.6 of this final guidance, CMS will publish certain information on the CMS website by November 30, 2025 for all initial price applicability year 2027 selected drugs where an MFP was agreed upon, including the selected drug, the initial price applicability year, and the MFP pricing file for that selected drug. CMS will also publish on the CMS website when a drug is no longer a selected drug and the reason for that change. If an agreement for an MFP is not reached for a selected drug, neither an MFP nor a public explanation for the MFP 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. CMS is committed to providing accessible educational materials to people with Medicare, and the pharmacies, mail order services and other dispensing entities that serve them, about the MFPs for selected drugs and how they can report a violation if they do not believe that they were able to access the MFP for a selected drug.

Comment: One commenter requested that CMS acknowledge limitations and avoid information that could be viewed as misleading when making high-level comments about proprietary

information in the explanation of the MFP. The commenter specifically noted that CMS defines R&D in ways that differ from the biopharmaceutical industry's definition and stated CMS should not provide misleading information based on these definitions.

Response: As discussed in the comments and responses for Appendix A of this final guidance, CMS appreciates commenters sharing their concerns regarding the R&D costs definitions and recommendations for other acceptable costs that should be included in the R&D costs definitions. CMS notes that based on experience with data submissions for initial price applicability year 2026, CMS has added to the R&D costs definitions in Appendix A of this final guidance some of the costs suggested by commenters for inclusion as acceptable R&D expenses. For example, as described in Appendix A, post-IND costs for indications that did not receive FDA approval and acquisition costs for failed or abandoned products should be reported as part of "All Other R&D Direct Costs."

Comment: A couple of commenters emphasized the importance of CMS publishing MFPs by November 30, 2025, for initial price applicability year 2027 so that Part D plans have time to operationalize provisions around formulary inclusion and inform dispensing entity negotiations and bid development.

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, 2025, the MFP for each drug selected for initial price applicability year 2027 for which CMS and the Primary Manufacturer have reached an agreement on an MFP.

Comment: A few commenters suggested that CMS publish the explanation of MFP for all selected drugs with an MFP for initial price applicability year 2026 before the negotiation process for initial price applicability year 2027 begins. One commenter requested CMS issue public explanations of MFP for initial price applicability year 2026 alongside its announcement of MFPs by September 1, 2024. One commenter noted that comments for the draft guidance were due before the explanations of MFP for initial price applicability year 2026 were published. Another commenter stated that while they acknowledge the statutory deadline for publishing explanations of the MFP, not having insights into how MFPs were determined made it challenging to provide constructive comment to the draft guidance. The commenter encouraged CMS to explore ways to share information in the interim about its approach in the negotiation process. One commenter asked that CMS delay drug selection for initial price applicability year 2027 until after explanations of the MFP for initial price applicability year 2026 are published. Commenters suggested an earlier publication of initial price applicability year 2026 explanations of MFP so that interested parties can review the explanation and understand CMS' negotiation process ahead of submitting section 1194(e) data for initial price applicability year 2027 by the March 1, 2025 deadline.

Response: CMS thanks these commenters for their feedback. Consistent with our response on page 69 of the revised guidance for initial price applicability year 2026, according to the statute, the public explanation of the MFP must be published no later than March 1, 2025 for initial price applicability year 2026 selected drugs. CMS understands commenters' interest in reviewing these public explanations in advance of the deadline for manufacturers of drugs selected for

negotiation for initial price applicability year 2027 to submit their information and will strive to release the public explanation of the MFP ahead of the March 1, 2025 statutory deadline, if practicable.

CMS recognizes that the July 2, 2024 deadline for comment on the draft guidance came before explanations of the MFPs negotiated for initial price applicability year 2026 will be published. CMS was not able to publish information on the negotiation process before this comment deadline as the negotiation period for initial price applicability year 2026 was still ongoing and MFPs were still being negotiated. CMS believes the information that will be published in the explanations of the MFP for initial price applicability year 2026 will provide valuable insight for future years.

As CMS is statutorily required to announce selected drugs for initial price applicability year 2027 by February 1, 2025, CMS cannot delay drug selection beyond this date.

Comment: One commenter stated that transparent processes are essential for public trust and accountability in the Negotiation Program. The same commenter said sharing methodologies and outcomes on the negotiations, including how prices are determined and how savings are passed to patients, with the public is crucial.

Response: Consistent with CMS' response on page 67 of the revised guidance for initial price applicability year 2026, the public 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 our response on page 67 of the revised guidance for initial price applicability year 2026, CMS is committed to providing accessible educational materials to people with Medicare, and the pharmacies, mail order services, and other dispensing entities that serve them, about the MFPs for selected drugs and how they can report a violation if they do not believe that they were able to access the MFP for a selected drug.

Comment: One commenter requested CMS make public all materials that would aid understanding of CMS' thinking and operations when developing the Negotiation Program and negotiation process. The commenter said that this better understanding would provide meaningful vehicles for public input that mirror practices in the Administrative Procedure Act (APA).

Response: Consistent with our response on 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 both transparency in the negotiation process to assure interested parties and the public that the negotiations were conducted in a fair manner, and that CMS attempted to achieve agreement on the lowest possible MFP for the selected drug for people with Medicare, with the need to maintain the confidentiality of certain information, including manufacturers' proprietary data. As

part of the public explanation of the MFP, 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 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 redact proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law.

Consistent with our response on page 8 of the revised guidance for initial price applicability year 2026, sections 11001(c) and 11002(c) of the IRA provide that the Secretary "shall 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." Thus, the draft guidance is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute.

Comment: One commenter had several questions for CMS about the Maximum Fair Price Layout File ("the MFP File"). The commenter asked CMS to clarify the meaning of the "xref NDC-11" field and asked if it is used when a manufacturer changes the NDC of an existing product. The commenter further noted that the field for the unit price is only specific to two digits after the decimal point when other CMS unit prices typically have five or six digits. The commenter also asked how often CMS will update the MFP file.

Response: The commenter is correct regarding the "xref NDC-11" field, and CMS has revised the definition in the MFP File for clarity. In addition, CMS has revised the number of rounded decimal places to publish the NDC-9 per unit price to the sixth decimal place. As stated by the commenter, publishing an NDC-9 per unit price rounded to the sixth decimal 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.

CMS refers the commenter to section 60.6 of this final guidance for additional information on when the various prices would be updated. In terms of when the MFP File would be updated for other factors (e.g., new NDC-11 of the selected drug is available), CMS is still assessing how often such changes occur for selected drugs to inform the frequency of updates needed to the MFP File to account for such changes.

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

Comment: One commenter requested that CMS abandon its bona fide marketing concept or, at a minimum, provide information on the process by which a drug would be removed from the selected drug list once a generic or biosimilar product was identified as having bona fide marketing.

Response: CMS retains the determination of bona fide marketing in this final guidance and its application to the removal of a drug from selection. The process for removing a drug from the

selected drug list will be handled within CMS. CMS details, in section 70 of this final guidance, the reasons for removal from the selected drug list and the process leading to removal.

Comment: One commenter suggested that if a generic or biosimilar is determined to be bona fide marketed after the negotiation period ends but prior to the initial price applicability year 2027, the MFP should never apply to this selected drug. In contrast, a couple of commenters stated that MFP should apply to a selected drug even if the generic or biosimilar is licensed and marketed after the negotiation period ends but before March 31, 2026 because the statute addresses deselection of a selected drug if a generic or biosimilar is determined to be licensed and marketed at least nine months prior to the start of a subsequent year.

Response: CMS reiterates its response on page 72 of the revised guidance for initial price applicability year 2026 that section 1192(c) of the Act requires a selected drug included on the selected drug list to 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, unless CMS makes the determination before or during the negotiation period that a generic drug or biosimilar product for the selected drug is approved or licensed and is marketed. CMS interprets this requirement such that a drug included on the selected drug list published for initial price applicability year 2027 will remain a selected drug for initial price applicability year 2027 unless CMS determines on or before November 1, 2025 (that is, on or before the end of the Negotiation Period for the initial price applicability year 2027) 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 2027 and the selected drug would cease to be a selected drug on January 1, 2028. 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. If CMS makes this determination between April 1, 2027 and March 31, 2028, then the selected drug will cease to be a selected drug on January 1, 2029, and the MFP will apply for 2027 and 2028. These circumstances are summarized in section 70 in Table 7.

Comment: One commenter urged CMS to consider what action to take if an authorized generic drug commands an outsized share of sales for a particular medication even when traditional generics are also simultaneously marketed. The commenter expressed concern that, if an authorized generic launches before traditional generics and secures a "first mover advantage" in the drug's commercial market, the authorized generic may remain the best-selling version of the drug despite having a higher price than traditional generics. This commenter encouraged CMS to consider the inclusion of additional measures which may include branded and authorized generic drugs for consideration for the program if traditional generics do not provide material competition to a manufacturer's branded and authorized generic drug.

Response: CMS thanks this commenter for their feedback and suggestion. Consistent with CMS' response on page 74 of the revised guidance for initial price applicability year 2026, 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 in the way envisioned by Congress. CMS does not see a need to include additional measures for authorized generics because this topic is already addressed in section 30.1, which states that 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) and authorized generics are drugs that are marketed pursuant to such NDA(s) and 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. Therefore, an authorized generic will be treated as the same qualifying single source drug, in that it will be subject to the same MFP negotiated for the qualifying single source drug as the brand name version of that drug.

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

Comment: One commenter stated that CMS should clarify that the calculation for the MFP refund should be applied in the same way to beneficiaries with Medicare Secondary Payer claims, and it should not be necessary for pharmacies to disclose proprietary financial information.

Response: CMS reiterates that the MTF will send claim-level data elements to the Primary Manufacturer that come through DDPS indicating that a plan approved the claim for a selected drug, including any Medicare Secondary Payer claims. In accordance with the definition of MFP-eligible individual in section 1191(c)(2) of the Act and section 80 of this final guidance, the MFP is required to be made available with respect to Medicare Secondary Payer claims involving the dispensing of a selected drug to 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 14-day prompt MFP payment window for a Primary Manufacturer to transmit the MFP refund payment begins when the MTF sends the claim-level data elements to the Primary Manufacturer. As discussed in section 40.4.1 of this final guidance, CMS will provide Primary Manufacturers with an SDRA that reflects the difference between the selected drug's WAC and MFP. CMS believes this difference 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. However, CMS also reiterates that provision of the SDRA claim-level data element is intended only to provide an additional data point that might assist the Primary Manufacturer in calculating the MFP refund. The Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP, including with respect to Medicare Secondary Payer claims. As discussed in section 40.4.1, the Primary Manufacturer and dispensing entity may 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 the particular unit of the selected drug.

CMS is not requiring dispensing entities to disclose proprietary financial information such as actual acquisition cost or negotiated reimbursement rates to be provided access to the MFP by the Primary Manufacturer of a selected drug. CMS notes that dispensing entities will be required to provide banking information to the MTF DM upon enrollment in the MTF DM, and this banking information may be shared with Primary Manufacturers to assist Primary Manufacturers in making the MFP available and providing ERAs or remittances to dispensing entities.

Manufacturer Plans for Effectuating MFP (Section 90.2.1)

Comment: A few commenters expressed concern with CMS' deadline of June 1, 2025, for the submission of a Primary Manufacturer's written plan to make MFP available to dispensing entities. The commenters indicated that a deadline of June 1, 2025, would be too close to the anticipated publication of this final guidance and any ICR related to the MTF requirements as discussed in the draft guidance for Primary Manufacturers to develop a comprehensive written plan to effectuate the MFP. Most of these commenters proposed changing the June 1, 2025 deadline to a new deadline of September 1, 2025. A couple of commenters recommended CMS provide more information about the MTF and its functionality in a timely manner that would enable manufacturers to develop informed plans to effectuate the MFP by the deadline.

Response: CMS thanks these commenters for their input and recognizes the effort that will be required by each Primary Manufacturer to develop a comprehensive plan to make MFP available to dispensing entities. As such, CMS revised the deadline for submission of the written plans to September 1, 2025, for selected drugs with a first initial price applicability year of 2026 and September 1, 2026 for selected drugs with a first initial price applicability year of 2027. In response to the commenters who recommended that CMS provide more information about the MTF to enable manufacturers to develop informed plans, CMS provided further information in this final guidance about the MTF, including information provided in section 90.2.1 of this final guidance regarding manufacturer plans for effectuating the MFP. Further, and also noted in section 90.2.1 of this final guidance, CMS plans to request Office of Management and Budget approval for an ICR for manufacturer plan submission.

Comment: Some commenters requested that CMS expedite the proposed ICR described in section 90.2.1 of this final guidance to clarify the specific contents CMS expects the manufacturer to include in its written plan to make the MFP available.

Response: CMS thanks the commenters for their feedback. CMS plans to publish the 60-day notice for the ICR related to the MTF as soon as practicable, with the current timeline for OMB approval in Spring 2025. As a part of the ICR, the requirements in section 90.2.1 of this final guidance will be distilled into a well-structured form populated by questions accompanied by free-text responses and check boxes that will provide CMS with the information necessary for Primary Manufacturers to satisfy the requirements described in section 90.2.1.

Comment: Some commenters expressed concern over CMS' plan to make the Primary Manufacturer's MFP effectuation plans publicly available on the IRA website, citing concerns of proprietary information being inadvertently shared despite any attempts at redaction. These

commenters suggested limiting availability of these plans to interested parties (e.g., the dispensing entities, Part D stakeholders, etc.).

Response: CMS thanks these commenters for their feedback. After considering these comments, CMS revised this final guidance to state that redacted versions of the Primary Manufacturers' MFP effectuation plans will be available to dispensing entities via the user interface of the MTF DM with the notice that dispensing entities could be liable to Primary Manufacturers for releasing proprietary information if the plans are disclosed or distributed without the Primary Manufacturer's approval. In addition, CMS may release a redacted version of these plans to other applicable stakeholders (e.g., supply chain entities) upon request as CMS anticipates that these plans may be subject to FOIA requests in the future.

Comment: One commenter suggested that CMS require manufacturers to maintain thorough documentation regarding their processes for nonduplication between the MFP and 340B ceiling price to disincentivize manufacturers from indiscriminately declining to pay claims based upon potential 340B status.

Response: CMS thanks the commenter for their feedback. CMS reiterates here, as stated throughout this final guidance, that Primary Manufacturers are expected to maintain complete and thorough documentation that must be made available to CMS upon request for compliance and auditing purposes.

Comment: One commenter requested that CMS clarify whether dispensing entities are required to align their reimbursement mechanisms with the Primary Manufacturer's plan to effectuate MFP.

Response: CMS thanks the commenter for their feedback. CMS reiterates that sections 40.4.4 and 90.2.1 of this final guidance indicate that Primary Manufacturers and dispensing entities are free to engage in discussions for alternative approaches to effectuating the MFP, regardless of whether the Primary Manufacturer participates in the MTF PM. If a Primary Manufacturer chooses to participate in the MTF PM, then the Primary Manufacturer's MFP effectuation plan will indicate this decision. 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 for the dispensing entity to 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). A Primary Manufacturer's decision to participate in the MTF PM does not preclude it or dispensing entities from negotiating separate mutually agreed upon agreements to provide MFP outside of the MTF PM. Consistent with standard business practices, either a Primary Manufacturer or dispensing entity may discuss with the other party alternative arrangements to effectuate the MFP; however, the Primary Manufacturer is required to update its MFP availability plan to specify these alternative arrangements consistent with the requirements described in section 90.2.1 of this final guidance. The Primary Manufacturer's redacted MFP effectuation plan will be available to dispensing entities via the MTF DM.

If a Primary Manufacturer declines to participate in the MTF PM and elects to establish its own payment facilitation methods, then the Primary Manufacturer's MFP effectuation plan is required to account for dispensing entities that elect to receive electronic transfer of funds and dispensing entities that do not. As discussed in section 40.4.2 of this final guidance, the MTF DM will include the dispensing entity's selected payment method preference among the claim-level data elements transmitted to the Primary Manufacturer. For dispensing entities that have indicated their preference to receive electronic transfer of funds, the Primary Manufacturer is required to provide an electronic reimbursement mechanism, and 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 were provided as a reimbursement mechanism. 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.

Comment: A couple of commenters requested that CMS designate a Primary Manufacturer's choice to participate in MTF payment functionality as a "safe harbor" from any potential enforcement actions related to MFP availability.

Response: CMS declines to designate a safe harbor related to a Primary Manufacturer's choice to participate in the MTF PM. 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.

Comment: One commenter suggested that CMS require dispensing entities that choose to not utilize the MTF payment functionality to provide their banking information to Primary Manufacturers 90 days prior to January 1, 2026.

Response: As discussed above, CMS clarifies in section 40.4.3.3 of this final guidance that the MTF PM will not require affirmative election of participation by dispensing entities for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer. Upon further consideration, CMS recognizes that the original concept of the MTF PM as a two-party platform requiring the dispensing entity's "participation" was inconsistent with the MTF PM's intended ministerial role as a mechanism through which Primary Manufacturers could transmit MFP

refund payments to be passed through to dispensing entities. 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 a means by which MFP refund payments can be passed through to dispensing entities at the Primary Manufacturer's election. However, this does not preclude a dispensing entity from reaching an outside agreement with the participating Primary Manufacturer for a separate arrangement to pay MFP refunds outside the MTF PM. CMS encourages dispensing entities to work with Primary Manufacturers to ensure that they receive their MFP refunds consistent with the Primary Manufacturer's MFP effectuation plan or any other alternative arrangement to which the two private parties agree. In addition, CMS plans for the MTF DM to collect and share the banking account information of dispensing entities that enroll in the MTF DM with Primary Manufacturers to assist the Primary Manufacturer in transmitting MFP refund payment to a dispensing entity outside of the MTF PM. CMS also intends to propose in future rulemaking to require Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM.

Comment: One commenter requested that CMS expand upon its internal risk assessment process for the Primary Manufacturer's MFP effectuation plan and indicate whether it would approve or deny a Primary Manufacturer's plan.

Response: CMS thanks this commenter for their input. As stated in section 90.2.1 of this final guidance, CMS directs Primary Manufacturers to review the requirements set forth for participation in the MTF in sections 40.4 through 40.4.5 of this final guidance, as CMS has designed the MTF DM and MTF PM with considerations it deems important to ensure manufacturer effectuation of the MFP. All plans submitted by Primary Manufacturers, whether they choose to pass payment through the MTF PM or not, will be assessed for their consistency with the requirements set forth in sections 40.4 through 40.4.5 of this final guidance. CMS will not formally approve or reject a Primary Manufacturer's plan but could request clarifications or identify areas where the plan appears to have vulnerabilities that might hinder effective MFP effectuation by the Primary Manufacturer. 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.

Comment: One commenter expressed support regarding CMS monitoring of pharmacy participation in the MTF PM by region and use of safeguards if participation declines in response to a manufacturer's approach to MFP access.

Response: CMS thanks the commenter for their feedback. CMS clarifies in section 40.4.3.3 of this final guidance that 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.

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

Comment: A couple of commenters emphasized the need for CMS to provide clear direction for different interested parties, including dispensing entities and beneficiaries, on how to use the

complaint and dispute system, including FAQs and process flows to educate interested parties on the process, including how to submit a complaint or dispute for different issues that may be encountered.

Response: CMS thanks these commentators for their input. CMS intends to conduct a variety of education and outreach efforts directed at all interested parties, including pharmacists and beneficiaries, related to the MFP, MFP availability, and the complaint process closer to the start of initial price applicability year 2026. CMS will also provide dispensing entities and Primary Manufacturers utilizing the MTF with additional information regarding the dispute process. CMS will also include information on the complaint and dispute process when manufacturers and dispensing entities enroll in the MTF DM.

Comment: A couple of commenters raised concerns with CMS' language in section 90.2.2 of this final guidance that indicated that complaints "will not necessarily require a specific resolution."

Response: CMS seeks to clarify this statement. Any complaints that involve operational issues with the MTF system will receive resolution from the MTF Contractor. All complaints submitted will receive a response from CMS acknowledging the submission and explaining the possible next steps CMS may take. CMS will review all complaints made regarding MFP availability; however, due to the potential volume of complaints, CMS does not believe it will be feasible for every complaint to receive a specific resolution. Not all complaints made may result in an investigation and/or enforcement action; CMS intends to complete an initial review of complaints received, including the evidence submitted, and make a decision regarding likelihood that the MFP was not made available before moving forward with an investigation. To aid this determination, CMS may reach out to the complainant for additional information.

Comment: Many commenters commented on the need for final guidance to clearly state that there is an expectation that interested parties, especially dispensing entities and Primary Manufacturers, work together in good faith to resolve issues before utilizing the complaint process established in this final guidance.

Response: CMS thanks these commenters for their responses and encourages dispensing entities and Primary Manufacturers to work together in good faith to resolve any issues regarding MFP availability before utilizing the established complaint process, as well as any issues that are outside the complaint and dispute process established in this final guidance. Documentation of efforts to resolve complaints should be submitted when a complaint is filed.

Comment: CMS received some comments relating to appeals for the disputes and complaints process. A couple of comments suggested that CMS adopt a three-tiered process similar to the process utilized under the Coverage Gap Discount Program and the forthcoming Manufacturer Discount Program.

Response: CMS thanks these commenters for their suggestion and would like to explain why an appeals process is not contemplated for disputes related to the MTF system. 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., for that 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.

Comment: A few commenters suggested the possibility of claw backs or a credit system in the context of the complaint and dispute process.

Response: CMS refers those commenters to sections 40.4.3.2 and 40.4.4.4 of this final guidance for discussion on how the MTF will handle credits for Primary Manufacturers with respect to payments passed through the MTF PM. Primary Manufacturers and dispensing entities have the ability to come to a separate agreement on providing access to the MFP, which may include an approach the two parties agree on.

Comment: Many commenters recommended the implementation of accountability measures for manufacturers that do not pay their "rebates," and asked for more detail on how disputes can be resolved, and which governmental agency will be responsible for helping adjudicate any complaints related to the "rebate process."

Response: CMS understood these commenters to be asking about accountability measures for a Primary Manufacturer that does not make the MFP available to dispensing entities via a retrospective refund. Sections 40.4 through 40.4.4 of this final guidance discuss the reporting and payment requirements related to MFP effectuation that a Primary Manufacturer must comply with when making the MFP available, or they may be subject to a CMP in accordance with section 1197 of the Act and described in section 100 of this final guidance. Section 90.2.2 of this final guidance establishes that a dispute will result in a finding issued by CMS, while a complaint may result in an enforcement action or audit. CMS encourages dispensing entities and Primary Manufacturers to work together in good faith to resolve any issues that are outside the complaint and dispute process established in this final guidance, and before utilizing the established complaint and dispute process. CMS notes that it is also possible for a Primary Manufacturer to make the MFP available to a dispensing entity by prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than MFP, as described in sections 40.4 and 90.2 of this final guidance.

Comment: A couple of commenters recommended that an MTF helpdesk for all stakeholders be required for contractors providing MTF-related services to dispensing entities and manufacturers utilizing the MTF system.

Response: CMS thanks these commenters for their input. CMS is requiring that all contractors engaged for the purpose of implementing the MTF system maintain a helpdesk to address any operational issues relating to use of the MTF system.

Comment: One commenter responded to CMS' request to identify evidence that should be required to be submitted as part of the dispute and complaint process with a recommendation that such evidence include the ERA or remittance and the WAC as published in the pharmaceutical pricing database compendia on the date of dispensing.

Response: CMS thanks this commenter for their input and agrees that both these pieces of evidence should be submitted as part of the dispute and complaint process, if applicable.

Comment: A couple of commenters requested that the complaint and dispute process established in final guidance covers instances where an MFP claim does not make it to the MTF, i.e., the PDE is rejected before the claim is transmitted to the MTF system.

Response: The complaints and disputes process established in this guidance is intended to cover the period from when PDE is received by the MTF DM system through when the MFP is provided to the beneficiary or dispensing entity. As such, CMS declines to extend the complaint and dispute process to cover PDE that are not received by the MTF DM system. CMS notes that any Part D enrollee who has a dispute about a plan's decision not to provide or pay for a Part D drug has the right to request a coverage determination from the plan and the right to appeal any coverage determination not fully favorable to the enrollee under the procedures specified in Subpart M of part 423.

Comment: One commenter suggested that Primary Manufacturers publish their process to identify 340B duplicate discounts.

Response: CMS thanks this commenter for their suggestion. As part of their plan for making MFP available, as required in section 90.2.1 of this final guidance, each Primary Manufacturer must include its process for nonduplication between the MFP and 340B ceiling price. CMS intends to make these plans available to dispensing entities via the MTF DM.

Comment: A few commenters provided information on additional steps or information they believed CMS should include in the complaint and dispute process. This included: the ability to attach evidence, the ability to raise recurring issues, and dispute and complaint tracking to capture overall trends.

Response: CMS thanks these commenters for their input. CMS intends to incorporate many of these aspects into the complaint and dispute process. Section 90.2.2 of this final guidance makes clear that for both complaints and disputes the entity initiating the action needs to submit evidence to support its position when making the report. If the entity sees evidence of recurring

issues, they should include that information when filing their complaint or dispute, including any evidence relating to previously filed disputes or complaints. CMS intends to track complaints and disputes raised over time to monitor overall trends and emerging compliance issues, and to make process improvements in the implementation of the MTF disputes and complaints process.

Comment: Many commenters objected to the requirement in section 40.4.1 of the draft guidance that Primary Manufacturers cannot withhold payment for disputed amounts pending the outcome of the dispute and will still be held to the 14-day prompt MFP payment window when filing a dispute.

Response: CMS thanks the commenters for their feedback; however, 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 directs commenters to section 40.4.3.2 of this final guidance for additional information.

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.

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 the draft guidance. CMS thanks this commenter for their comment. The dispute process established is intended to allow manufacturers and dispensing entities to raise a specific, identifiable challenge with a technical aspect of the MTF system and process. As Part D plans are not directly interacting with the MTF system, the dispute process is not the appropriate mechanism for Part D plans to raise any 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 suggested that CMS establish a dispute mechanism that allows for the correction to MFP refund payment amounts based on additional validation that is performed or additional data that are received after a payment has been made.

Response: Section 40.4.3.2 of this final guidance describes the claim adjustment process that will be used in instances where the Primary Manufacturer has elected to pass payment through the MTF PM, and a dispensing entity and Primary Manufacturer determine that additional payment needs to be passed through the MTF PM to make the MFP available. This is the process by which a claim would be reopened if additional validation or data indicate that additional payment is needed on the claim to make the MFP available. The Primary Manufacturer would notify CMS so the claim could be reopened. Section 40.4.3.2 of this final guidance establishes a credit/debit ledger system for Primary Manufacturers when payment is passed through the MTF PM to account for circumstances where a claim may be adjusted or reversed. For Primary

Manufacturers that choose not to participate in the MTF PM or that participate in the MTF PM but have agreed with certain dispensing entities on alternative arrangements, as part of the plan to make MFP available required under section 90.2.1 of this final guidance, the Primary Manufacturer must explain their ledger or adjustment system.

Comment: One commenter indicated their belief that CMS should go through notice-and-comment rulemaking to establish reporting of violations and a process for dispute resolution, and then indicated several factors they believed should be incorporated into that process: (1) equal access to the process by all parties; (2) competence and independence of the investigators receiving and acting on the reported violations; (3) clear parameters of what can be reported as violations; and (4) a defined process for how a report should be received, handled, communicated, and resolved. This commenter also remarked on the need for a fair hearing process related to potential CMPs.

Response: CMS thanks this commenter for their input. Sections 11001(c) and 11002(c) of the IRA state that CMS "shall 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 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. When CMS begins working on regulations for the Negotiation Program, CMS will consider the factors listed by the commenter when drafting the CMP sections.

In relation to a fair hearing process for potential CMPs, 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 for a hearing, if requested by the manufacturer, if CMS makes a determination to impose a CMP. Any external stakeholders who believe there has been a violation related to MFP availability should submit a complaint following the process established in section 90.2.2 of this final guidance.

Comment: One commenter requested that CMS utilize the MTF where appropriate to proactively address circumstances where manufacturers are slow to provide refunds.

Response: CMS intends to establish a robust oversight program and to monitor timely effectuation of the MFP on an ongoing basis. The MTF will play a role in such oversight by enabling CMS to track payment status data and monitor trends in timely refund payments by all participating Primary Manufacturers. Further, CMS is placing requirements for timely data reporting to facilitate our ability to monitor and administer the Negotiation Program. Through these mechanisms, CMS is committed to ongoing and proactive monitoring and oversight throughout the implementation of the Negotiation Program.

Comment: One commenter suggested that CMS enable providers to issue complaints and disputes to be used to inform enforcement activity and support the prompt resolution of disputes.
Response: CMS thanks this commenter for their input. The complaint process described in section 90.2.2 of this final guidance is available to all stakeholders, including providers, and CMS welcomes providers to use the complaint process to report MFP-related issues. The dispute process is limited to those stakeholders who will be using the MTF system, that is, dispensing entities and Primary Manufacturers.

Comment: Some commenters requested that CMS establish clear timelines for the complaint and dispute process, with a couple of commenters encouraging CMS to adopt the timelines utilized under the CGDP and its successor program, the Manufacturer Discount Program. Some commenters suggested that CMS establish timelines for CMS responses to a dispute and a complaint.

Response: CMS thanks these commenters for their feedback. In this final guidance, CMS is establishing that 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. For example, for a Primary Manufacturer with a complaint or dispute regarding claim-level data elements, this may be 120 days from the date the data elements in question were transmitted to the Primary Manufacturer via the MTF DM. For dispensing entities, this may be 120 calendar days from the date the ERA is made available via the MTF DM or by the Primary Manufacturer, as applicable. For a beneficiary or other stakeholder, this may be 120 days from the date that the MFP was not made available. CMS is choosing a 120-day timeline, as opposed to the 60-day timeline implemented under the CGDP/Manufacturer Discount Program, to align with the 120-day timeline associated with the ability to appeal a Medicare claim determination. CMS believes this is a more appropriate timeframe because the MFP effectuation process may span several weeks, and the longer timeframe accommodates this process. 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.

Comment: One commenter recommended that parties have 90 days to take corrective action following a final dispute or complaint decision.

Response: CMS thanks this commenter for their input. Parties are encouraged to take corrective action as soon as is practicable, if appropriate, following the resolution of a dispute or complaint. In the event where the outcome of a complaint results in a decision by CMS to move forward with a potential enforcement action, CMS will follow the process outlined in section 100.2 of this final guidance. That is, CMS will send the Primary Manufacturer a Notice of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. The Primary Manufacturer will have 10 business days to respond to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other facts for CMS' consideration. CMS appreciates commenters' request for additional time to take corrective action but believes that 10 business days provides sufficient time for a Primary Manufacturer to either take corrective action or provide CMS with information that may impact CMS' decision, while ensuring that program operations are not unduly delayed.

Civil Monetary Penalties (Section 100)

Comment: One commenter requested that CMS apply civil monetary penalties (CMPs) to pharmacies to ensure program compliance.

Response: Section 1197 of the Act provides that the Primary Manufacturer of a selected drug that enters into a Negotiation Program Agreement may be subject to a CMP for: (1) failure to ensure access to a price that is less than or equal to the MFP for MFP-eligible individuals and pharmacies, mail order services, and other dispensing entities that dispense 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. Section 1197 does not provide CMS with the authority to assess CMPs against dispensing entities related to their interaction with the Negotiation Program.

Comment: One commentator recommended that CMS rely on its statutory authority to establish procedures to require that Primary Manufacturers make timely reconciliation payments to pharmacies outside of CMPs, because the commenter identified CMPs as "inadequate."

Response: Section 1197(a) of the Act provides that the Primary Manufacturer of a selected drug that enters into a Negotiation Program Agreement may be subject to a CMP for failure to ensure access to a price that is less than or equal to the MFP for MFP-eligible individuals and pharmacies, mail order services, and other dispensing entities that dispense the selected drug with respect to MFP-eligible individuals. Additionally, under section 1197(c) of the Act, failure by a Primary Manufacturer to timely meet MTF reporting requirements, including reporting claim-level payment elements in the 14-day prompt MFP payment window, may result in the imposition of a statutorily defined CMP, with an inflation adjustment, per day for each day of the violation. CMPs are the only enforcement mechanisms authorized under section 1197 of the Act to carry out the provisions of the Negotiation Program.

Comment: A few commenters expressed support for CMS notification of a potential deficiency and the opportunity for corrective action. A few comments also requested at least 30 days to cure a potential compliance issue, particularly in the early years of the Negotiation Program. One commenter resubmitted their comments regarding corrective action from the initial price applicability year 2026 initial guidance and stated that CMS did not consider their recommendations or the recommendations of other commenters.

Response: CMS appreciates commenters' feedback. CMS provided additional details in the draft guidance, which have been preserved in the final guidance, about opportunities for the Primary Manufacturer to engage in corrective action in applicable circumstances (refer to sections 100.1 and 100.2 of this final guidance) and provided examples of substantive violations in section 100 that would warrant the issuance of a CMP based on agency discretion. CMS appreciates commenters' request for additional time to cure potential compliance violations through the informal process described in section 100.2 of this final guidance but 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. As discussed in sections 100.1 and 100.2 of this final guidance, CMS will provide written information that identifies the compliance issue.

CMS disagrees with the statement that CMS did not consider recommendations provided during the 2026 initial guidance comment period. While CMS read and addressed comments received timely on the 2026 initial guidance, CMS is not required to adopt all recommendations. CMS responses to timely comments can be found in section C on pages 8 through 9 of the revised guidance for initial price applicability year 2026.

Comment: A couple of commenters stated that CMPs may only be established via notice-and-comment rulemaking and that such rulemaking should include additional detail on the scope of violations, the CMP amount that would be due for in-scope violations, procedures for determining a violation occurred, and a review and appeals process.

Response: Regarding the use of notice-and-comment rulemaking for initial price applicability year 2027 policies, CMS notes that sections 11001(c) and 11002(c) of the IRA provide that the Secretary "shall 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." Thus, this guidance is not subject to the notice-and-comment requirement of the APA or the Medicare statute and this guidance is consistent with the statutory requirement to use program guidance to implement sections 11001 and 11002 of the IRA for 2026, 2027, and 2028.

Comment: A couple of commenters expressed concern that in section 100 of the draft guidance CMS describes discretion with respect to the imposition of CMPs for failure to provide access to the MFP for MFP-eligible individuals and dispensing entities that is not aligned with the statute. One commenter stated that manufacturers must make the MFP available and meet the 14-day prompt MFP payment requirement described in section 40.2 of the draft guidance and implied that CMS does not have discretion to determine whether a CMP is warranted if such requirements are not met. The commenter also stated that providing the Primary Manufacturer with 10 business days to cure a violation of this requirement will further delay receipt of the MFP refund to pharmacies who bear financial risk for the cost of a drug dispensed to an MFP-eligible individual or entity. One commenter stated that the discretion outlined in draft guidance related to CMPs was not clear and consistent and urged CMS to establish a compliance process that is aligned with IRA statutory requirements.

Response: CMS appreciates commenters' feedback. If the Primary Manufacturer fails to ensure access to a price less than or equal to the MFP, section 1197(a) of the Act provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals and dispensing entities and the MFP for such drug for such year, which would be assessed following the process established in section 100.1 of this final guidance. In contrast it would be a violation of the Negotiation

Program Agreement if a Primary Manufacturer fails to provide the claim-level payment elements within the 14-day prompt MFP payment window and section 1197(c) of the Act provides for a CMP for violations of certain terms of the Negotiation Program Agreement, which would be assessed following the process established in section 100.2 of this final guidance; the CMP would accrue at the statutorily specified amount, with an inflation adjustment, for each day that the claim-level payment elements are late. CMS also notes that the 14-day prompt MFP payment window was adopted to align with the timing requirement in the longstanding prompt pay rules for plan sponsors in Part D, as described in section 40.4 of this final guidance.

CMS also appreciates commenters' interest in ensuring that administration of CMPs under section 1197 of the Act is in accordance with the requirements of section 1128A of the Act. In the initial price applicability year 2026 revised guidance as well as in this final guidance, CMS provided information about compliance violations that may result in CMPs being issued, including examples of substantive violations, and the agency's plans for communications surrounding potential and identified compliance violations. CMS also provided a series of informative example scenarios on the scope and calculation of CMPs when applicable. Please see section 100 of this final guidance for additional information.

CMS appreciates the concern that the 10-business day opportunity to cure the noncompliance before CMS makes a decision on whether to assess a CMP for failure to ensure access to the MFP will lead to a delay in receipt of MFP by dispensing entities. While the statute describes the CMP amount and the violation, CMS adopted the process and procedures described in section 100 of this final guidance to provide transparency on when CMS may issue a CMP, including the process of providing an opportunity to cure a compliance issue. This is a necessary and appropriate means to standardize the compliance and enforcement process. CMS reviewed examples of CMP processes in other CMS programs to develop the procedures outlined in this guidance. Section 1197 of the Act indicates violations that warrant a CMP and defines the amounts of CMPs, which will be applied accordingly.

Comment: One commenter requested more information about CMS' plan to implement the CMP process, including scope of violations and amount of CMP that would be due for each; detailed procedures for determination of a violation and imposition of CMPs; and a clear review and appeal process.

Response: CMS thanks this commenter for their feedback. In this final guidance, CMS sought to clarify procedures for implementing CMPs. Section 100.4 of this final guidance discusses CMPs assessed under section 1197(c) of the Act for violations of certain terms of the Negotiation Program Agreement. In this section, CMS clarified that it will issue a CMP Notification with appeal rights once the accrual of the potential statutorily specified per day CMP has ceased, and the Primary Manufacturer is assessed a penalty amount by CMS. This clarification is intended to align the process for all CMPs that may be assessed under the Negotiation Program, simplifying CMP processes for the Primary Manufacturer, and giving the Primary Manufacturer the opportunity to appeal the CMP determination. 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 to appeal, if requested by the Primary

Manufacturer, if CMS makes a determination to impose a CMP. The CMP Notification will contain information on how to file an appeal. CMS also updated section 90.1 of this final guidance to clarify the processes CMS will follow when requesting information from Primary Manufacturers as part of its requirement to administer or monitor compliance with the Negotiation Program, including the type of information it may request; the types of communications CMS may send to the Primary Manufacturer, including Requests for Corrective Action Plans, Notifications of Potential Noncompliance, and/or Violation Notices; and the potential excise tax and CMP liability where a Primary Manufacturer does not comply with CMS' request.

Part D Formulary Inclusion of Selected Drugs (Section 110)

Comment: Some commenters expressed support for CMS continuing the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 and providing Part D plan sponsors with flexibility in formulary management, consistent with the IRA, which does not specify how selected drugs are required to be included on Part D formularies. Some commenters noted support for CMS' commitment to maintaining a robust formulary review process and monitoring plan formularies to determine whether, and if so, the extent to which, plans are disadvantaging selected drugs or non-selected drugs. Some other commenters disagreed that CMS does not have sufficient information to determine whether to change its formulary inclusion policies and expressed disappointment 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 and increase transparency by making public the results of its formulary reviews. A couple of commenters recommended CMS provide for comment the criteria it will use for the clinical justification process to help ensure consistency in its formulary reviews. One commenter recommended CMS provide manufacturers directly impacted by a formulary and/or tiering determination with access to plan sponsor formulary justification statements that are submitted to CMS during the formulary review process.

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 page 82 of the revised guidance for initial price applicability year 2026, 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, consistent with CMS' response on page 82 of the revised guidance for initial price applicability year 2026, 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.

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, multiple IRA Part D redesign provisions take effect in 2025 that impact Part D plan sponsors' benefit and formulary design choices. Additionally, the formulary inclusion requirement in section 1860D-4(b)(3)(I) of the Act has not taken effect yet, and plan sponsors will not submit their formularies for the first contract year in which MFPs are in effect (i.e., contract year 2026) until 2025. For these reasons, CMS will continue monitoring Part D plans' compliance with all applicable formulary requirements and treatment of selected drugs and, for contract year 2027, will maintain the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026.

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 contacting 1-800-MEDICARE. 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 couple of commenters recommended CMS not require that Part D formularies include every dosage form and strength of a selected drug, noting that plans could comply with

the changes in law made by the IRA if only one dosage form and strength of the selected drug is included. One commenter requested clarification from CMS regarding the application of mandatory coverage under section 1860D-4(b)(3)(I)(i) of the Act when a drug is determined to meet bona fide marketing between the selected drug publication date and the end of the negotiation period for an initial price applicability year. Another commenter recommended that CMS promptly notify Part D plan sponsors, such as through a CMS HPMS memo, when the formulary inclusion requirement no longer applies to a previously selected drug.

Response: Consistent with CMS' response on pages 82 and 83 of the revised guidance for initial price applicability year 2026, 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. In response to the comment requesting clarification on when the formulary inclusion requirement would cease to apply, CMS refers readers to section 70 of this final guidance, which, in accordance with section 1192(c) of the Act, details when a selected drug will cease to be a selected drug because CMS determines that a generic drug or biosimilar that identifies as its reference-listed drug or reference product a drug or product that is included in the selected drug has been approved or licensed and is marketed pursuant to such approval or licensure. As described in section 70 of this final guidance, if CMS determines the statutory criteria in section 1192(c) of the Act for generic competition are met for a selected drug and thus the drug is removed from the selected drug list, CMS will publish such information on the CMS website. CMS notes 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. Accordingly, if CMS makes this determination between November 2, 2025 and March 31, 2027, for a drug selected for initial price applicability year 2027, then the drug will cease to be a selected drug on January 1, 2028 and the MFP will apply for 2027. If CMS makes this determination between April 1, 2027 and March 31, 2028, then the selected drug will cease to be a selected drug on January 1, 2029, and the MFP will apply for 2027 and 2028. As stated on page 83 of the revised guidance for initial price applicability year 2026, CMS also notes that, as specified by section 1860D-4(b)(3)(I)(ii) of the Act, 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).

CMS thanks the commenter for their suggestion that CMS notify Part D plan sponsors, such as through a memo via the CMS HPMS, when the formulary inclusion requirement no longer applies to a previously selected drug. As described in section 60.6 of this final guidance, CMS will publish on the CMS website when a drug is no longer a selected drug and the reason for that change and will update the MFP pricing file to indicate that a drug has been removed from the selected drug list. CMS is considering sending a memo via the CMS HPMS when the MFP pricing file is updated to reflect that a drug has been removed from the selected drug list.

Comment: Many commenters expressed concern that Part D plan sponsors may be incentivized to steer patients away from selected drugs by placing selected drugs on less favorable tiers

compared to non-selected drugs and recommended CMS establish explicit requirements for formulary placement of selected drugs by, for example, requiring that selected drugs with an MFP in effect are placed on the most favorable or lowest-cost formulary tier or at minimum, on the formulary tier and level of cost sharing predating selection. A couple of commenters interpreted the draft guidance as establishing new restrictions on formulary placement of selected drugs and requiring that selected drugs with MFPs be preferred brand drugs by default. A couple of commenters recommended CMS rely on input from Pharmacy & Therapeutics (P&T) Committees and scientific evidence to determine tier placement within formularies, rather than imposing a coverage mandate for selected drugs.

Response: CMS appreciates these commenters' feedback. Consistent with CMS' response on page 83 of the revised guidance for initial price applicability year 2026, CMS generally expects that people with Medicare taking selected drugs will benefit from the lower negotiated MFPs. While CMS understands that not all selected drugs and drug classes will present Part D sponsors and their P&T Committees with the same formulary considerations and might not warrant the same formulary placement in all situations, CMS remains 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. 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 2027. Many commenters expressed concern that plans will apply utilization management not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs that may be associated with higher rebates and recommended CMS limit or prohibit utilization management for selected drugs. For example, a few commenters suggested

CMS clarify that utilization management requirements should not be more restrictive than the terms of a selected drug's FDA-approved label. A couple of commenters expressed concern about the extent to which beneficiaries could be steered toward selected drugs by plans imposing utilization management on non-selected drugs.

Response: CMS thanks these commenters for their feedback. Consistent with CMS' response on page 84 of the revised guidance for initial price applicability year 2026, CMS shares the commenters' concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs 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. 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 utilization management requirements, CMS will use its formulary review process to assess any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy) or where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug 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). 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 by imposing utilization management that is not based on medical appropriateness on non-selected drugs. CMS reviews all Part D plan formularies to ensure they comply with statutory and regulatory requirements and, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, 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 utilization management in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected and non-selected drugs and inform new requirements for future contract years.

Comment: One commenter recommended CMS ensure that people with Medicare not pay more out-of-pocket for a drug with an MFP in effect than they were paying previously, and that CMS perform an evaluation at the end of an initial price applicability year to assess the extent to which beneficiaries realized savings.

Response: CMS appreciates this feedback. Consistent with CMS' response on page 83 of the revised guidance for initial price applicability year 2026, CMS generally expects that people with Medicare taking selected drugs will benefit from the lower negotiated MFPs. 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. Additionally, for contract year 2027, CMS is not implementing explicit formulary tier placement requirements for selected drugs, but section 110 of this final guidance describes how CMS will use its formulary review process to assess potentially concerning formulary review findings.

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

Comment: A couple of commenters stated that selected drugs should not be subject to inflation rebates. 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.

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.[50] Specifically, the rebate calculation specified in section 1847A(i)(3)(A)(ii) of the Act references section 1847A(b)(1)(B) of the Act, which 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 revised Medicare Part B Drug Inflation Rebate Guidance and the revised Medicare Part D Drug Inflation Rebate Guidance, which were published on December 14, 2023 and implemented policies relating to the Medicare Prescription Drug Inflation Rebate Program for 2022, 2023, and 2024.[51] CMS has proposed to codify, with modification and additional clarification, the policies set forth in the revised Medicare Part B Drug Inflation Rebate Guidance and the revised Medicare Part D Drug Inflation Rebate Guidance in proposed parts 427 and 428 of title 42, Chapter IV of the Code of Federal Regulations.[52]

Definitions for Purposes of Collecting Manufacturer-Specific Data (Appendix A)

Comment: Some commenters suggested that CMS' definition of R&D costs is too narrow and recommended CMS allow reporting of other relevant costs, for example, costs of ongoing studies of a drug, costs related to new indications or formulations under development but not approved by the FDA, acquisition costs for both marketed and failed drug candidates, costs related to real-world evidence generation, partnering and licensing agreements, and milestone payments. One commenter noted that the rights to hold an NDA / BLA can be acquired via different deal structures and suggested CMS acknowledge that the definition of acquisition costs includes costs

[50] See sections 1847A(i) and 1860D-14B of the Act.
[51] 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.
[52] CMS, Proposed 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," July 31, 2024 (89 *Federal Register*, 61766).

associated with licensing arrangements, co-development or clinical product supply agreements, and/or milestone payments. One commenter stated that global sales should be considered in the definition of net revenue for the selected drug and that CMS should not use inflated value metrics for coupons, goods donated, or other forms of voluntary access concessions when calculating the global, total lifetime net revenue for the selected drug.

A few commenters noted the complexity of accounting for R&D spending for a specific drug and recommended CMS provide additional clarification, such as by providing additional examples of acceptable costs. A couple of commenters expressed concern that CMS' reporting requirements related to R&D costs are inconsistent with existing financial accounting practices, such as U.S. Generally Accepted Accounting Principles (GAAP) and SEC requirements, which do not require reporting of R&D costs at a product-specific level or to categorize R&D data in the manner CMS describes. A few commenters recommended that CMS streamline R&D reporting categories or allow manufacturers to attest to whether R&D costs have been recouped and to report a single number for R&D costs. One commenter suggested CMS consider the reasons for why R&D costs were not recouped. Two commenters recommended CMS require that R&D costs be reported within the disaggregated categories described. One commenter suggested CMS clarify that R&D should be reported as out-of-pocket spending and not be capitalized or risk adjusted.

Response: CMS appreciates commenters sharing their concerns regarding the R&D costs definitions and recommendations for other acceptable costs that should be included in the R&D costs definitions. CMS notes that based on experience with data submissions for initial price applicability year 2026, CMS has added to the R&D costs definitions in Appendix A of this guidance some of the costs suggested by commenters for inclusion as acceptable R&D expenses. For example, as described in Appendix A, post-IND costs for indications that did not receive FDA approval and acquisition costs for failed or abandoned products should be reported as part of "All Other R&D Direct Costs." Further, in response to recommendations submitted by commenters on the draft guidance for initial price applicability year 2027, CMS has revised the definition of "All Other R&D Direct Costs" to explicitly include costs associated with real-world evidence generation for purposes of supporting the safety or effectiveness of a selected drug or supporting or satisfying FDA postmarketing requirements or commitments. Manufacturers should submit additional R&D direct costs not included in other R&D definitions as part of "All Other R&D Direct Costs," as applicable.

Consistent with CMS' response on page 88 of the initial price applicability year 2026 revised guidance, CMS believes that for the purpose of the Negotiation Program, the definition of R&D costs is sufficiently broad and is intended to accommodate differences in accounting policies and cost allocations across different manufacturers. CMS understands that the rights to hold an NDA / BLA can be acquired via different deal structures and confirms that acquisition costs may include costs associated with licensing arrangements, co-development or clinical product supply agreements, and milestone payments. CMS also confirms that it will use the Primary Manufacturer's global total lifetime net revenue for the selected drug when determining the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug. Global, total lifetime 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.

CMS agrees with commenters that accounting for R&D spending may be complex and thus provides more detailed reporting instructions for Primary Manufacturers in the Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452), which will publish for a 30-day public comment period during Fall 2024. As described in the instructions of the Negotiation Data Elements and Drug Price Negotiation Process ICR, R&D costs must be reported within the disaggregated categories specified in Appendix A of this final guidance, and monetary values must be determined using the methodologies described throughout the document and when applicable, consistent with GAAP. CMS understands that requiring manufacturers to report R&D costs at the product-specific level may be inconsistent with GAAP or SEC requirements. However, section 1194(e)(1) of the Act requires that the Primary Manufacturer reports R&D costs "for the drug." When calculating monetary values, the Primary Manufacturer may assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment, consistent with other studies on R&D costs in the pharmaceutical industry, but should not otherwise adjust the monetary amounts provided.

Comment: One commenter stated that CMS' description of current unit production costs in Appendix A is clear, detailed, and comprehensive, but recommended CMS clarify that capitalized production facility costs must be proportional to their volume or revenue across the full facility to avoid double counting across products. A few commenters raised concerns with obtaining or reporting information about current unit costs of production and distribution as described in the draft guidance, which one commenter stated is inconsistent with reporting requirements of other governmental bodies such as the SEC. This commenter recommended CMS request production and distribution data as of the close of the manufacturer's most recent fiscal year or with the date of a quarter close such as September 30, 2024 or December 31, 2024 to align with the company's external financial reporting. One commenter recommended that CMS include channel fees in its definition of distribution costs and that CMS specify that the exclusion of "transfer prices" does not apply to actual costs to produce and distribute a selected drug incurred by different "members of the same controlled group of the Primary Manufacturer." This commenter provided an example in which one member of a controlled group incurs costs to manufacture the active pharmaceutical ingredient of a drug (which could include purchase of raw ingredients), and another member of the same controlled group incurs costs related to the formulation and preparation of the finished drug product, and asked CMS to confirm that the expenses associated with these activities meet the definition of production and distribution costs and are not considered transfer prices. Another commenter recommended CMS allow discretion for manufacturers to describe production and distribution costs which they are able to report and to provide a narrative explanation describing how these costs were calculated.

Response: CMS thanks these commenters for their feedback. CMS refers commenters to the Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452), which will publish for a 30-day comment period in Fall 2024 and will provide additional instructions for submitting explanations of various calculations, including unit production and distribution costs. Consistent with CMS' response on page 89 of the initial price applicability year 2026 revised guidance, the definitions of unit costs of production and distribution are

intended to be sufficiently broad to account for various costs associated with producing and distributing drugs or biological products. CMS declines to explicitly include additional expenses such as channel fees in its definition of costs of distribution and notes that the definition generally refers to all (direct and allocation of indirect) costs related to packaging, labeling, and shipping operating costs for facilities and transportation. In response to comment, CMS has revised the definition of current unit costs of production and distribution of the selected drug to specify that costs should be reported for the 12-month period ending December 31, 2024, instead of October 31, 2024, to align with the end of a fiscal quarter based on SEC filings. CMS appreciates the commenter's request for clarification regarding transfer prices. In the example provided, if the two entities within the controlling group are either the Primary Manufacturer or a Secondary Manufacturer, the expenses associated with these activities generally would meet the definition of production costs. However, the costs reported should reflect the costs attributable to production and distribution expenses incurred individually by those entities, rather than the transfer price for transactions between those two entities.

Comment: A few commenters recommended CMS remove federal tax credits from the definition of prior Federal financial support and limit consideration of prior Federal financial support to only products with a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency. One commenter recommended that prior Federal financial support exclude indirect federal funding (e.g., provision of funding to a third party which then provides funding to the manufacturer), which manufacturer accounting systems may not be able to capture. A couple of commenters recommended that prior Federal financial support be expanded to include, for example, incentives such as priority review vouchers awarded by the FDA and Federal financial support provided through public-private partnerships with government, academia, or non-profit organizations. A couple of commenters recommended that CMS broaden the timeframe for reporting of prior Federal financial support, noting that the IRA does not limit the timeframe of such support and that federal investments in research may occur decades before an IND application is submitted to the FDA. One commenter requested CMS clarify the applicable time period for reporting of prior Federal financial support. A couple of commenters suggested different ways for reporting on prior Federal financial support, such as using estimation based on National Institutes of Health (NIH) product-related research investments and collecting information on when in the drug development process Federal financial support was provided.

Response: CMS thanks these commenters for their feedback. Consistent with CMS' response on pages 88 and 89 of the initial price applicability year 2026 revised guidance, CMS disagrees that tax credits should be excluded from the definition of prior Federal financial support. The federal government supports drug research through tax incentives. The statute does not require that CMS only consider direct expenditures in prior Federal financial support or only government interest patents. In response to commenters' requests regarding inclusion of Federal financial support provided through a third party (e.g., academia or a non-profit), CMS confirms that the definition of prior Federal financial support does not include indirect funding such as that provided by a U.S. federal agency to a third party which then provided that funding to a Primary Manufacturer. Based on CMS' experience with Primary Manufacturers' data submissions for initial price applicability year 2026, CMS broadened the definition of "Federal financial support for novel therapeutic discovery and development" from the revised guidance for initial price applicability

year 2026 to include in-kind contributions. CMS declines to collect information on when in the drug development process Federal financial support was provided or to further expand the definition of prior Federal financial support to include priority review vouchers, which are granted by the FDA for the purpose of expediting the review of an NDA or BLA and are not associated with a dollar amount unless sold to another manufacturer. CMS also disagrees with commenters that it should broaden the timeframe for reporting prior Federal financial support. Primary Manufacturers are instructed to report prior Federal Financial support provided for the time period beginning with the date of initial discovery of the drug or the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that FDA-approved indication of the selected drug went into effect. CMS does not expect a Primary Manufacturer to report Federal financial support provided for the period prior to its acquisition of the rights to the selected drug. CMS refers interested parties to the Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452), which will publish for a 30-day comment period in Fall 2024 and will provide additional instructions regarding categories of prior Federal financial support that should be reported.

Comment: Some commenters recommended CMS withdraw or clarify certain metrics or limit reporting to existing price reporting metrics related to market data and revenue and sales volume data (e.g., WAC, AMP, FSS price). One commenter requested clarification if the FSS price is the FSS price negotiated with the Department of Veterans Affairs (VA) for other government agencies, exclusive of temporary price reductions and blanket purchase agreements. A few commenters specifically opposed CMS' approach to require Primary Manufacturers to report manufacturer net Medicare Part D price, stating that this is not a standard metric that is reported to other federal programs, and expressing concern with being able to determine price concessions from different entities across the pharmaceutical supply chain. One commenter also stated that CMS should not require manufacturer submission of manufacturer net Medicare Part D price when CMS demonstrated its ability to calculate this price point itself in initial price applicability year 2026. One commenter also opposed collection of the manufacturer U.S. commercial average net unit price. A couple of commenters also were concerned with CMS requesting data on patient assistance, noting that patient assistance is not a form of price concession or remuneration. One commenter requested CMS remove all reporting of patient assistance or, minimally, clarify that patient assistance programs are defined as charitable free drug programs. Another commenter requested that CMS share the manufacturer net Medicare Part D price for therapeutic alternatives with other manufacturers. One commenter stated that the information collected pursuant to the definitions is considered confidential and proprietary information.

Response: CMS appreciates these commenters' concerns. Consistent with CMS' response on page 90 of the initial price applicability year 2026 revised guidance, the statute requires CMS to broadly consider market data and revenue and sales data. CMS considers these data to include WAC, Medicaid best price, AMP, FSS price, Big Four price, U.S. commercial average net unit price, and manufacturer net Medicare Part D average unit price, among other data. Data related to these definitions will be considered, in part, as the basis for offers and counteroffers. CMS confirms that the FSS price generally excludes temporary price reductions and blanket purchase agreements. As described in Appendix A, patient assistance programs include manufacturer-run patient assistance programs that provide financial assistance such as coupons or copayment

assistance or free drug products. For initial price applicability year 2027, CMS has added the metric "manufacturer net Medicare Part D average unit price," which, as calculated by the Primary Manufacturer, must reflect specific data, such as CGDP payments and supply chain concessions offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers and utilization, that may differ from the PDE data to which CMS has access. CMS disagrees that this is a price point that CMS has demonstrated the ability to calculate itself for initial price applicability year 2026, as the "manufacturer net Medicare Part D average unit price," as defined in Appendix A of this final guidance, is inclusive of data not reflected in CMS' calculation of the plan-specific enrollment weighted amount. Further, by requiring Primary Manufacturers to submit the manufacturer net Medicare Part D average unit price as part of their section 1194(e)(1) data submissions, CMS could consider this metric in the development of the initial offer. Additionally, CMS has added the term "manufacturer net Medicare Part D average unit price – best" for the sole purpose of collecting the related data element under section 1194(e)(1)(E) of the Act. CMS refers interested parties to the Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452), which will publish for a 30-day public comment period in Fall 2024 and includes instructions for calculating and reporting metrics in the Market Data and Revenue and Sales Data section.

With respect to the comment about confidential and proprietary information, including trade secrets and confidential commercial or financial information, CMS will protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers (described in section 40.2.1 of this final guidance) as required under section 1193(c) of the Act and other applicable law.

Comment: A few commenters suggested CMS narrow the scope of patent and exclusivity reporting requirements to, for example, exclude expired patents and exclusivities or confirm that manufacturers are not required to submit non-public patent information (e.g., about pending applications that have not been published) or information about abandoned patent applications. One commenter requested clarity with respect to certain terms used in this section, including the meaning of patents "linked to" or "relating to" the selected drug. A few commenters suggested that only patents and patent applications directly related to the selected drug or patents and patent applications from third parties that have a business relationship with the Primary Manufacturer related to the selected drug should be considered. One commenter suggested that patents and patent applications be limited to whether the selected drug will remain a single source drug. One commenter also recommended CMS obtain information about approved patent applications and marketing applications from FDA resources such as the Orange Book and Purple Book and that manufacturers be allowed to reference those sources in their submissions to CMS to reduce burden.

Response: CMS thanks these commenters for their suggestions. Section 1194(e)(1)(D) of the Act explicitly requires manufacturers to submit "data on pending and approved patent applications." As such, CMS disagrees that Primary Manufacturers should not be required to submit non-public or pending patent applications. CMS also disagrees that expired patents and exclusivities should be excluded from reporting requirements, as the statute does not specify such exclusion. Further, because negotiation eligibility of a drug is based, in part, on the amount of time a drug has been on the market (i.e., at least 7 years for a small molecule drug approved

under an NDA or at least 11 years for a biological product licensed under a BLA), CMS expects that many primary patents (e.g., those covering the active ingredient of a drug or biological product) would have expired by the time such drug or biological product would be selected for negotiation, as the term of a patent granted by the USPTO is generally 20 years, and primary patents are typically granted early in a product's life cycle and years before FDA approval. Similarly, CMS expects that many exclusivities—particularly for small molecule drugs, which range from 6 months to 7 years—would have expired by the time a drug or biological product would be selected for negotiation. In response to commenters' concerns about the scope of required patent and exclusivity information, CMS has clarified in Appendix A of this final guidance that relevant patents and patent applications do not include patent applications that were denied by the USPTO. CMS has also added examples in Appendix A of this final guidance of the types of patents and patent applications CMS considers to be related to the selected drug to provide additional clarity for Primary Manufacturers regarding patent submission requirements. Otherwise, CMS believes Appendix A of this final guidance sufficiently describes the types of patents and patent applications that CMS considers to be related to the selected drug and thus should be submitted to CMS. CMS refers interested parties to the Negotiation Data Elements and Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452), which will provide additional instructions for reporting patent and exclusivity information for a selected drug.

Consistent with CMS' response on page 90 of the initial price applicability year 2026 revised guidance, while CMS understands that certain patent information is submitted to other agencies and is publicly available in the FDA Orange and Purple Books, section 1194(e)(1)(D) of the Act requires that manufacturers submit patent information to CMS. Although some of the requested data may be publicly available, CMS may not be able to ensure that such data are complete or up to date. Further, other information required by section 1194(e)(1)(D) of the Act, for example, information about pending patent applications, may not be publicly available.

Comment: Some commenters requested clarity or revisions to the definitions related to collection of evidence for therapeutic alternatives, including outcomes, health equity, specific population, unmet medical need, and therapeutic advance. One commenter suggested CMS should include "patients with multiple comorbidities" in the definition of specific populations and "cost of case outcomes" in the definition of outcomes. One commenter requested clarification from CMS as to why an improvement must be "substantial" to be considered a therapeutic advance. Another commenter requested clarification if substantial improvements include safety and efficacy. One commenter suggested including the use of a drug's therapeutic profile and harmonizing with the FDA's definition of unmet medical need. Another commenter requested CMS explain which specific elements of the FDA guidance that CMS states CMS will refer to when considering if a drug addresses an unmet medical need for purposes of the Negotiation Program [Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" (May 2014)] and how they are weighted when CMS considers unmet medical need.

Response: CMS refers commenters to section 60.3.3.2 of this final guidance and related public comment summaries and CMS responses in this final guidance regarding the policies for how a selected drug is evaluated and compared to a therapeutic alternative for the purposes of adjusting the starting point to determine the initial offer price, among other factors, using the negotiation

factors outlined in section 1194(e)(2) of the Act. CMS thanks commenters for their recommendations to the definitions included in Section I of the Negotiation Data Elements and Drug Price Negotiation Process ICR (as captured in Appendix A) and declines to revise the terms of outcomes, specific population, unmet medical need, and therapeutic advance.

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

Comment: One commenter expressed concerns about the impact the IRA will have on Part B reimbursement, stating that the Part B add-on reimbursement would decrease because it would be based on the MFP.

Response: Part B reimbursement as it relates to the IRA is outside the scope of this final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 and will be addressed in future guidance or rulemaking, as appropriate.

Comment: A couple of commenters wrote that CMS must dedicate resources to and improve education for patients about the Medicare Prescription Payment Plan.

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

Comment: One commenter expressed concern that the Negotiation Program provisions of the IRA, such as the excise tax, will be harmful for patients and taxpayers.

Response: This comment is outside the scope of this final guidance. The Department of the Treasury and the Internal Revenue Service (IRS) are in the process of rulemaking to establish regulations that govern the administration of the excise tax.

Comment: One commenter stated that to increase price transparency and to better inform the public about the outcomes of drug price negotiations Congress should enact legislation to make both non-FAMP and AMP publicly available.

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

Comment: One commenter suggested CMS reconsider the use of WAC as the standardized pricing metric when drugs covered under Part B are included in future years of the program.

Response: This comment is outside the scope of this final guidance for initial price applicability year 2027 and will be addressed in future guidance or rulemaking, as appropriate.

Comment: One commenter noted that 340B sales and units are excluded from the calculation of ASP under Part B and MDRP price calculations. The commenter requests that CMS clarify that 340B sales and units should continue to be excluded from these government price calculations for selected drugs, including when the MFP is lower than the 340B ceiling price.

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

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)[53] 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.

Sections 11001(c) and 11002(c) of the 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, the Centers for Medicare & Medicaid Services (CMS) is issuing this final guidance for implementation of the Negotiation Program for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027.

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 that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute.

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, 2025 of the selected drug list for initial price applicability year 2027 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, 2025, to prepare for the possibility that a drug they manufacture might be

[53] 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.

included on the selected drug list for initial price applicability year 2027. 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, 2025, 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, 2025, and gather information for potential submission to CMS by the statutory deadline of March 1, 2025. In addition, for the reasons explained below, the deadline for a manufacturer to submit a request for a Small Biotech Exception under 1192(d)(2) of the Act or a request for a Biosimilar Delay under section 1192(f) of the Act will be in mid-December 2024. 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 example, CMS will engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data and payment between pharmaceutical supply chain entities. The MTF will have two distinct modules, the MTF Data Module (MTF DM), to support the verification that the selected drug was dispensed to an MFP-eligible individual and the MTF Payment Module (MTF PM), a voluntary option to pass payment for MFP refunds from Primary Manufacturers to dispensing entities. Enrollment in the MTF DM is mandatory for Primary Manufacturers, as Primary Manufacturers must receive data from the MTF DM identifying their obligation to make payment to a dispensing entity. Primary Manufacturers must transmit MFP refund payments within 14 days of the MTF transmitting this data. CMS anticipates activities with respect to the MTF throughout late 2024 and 2025 that will include developing, building, testing, data collection and security, and onboarding of manufacturers and dispensing entities.

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 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 2027 (January 1, 2027 to December 31, 2027), including clarifying certain policies that CMS set forth in "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027." This final guidance also sets forth additional policies regarding manufacturer effectuation of the MFP in 2026 and 2027, and specifies the requirements that will be applicable to manufacturers of drugs that are selected for negotiation and 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 this final guidance, CMS has made certain changes to policies discussed in the draft guidance in

response to comments received or based on the agency's further consideration of the relevant issues.

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 this 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 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 2027, building on the revised guidance for initial price applicability year 2026 to apply the experience of CMS and early lessons learned to date from the negotiation process. This final guidance also sets forth additional policies regarding manufacturer effectuation of the MFP in 2026 and 2027, including the use of an MTF to facilitate the exchange of data and

payment between pharmaceutical supply chain entities. Given the timing overlap between the development of the final guidance for initial price applicability year 2027 and the negotiation period for initial price applicability year 2026, CMS has made certain additional adjustments in the final guidance based on the agency's experience, including experience from the first cycle of negotiations.

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. 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 and, if applicable, renegotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) impose civil monetary penalties (CMPs) in accordance with section 1197 of the Act. 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 states that the Department of the Treasury is in the process of rulemaking to establish regulations that govern the administration of the excise tax).

Topics that are not relevant to Negotiation Program implementation for initial price applicability year 2027 or for MFP effectuation in 2026 and 2027 are not addressed in this guidance. CMS intends to provide additional information in the future related to implementation for initial price applicability year 2028 and beyond.

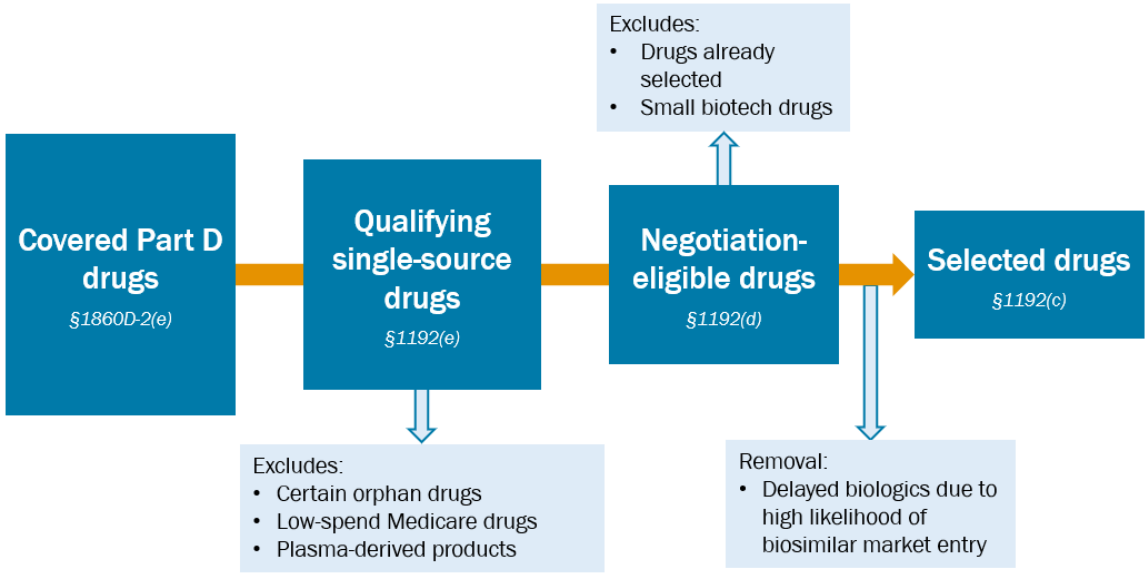
30. Identification of Selected Drugs for Initial Price Applicability Year 2027

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) of the Act, using Total Expenditures[54] 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, 2023, and October 31, 2024, and other information described below, CMS will identify negotiation-eligible drugs for initial price applicability year 2027 as described in section 30.2 of this final guidance (in this step, CMS will also exclude certain drugs in accordance with sections 1192(d)(2) and (3) of the Act).

[54] 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)). The term "gross covered prescription drug costs" is also defined in the Part D regulations at 42 C.F.R. § 423.308.

In accordance with section 1192(d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2027 according to the Total Expenditures for such drugs under 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 biologics 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 D of Title XVIII of the Act for negotiation for initial price applicability year 2027 (described in section 30.3 of this final guidance) and publish a list of up to 15 selected drugs not later than February 1, 2025 (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 2027 is included further below.

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2027



30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

For initial price applicability year 2027, 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) 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; 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; 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.

Section 1192(d)(3)(B) of the Act states that CMS shall use data that are aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or package type of the drug 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[55] using:

- For drug products, all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA),[56] 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 that are publicly available and other relevant publicly available sources 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[57] that are marketed pursuant to such NDA(s); (2) authorized generic drugs that are marketed pursuant to such NDA(s); or (3) multi-market

[55] 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.
[56] As described in section 505(c) of the FD&C Act.
[57] For purposes of the Negotiation Program, the terms "repackage" and "relabel" have the meaning specified in 21 C.F.R. § 207.1.

approval (MMA)[58] products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s); [59]

- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA),[60] 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 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 that are publicly available and other relevant publicly available sources 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) authorized biological products that are marketed pursuant to such BLA(s); or (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s).[61]

CMS will identify the active moiety or active ingredient of the drug using public sources such as RxNorm, OpenFDA, FDALabel, 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.

As an example, illustrated in Table 1 below, 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. 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

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

[59] 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.

[60] As described in section 351(a) of the PHS Act.

[61] 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.

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		

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[62] 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[63] 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 both) 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.

Applying statutory criteria for qualifying single source drugs:

[62] CMS is interpreting the reference to "licensed under section 351(a) of such Act" to mean licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.
[63] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 C.F.R. § 300.50.

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, as applicable, and the selected drug publication date. To determine the date of approval or licensure for a potential qualifying single source drug with more than one FDA application number, CMS will use the earliest date of approval or licensure of 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. The selected drug publication date for initial price applicability year 2027 is February 1, 2025, as specified in section 1191(b)(3) of the Act. As such, for initial price applicability year 2027, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before February 1, 2018, 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, 2014.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and February 1, 2025, 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, 2025), 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.

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 under section 505(j) of the FD&C Act, 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. CMS will use FDA reference sources, including the Orange Book[64] and Purple Book,[65] to determine whether a generic drug or biosimilar biological product66 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 2027.

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 2027, CMS will review PDE data for the 12-month period beginning January 16, 2024 and ending January 15, 2025, using PDE data

[64] See: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
[65] See: https://purplebooksearch.fda.gov/.
[66] 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.

available on January 16, 2025, as well as Average Manufacturer Price (AMP)[67] data for the 12-month period beginning December 1, 2023 and ending November 30, 2024, using the AMP data reported to CMS by December 31, 2024, 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, 2025, in accordance with section 1192(a) of the Act.

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 an approved generic drug or licensed biosimilar is being marketed on a bona fide basis is a totality of the circumstances inquiry that 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 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 selected drug, as articulated further in sections 70 and 90.4 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 2027. If CMS determines that the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2027 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.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(A) of the 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 only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication (or indications)[68] is for such disease or condition. 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. A drug that has orphan designations for more than one rare

[67] "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.

[68] For purposes of applying the Orphan Drug Exclusion, CMS understands "approved indication," as that term is used in section 1192(e)(3)(A) of the Act, to refer to the FDA-approved indication that is described in information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s).

disease or condition will not qualify for the Orphan Drug Exclusion, even if the drug has not been approved for any indications for the additional 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 designations or withdrawn approvals as disqualifying a drug from the Orphan Drug Exclusion.

To qualify for the Orphan Drug Exclusion, all dosage forms and strengths of the qualifying single source drug described in section 30.1 of this final guidance must meet the criteria for exclusion. CMS will use the FDA Orphan Drug Product designation database[69] and information on FDA-approved indications from other publicly available databases and documents (such as FDALabel, FDA Online Label Repository, Drugs@FDA, and NLM Daily Med[70]) 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 a drug is designated for, or approved for indications for, one or more rare disease(s) or condition(s). In the event that a drug or biological product loses Orphan Drug Exclusion status, pursuant to sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act, CMS will use the date of the earliest approval of the drug or licensure of the biological product (as described above in section 30.1) to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act.

CMS continues to evaluate whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development.

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 less than $200 million, increased by the percentage increase in the consumer price index for all urban consumers (CPI-U)[71] for the period beginning on June 1, 2023 and ending on September 30, 2024,[72] in combined expenditures under Medicare Part B and Part D when identifying qualifying single source drugs ("the Low-Spend Medicare Drug Exclusion"). For initial price applicability year 2027, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify PDE data combined with Part B claims data for each potential qualifying single source drug for dates of service during the 12-month period beginning November 1, 2023 and ending October 31, 2024. 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

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

[70] 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/.

[71] 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/).

[72] Section 1192(e)(3)(B)(ii) of the Act specifies that, for initial price applicability year 2027, CMS increase the $200 million amount by "the annual percentage increase" in the CPI-U "for the period beginning on June 1, 2023, and ending on September 30, 2024." CMS interprets this language to mean that, for initial price applicability year 2027, the $200 million amount is increased by the percentage increase in the CPI-U from June 2023 to September 2024.

service described above that have been submitted no later than 30 days[73] after October 31, 2024, i.e., by November 30, 2024. CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug.[74] To allow a reasonable amount of time for providers and suppliers to submit Part B claims, CMS will use Part B claims data for the dates of service described above that have been submitted no later than 30 days after October 31, 2024, i.e., by November 30, 2024.

- For each potential qualifying single source drug as described in section 30.1 of this final guidance, CMS will use PDE data to calculate the Total Expenditures under Part D and Part B claims data to calculate the total allowed charges under Part B, inclusive of beneficiary cost sharing, for purposes of determining Total Expenditures under Part B.[75] Payment for drugs and biological products covered 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 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 Average Sales Price (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 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. Expenditures for a drug or biological product that are bundled or packaged into the payment for another service will be excluded from the calculation of total allowed charges under Part B.
- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2027 any drugs for which the sum of Total Expenditures under Part D and Part B is less than $200 million, increased by the percentage increase in the CPI-U for the period beginning on June 1, 2023, and ending on September 30, 2024.

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

[73] For purposes of this final guidance, CMS defines all days as calendar days unless otherwise specified in statute, guidance, or regulation.

[74] In response to comments on page 51 and as described in section 40.4.2.1 of this final guidance, CMS provides that, for operational reasons at this time for 2026 and 2027, 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, 60.2.1, 60.3.2, and 60.5 of this final guidance that, for initial price applicability year 2027, 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 rankings of negotiation-eligible drugs (section 30.2), the ceiling for the MFP (section 60.2.1), the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative(s) (section 60.3.2), and the application of the MFP across dosage forms and strengths (section 60.5).

[75] For the purposes of this final guidance, Total Expenditures under Part B are calculated as the sum of the total allowed amounts from Part B professional claims and the total paid amounts from Part B facility claims.

products,[76] and will refer to databases such as FDALabel and the FDA Online Label Repository[77] to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA, as appropriate.

30.2 Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2027

In accordance with sections 1192(a) and 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2027 is a qualifying single source drug that is among the 50 qualifying single source drugs with the highest Total Expenditures under Part D. CMS will identify the negotiation-eligible drugs for initial price applicability year 2027 as follows:

- CMS will identify all qualifying single source drugs for initial price applicability year 2027 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 PDE data for each 11-digit National Drug Code (NDC-11)[78] of a qualifying single source drug for dates of service during the 12-month period beginning November 1, 2023 and ending October 31, 2024. 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 have been accepted no later than 30 days after October 31, 2024, i.e., by November 30, 2024. CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug.
- 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 drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act; (2) remove drugs that are subject to the exception for small biotech drugs, 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.
- These 50 drugs will be considered negotiation-eligible drugs for initial price applicability year 2027.

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, 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 with its active moiety / active ingredient, until CMS has identified 50 negotiation-eligible drugs.

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

[76] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[77] FDA Label: https://nctr-crs.fda.gov/fdalabel/ui/search; FDA Online Label Repository: https://labels.fda.gov/.
[78] 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.

Exception" or "SBE"). The statute requires that CMS consider, for Part D drugs, Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures for the qualifying single source drug under Part D during 2021, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had the Coverage Gap Discount Program (CGDP) Agreement in effect for the qualifying single source drug during 2021 had a CGDP Agreement in effect during 2021.[79] To identify and exclude such small biotech drugs, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug: (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the qualifying single source drug had a CGDP Agreement in effect during 2021.

For the purposes of the SBE, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all 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 entity that had the CGDP Agreement in effect for the qualifying single source drug on December 31, 2021 (the "2021 Manufacturer"). Accordingly, for the purpose of the SBE, "controlled group" of the 2021 Manufacturer means all corporations or partnerships, sole proprietorships, and other entities that were treated as a single employer under subsection (a) or (b) of section 52 of the IRC and the Department of the Treasury regulations thereunder with the 2021 Manufacturer. However, CMS does not have information about which entities were treated as a single employer with the 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 ("Submitting Manufacturer") must submit information to CMS about the 2021 Manufacturer, its controlled group, and its products 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.

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), 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.[80] Because the earliest effective date for this limitation is January 1, 2025 for acquisitions prior to January 1,

[79] As stated in section 50.1.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated November 17, 2023, 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.

[80] See section 50.1 of the Manufacturer Discount Program Final Guidance; see also the November 17, 2023 CMS Health Plan Management System ("CMS HPMS") memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers" for more information.

2025, this requirement applies to requests for the SBE starting in initial price applicability year 2027. Therefore, for initial price applicability year 2027, in order for the Submitting Manufacturer to have its qualifying single source drug 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, 2025.81 For purposes of implementing the 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 1860D-14C(g)(4)(B)(ii) or a specified small manufacturer under 1860D-14C(g)(4)(C)(ii). 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 became the NDA / BLA holder.

CMS is releasing a revision of the currently approved Small Biotech Exception Information Collection Request (ICR), entitled "Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027" (CMS-10844, OMB 0938-1443) (hereinafter the "SBE and Biosimilar Delay ICR"), on October 2, 2024, for a 30-day public comment period that will close on November 1, 2024.[82]

The SBE and Biosimilar Delay ICR Forms address the collection of information for initial price applicability year 2027 only. A manufacturer seeking to have the SBE apply to its drug for initial price applicability year 2027 must submit a request for an SBE for initial price applicability year 2027 regardless of whether the manufacturer submitted a request for initial price applicability year 2026. For initial price applicability year 2027, sections 1191(a) and 1192(d) of the Act require CMS to evaluate whether a qualifying single source drug qualifies as a negotiation-eligible drug under 1192(d) based on Total Expenditures under Part D only, including with respect to the SBE. As a result, the initial price applicability year 2027 information collection to evaluate whether a qualifying single source drug meets the expenditure criteria is collecting information relevant to Total Expenditures only under Part D.[83]

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[81] In future years, CMS shall also consider whether the acquiring entity is a manufacturer that will not meet the definition of specified manufacturer at the beginning of the plan year immediately following the acquisition.

[82] To view the SBE and Biosimilar Delay ICR Forms available for a 30-day public comment period, and a summary of changes made to the proposed 30-day SBE ICR Form for initial price applicability year 2027 in comparison to the 60-day SBE ICR Form proposed for initial price applicability year 2027 (CMS-10844, OMB 0938-1443), see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016. The 30-day notice for public comment for initial price applicability year 2027 includes the SBE ICR and the Biosimilar Delay ICR Forms in the same Federal Register notice (see section 30.3.1 of this final guidance). CMS believes that combining these ICR Forms into one notice will streamline review of these documents for interested parties.

[83] 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

As specified in the SBE and Biosimilar Delay ICR Forms, CMS anticipates that the Submitting Manufacturer will submit a request for a Small Biotech Exception using the CMS Health Plan Management System ("CMS HPMS") by the date specified by CMS.[84] 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 and/or the Biosimilar Delay, as well as provide CMS with time to make a determination prior to the initial price applicability year 2027 selected drug publication date. CMS will provide the submission deadline once the SBE and Biosimilar Delay ICR for initial price applicability year 2027 is finalized. 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)).

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. 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 2027.
2. Provided the limitation does not apply, CMS will identify the 2021 Manufacturer of the qualifying single source drug on December 31, 2021 based on information submitted in the request for an SBE.
3. CMS will identify the complete set of NDC-11s for which the 2021 Manufacturer and any member of the 2021 Manufacturer's controlled group as of December 31, 2021 had a CGDP Agreement as of December 31, 2021.
4. Using the complete set of NDC-11s for which the 2021 Manufacturer or any member of the 2021 Manufacturer's 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.
5. Using the PDE data for: (1) the qualifying single source drug; (2) the complete set of covered Part D drugs for which the 2021 Manufacturer or any member of the 2021

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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).

[84] As specified in the SBE and Biosimilar Delay ICR Forms available for a 30-day public comment, CMS will provide the deadline for submissions upon approval of the SBE and Biosimilar Delay ICR from the Office of Management and Budget. CMS anticipates providing a 30-day submission period. 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 Health Plan Management System (HPMS)" PDF, available at: https://www.cms.gov/about-cms/information-systems/hpms/user-id-process. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

Manufacturer's controlled group had a CGDP Agreement as of December 31, 2021; and (3) all covered Part D drugs, 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 covered Part D drugs; 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 covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP Agreement in effect during 2021.

The Total Expenditures under Part D for all covered Part D drugs will be determined using PDE data for all covered Part D drugs. The Total Expenditures under Part D for the qualifying single source drug and the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP Agreement in effect during 2021 will only include PDE data for NDC-11s with labeler codes associated with the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group.

For initial price applicability year 2027, the term "negotiation-eligible drug" will exclude any covered Part D drugs that are qualifying single source drugs that meet these 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 2027 does not mean that this drug will continue to qualify for the SBE for initial price applicability year 2028. The Submitting Manufacturer must submit a request for the drug to be considered for the exception for initial price applicability year 2028.

CMS anticipates notifying the Submitting Manufacturer in February 2025 of its determination whether the Submitting Manufacturer's qualifying single source drug qualifies for the SBE for initial price applicability year 2027. This information will only be shared after the selected drug list for initial price applicability year 2027 has been published. CMS will publish the number of drugs that receive the SBE for initial price applicability year 2027 as part of publishing the selected drug list no later than February 1, 2025. For initial price applicability year 2026, CMS received SBE requests which resulted in CMS determining four qualifying single source drugs qualified for the SBE.[85] The determination that these drugs qualified for the SBE applied only to initial price applicability year 2026; the manufacturers of these drugs must submit new requests to be considered for the exception for initial price applicability year 2027.

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1192(b) of the Act.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2027

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 2027 as follows:

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[85] Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026 Fact Sheet, available at https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

1. CMS will rank the 50 negotiation-eligible drugs identified, as described in section 30.2 of this final guidance, by Total Expenditures under Part D in descending order: the negotiation-eligible drug with the highest Total Expenditures under Part D will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part D will be listed last.
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 2027.
    - In the event that two or more negotiation-eligible drugs have the same Total Expenditures under Part D to the dollar and such 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 Biologics 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 50 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 herein referred to as 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. 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 Biosimilar Delay request, as described in this section 30.3.1.

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. CMS did not grant any Initial Delay Requests for initial price applicability year 2026; therefore, Additional Delay Requests are not relevant for initial price applicability year 2027 and will be covered in future guidance or rulemaking, as applicable. CMS solicited comment regarding the types of documentation and information that may constitute "clear and convincing evidence [that] the manufacturer of [the] biosimilar biological product has made a significant amount of progress towards both such licensure and the marketing of such biosimilar biological product" under section 1192(f)(2)(B)(i)(II) of the Act to inform CMS' policy development for this issue.

CMS is releasing the SBE and Biosimilar Delay ICR on October 2, 2024 for a 30-day comment period that will close on November 1, 2024. As specified in the SBE and Biosimilar Delay 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.[86] CMS anticipates providing a 30-day submission window. Information regarding the submission of an Initial Delay Request is addressed in detail within the SBE and Biosimilar Delay ICR Forms. This section 30.3.1 and the following subsections of this section 30.3.1 include details on the policies for implementation of the Biosimilar Delay for initial price applicability year 2027. Information on other policies related to section 1192(f) of the Act will be included in future guidance or rulemaking, as applicable, including, but not limited to, the application and calculation of rebates described in section 1194(f)(4) of the Act.

Information submitted in an Initial 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)).

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:

- 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.
- 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 a high likelihood that the Biosimilar will be licensed and marketed by February 1, 2027, as described in section 30.3.1.2 of this final guidance. Similar to the process described in section 30.1 of this final guidance, for purposes of

[86] As specified in the Supporting Statement for the SBE and Biosimilar Delay ICR Forms, available for a 30-day public comment, CMS anticipates opening the CMS HPMS for submissions of an Initial Delay Request by Fall 2024; in the event that its completion is delayed, CMS will use the same submission process deployed for initial price applicability year 2026 (refer to the SBE and Biosimilar Delay 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 Health Plan Management System (HPMS)" PDF, available at: https://www.cms.gov/about-cms/information-systems/hpms/user-id-process. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

> 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.

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, 2027.

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 price applicability year 2027, 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 is as follows: per section 30.3.1.2 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, 2027, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than January 15, 2025. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 pm Pacific Time (PT) on January 15, 2025, 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, 2025, in accordance with section 1192(a) of the Act.

The list of selected drugs published for initial price applicability year 2027 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, 2025, 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 2027 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 2027 is published, but no later than February 28, 2025, 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 that 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 2027 absent the Initial Delay Request; or
- failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2027.

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 2027, 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 2027, absent successful Initial Delay Requests, as part of publishing the selected drug list no later than February 1, 2025.

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 2027, 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, 2025. CMS solicited comments from interested parties regarding this date in the draft guidance. CMS is specifying the notification date based on the comments received and operational considerations, including allowing for sufficient notice prior to the publication of the selected drug list for initial price applicability year 2028.

30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2027

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 2027 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 2027. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, 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 2027, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2011, and January 1, 2015.
    - 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 2027. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2027, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years prior to the start of the initial price applicability year on January 1, 2027.
3. 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.
    - 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 of 1986, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.
    - 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 2027, 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, 2025, as violating this requirement.

7. In accordance with section 1192(f)(1)(A) of the Act and as described in detail in section 30.3.1.2 of this final guidance, CMS must determine 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.

30.3.1.2 High Likelihood

In accordance with section 1192(f)(1)(A) of the Act, CMS will review Initial Delay Requests to determine whether 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. Accordingly, for Initial Delay Requests submitted with respect to initial price applicability year 2027, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2027, 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, 2027, based on the criteria described below, CMS will deny the Initial Delay Request.

In accordance with section 1192(f)(3) of the Act, Initial Delay Requests must demonstrate both of the following in order 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 the FDA.[87]
    - For Initial Delay Requests submitted with respect to initial price applicability year 2027, the Biosimilar's application for licensure must be approved or accepted for review by the FDA no later than January 15, 2025 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 2027.
    - Note that if the Biosimilar's application for licensure has not been accepted for review by January 15, 2025, including in the case where the Biosimilar Manufacturer submitted an application for licensure that has not been accepted for review by the FDA or for which a filing determination is pending, CMS will deny the Initial Delay Request for initial price applicability year 2027.
2. Clear and convincing evidence that the Biosimilar will be marketed before February 1, 2027 (the date that is two years after the statutorily-defined selected drug publication date for the initial price applicability year), 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.

[87] 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.

For Initial Delay Requests submitted for initial price applicability year 2027, to demonstrate clear and convincing evidence that the Biosimilar will be marketed before February 1, 2027, CMS requires 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 Manufacturer as part of its Initial Delay 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 Initial Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before February 1, 2027. 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 are 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 (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before February 1, 2027, without imposing improper constraints on the Biosimilar Manufacturer.[88]

Second, the Initial Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before February 1, 2027. 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, 2027; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. CMS chose these 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.

[88] As 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, 2025.

In determining whether an Initial Delay Request satisfies the high likelihood threshold, CMS may use all the information described in section 30.3.1 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 February 1, 2027:

- 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 the 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.

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 2027 no later than February 1, 2025. This list will include the 15 (or all, if such number is less than 15) drugs covered under Part D selected for negotiation for initial price applicability year 2027, including the active moiety / active ingredient for each selected drug and the NDC-9s and NDC-11s for the selected drug. The NDC-9s and NDC-11s for each selected drug will be identified by compiling all NDC-11s that had Part D PDE utilization in the 12-month period beginning November 1, 2023 and ending October 31, 2024, as well as any additional NDC-11s associated with the NDAs / BLAs of the selected drug as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (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 (e.g., NDC-11s of drugs excluded from Part D coverage under section 1860D-2(e)(2)(A) of the Act or NDC-11s that have utilization under Part B but no utilization under Part D).[89] CMS will post the selected drug list, including the NDC-9s and NDC-11s for each selected drug, on the CMS IRA website and update this information in accordance with section 40.2 of this final

[89] CMS acknowledges that, for some selected drugs, the NDC-9s and NDC-11s published pursuant to this section might not reflect all NDCs marketed pursuant to the approved NDA(s) / BLA(s). For example, if a selected drug includes one NDC-9 that has no current or future Part D PDE utilization (e.g., the NDC-9 is utilized only in Part B settings of care), that NDC-9 and associated NDC-11s would not be published as part of the NDC-9s and NDC-11s of the selected drug for initial price applicability year 2027.

guidance.[90] 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 an MFP with "the manufacturer" of the selected drug. 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 2027, 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 "Primary Manufacturer").

Likewise, for initial price applicability year 2027, 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 generics 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 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," herein 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, 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 guidance, which CMS has determined are necessary for purposes of administering and monitoring compliance with the Negotiation Program.

[90] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

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. The scope of Primary Manufacturer 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 that are providing a selected drug to an MFP-eligible individual, 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 requires that for initial price applicability year 2027, 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 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;
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities that dispense the selected drug to those individuals, 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 under the procedures to apply 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 MFP-eligible individuals, pharmacies, mail order services, and other dispensing entities, as described in section 40.5, section 90, and section 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 2027 is February 28, 2025. The Primary Manufacturer must use the CMS HPMS to identify the relevant authorized representative(s) and effectuate the Agreement.[91]

CMS recommends, but does not require, that within five days following publication by CMS, of the list of selected drugs for initial price applicability year 2027, which will occur no later than February 1, 2025, the Primary Manufacturer submit to CMS the name(s), title(s), and contact information for the representative(s) authorized to execute the Agreement. CMS recommends taking this 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. The authorized representatives should follow instructions made available on the CMS HPMS webpage to gain access to the CMS HPMS. To be eligible for electronic signature access in the CMS HPMS, 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 direct delegated authority to perform electronic signatures on behalf of one of the individuals previously noted. 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, 2025.

The negotiation period for initial price applicability year 2027 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, 2025. If an Agreement is fully executed before February 28, 2025, 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, 2025, then pursuant to 26 U.S.C. § 5000D(b)(1), a period will begin on March 1, 2025, during which the Primary Manufacturer could be exposed to potential excise tax liability. Instructions and a template of the Agreement are available on the CMS IRA website.[92]

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,[93] 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 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

[91] See: https://hpms.cms.gov/app/ng/home/.
[92] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.
[93] The CGDP, established under section 1860D-14A of the Act, remains in place through December 31, 2024. Because the CGDP will sunset at this time, 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 and remain in place until the program sunsets.

under the Medicaid Drug Rebate Program and the Manufacturer Discount Program.[94] If CMS determines the Primary Manufacturer's notice complies with these requirements, 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. CMS has determined (and hereby provides notice) that it will automatically grant such termination requests 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 has determined it would not be willing to enter into an Agreement for the Negotiation Program if one of its drugs is listed as a selected drug and has submitted a notice of its decision and its request for termination as described above, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request. 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; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

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[95] of each selected drug must submit to CMS the following information with respect to the selected drug: information on the non-Federal average manufacturer price ("non-FAMP") (defined in 38 U.S.C. § 8126(h)(5)), as described in section 50.1.1 and Appendix A of this final guidance, and any information that CMS requires to carry out negotiation, including but not limited 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, 2025 for initial price applicability year 2027.

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

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[94] 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.

[95] In sections 40.2-40.5, 40.7, 50, 60-60.6, 60.8, 90, 100-100.2, and 100.4 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.

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 and Appendix A of this final guidance, must reflect any NDCs included in the selected drug marketed by any Secondary Manufacturer(s), and 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 2027, 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 in the 12-month period beginning November 1, 2023 and ending October 31, 2024, 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 (e.g., NDC-11s of drugs excluded from Part D coverage under section 1860D-2(e)(2)(A) of the Act or NDC-11s that have utilization under Part B but no utilization under Part D). This list will include any NDC-11s of the selected drug marketed by the Primary Manufacturer and 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 marketed and controlled solely by a manufacturer that is not the Primary Manufacturer or a Secondary Manufacturer;
- whether any of the listed NDC-11s represent a sample 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 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 2027. The NDC-11s on this list will be included in ceiling calculations for initial price applicability year 2027 as described in section 60.2, to the extent data are 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 2027 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 for any Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug; if CMS believes these new NDC-11s are likely to have Part D utilization in the future, these NDC-11s will 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 Manufacturer, but that are newly marketed or controlled by a Primary Manufacturer or 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 of the final guidance 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)).[96]

CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information, 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 2027, CMS will treat information on non-FAMP as proprietary.

[96] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

For initial price applicability year 2027, 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. Specifically, 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 the data on prior Federal financial support and approved patent applications, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation of the MFP by March 1, 2026, for initial price applicability year 2027 (see section 60.6.1 of this final guidance). 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 and the public that are determined to be non-proprietary but will not include any protected health information (PHI) or personally identifiable information (PII). CMS will 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.

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 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 these exchanges.

40.2.3 Opportunity for Corrective Action Following Information Submission

Recognizing the substantial role that manufacturer-submitted information will play in the negotiation process and in administering and monitoring the Negotiation Program, CMS will provide 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 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 warranted, CMS may issue a Request for a Corrective Action Plan (CAP) 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 Primary Manufacturer's response to the Request for a CAP is additional 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 a timely response to the Request for a CAP may result in the Primary Manufacturer being subject to a CMP as authorized under section 1197(c) of the Act as described in section 100.2 of this final guidance. If CMS decides to assess a CMP, the process established in section 100.4 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, CMS and a Primary Manufacturer may renegotiate the MFP for a selected drug, beginning with 2028. CMS plans to release future guidance related to the renegotiation process.

40.4 Providing Access to the MFP in 2026 and 2027

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 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. 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 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 the revised guidance for initial price applicability year 2026 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).

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 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 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 this final guidance, CMS will update the MFP file as needed if NDC-9s or NDC-11s are added or removed for the selected drug.

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.[97] 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 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 Part D MFP-eligible individuals will have access to the MFP at the point-of-sale. While section 1193(a) of the Act requires the Primary Manufacturer to provide access to the MFP to MFP-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 provides 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. CMS requires that the Primary Manufacturer establish processes to ensure that entities dispensing drugs to MFP-eligible individuals—including pharmacies, mail order services, and other dispensing entities—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 for the selected drug (as discussed in more detail in section 40.4.1) 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 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. That is, 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 that verify the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturer (hereinafter referred to as the "14-day prompt MFP payment window").

Upon further consideration and review of comments from interested parties, CMS notes that it is clarifying from the draft guidance 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 draft guidance, CMS intends for the 14-day prompt MFP payment window to align with the timing requirement in the

[97] 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.

longstanding prompt pay rules in Part D for plan sponsors.[98] 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 pharmacies, mail order services, and other dispensing entities that dispense 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 a Secondary Manufacturer(s) and dispensed 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.

Based on CMS' continuous engagement with and extensive feedback from interested parties, for 2026 and 2027, CMS will engage an MTF Contractor[99] for the Negotiation Program 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 40.4.2 of this final guidance. CMS initiated the MTF data exchange acquisition process for the MTF Data Module (hereinafter the "MTF DM") concurrent with publication of the draft 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.

After conducting listening sessions regarding payment options outlined in draft guidance, reviewing comments on the draft guidance, and hearing that interested parties were very interested in payment facilitation in addition to data facilitation, CMS has also initiated the acquisition process for an MTF Payment Module (hereinafter the "MTF PM") to facilitate

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[98] 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.

[99] For the purposes of this guidance, CMS uses the term "MTF Contractor" or "MTF Contractors" to refer generally to the contractor(s) that CMS plans to engage to provide services in connection with the MTF, including the MTF DM and MTF PM.

passing through payments from Primary Manufacturers that elect to use the MTF PM that will complement the data-related activities of the MTF DM. While CMS is committed to helping facilitate exchange of data and passing through 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.

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, or the MFP refund, 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 intends to consider further the issue of determining actual acquisition cost and may address it in future guidance.

CMS stated in the revised guidance for initial price applicability year 2026 that it was exploring the option of allowing Primary Manufacturers to use a standardized refund amount, such as the WAC of the selected drug minus the MFP (WAC-MFP). 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,[100] 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. In development of the draft and final guidance for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027, CMS considered other options for a standardized pricing metric to calculate a standard default refund amount (SDRA) to operationalize refund payment processes, including National Average Drug Acquisition Cost (NADAC), Average Wholesale Price (AWP), and ASP.

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. WAC, as defined by

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

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. 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.

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.

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.

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 (e.g., 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 will 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. 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 will engage 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 future rulemaking, CMS intends to propose requiring Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM. 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 that uses the X12 835 standard adopted under Health Insurance Portability and Accountability Act (HIPAA) (ERAs), access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered Part D drugs, 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 will bear the cost of operationalizing the MTF DM. 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 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 transmitting the MFP refund for each claim for a selected drug; (3) collect 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 2026 and 2027. 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 moves through acquisition and information system development.

Figure 2: Diagram of MTF Data Flow*

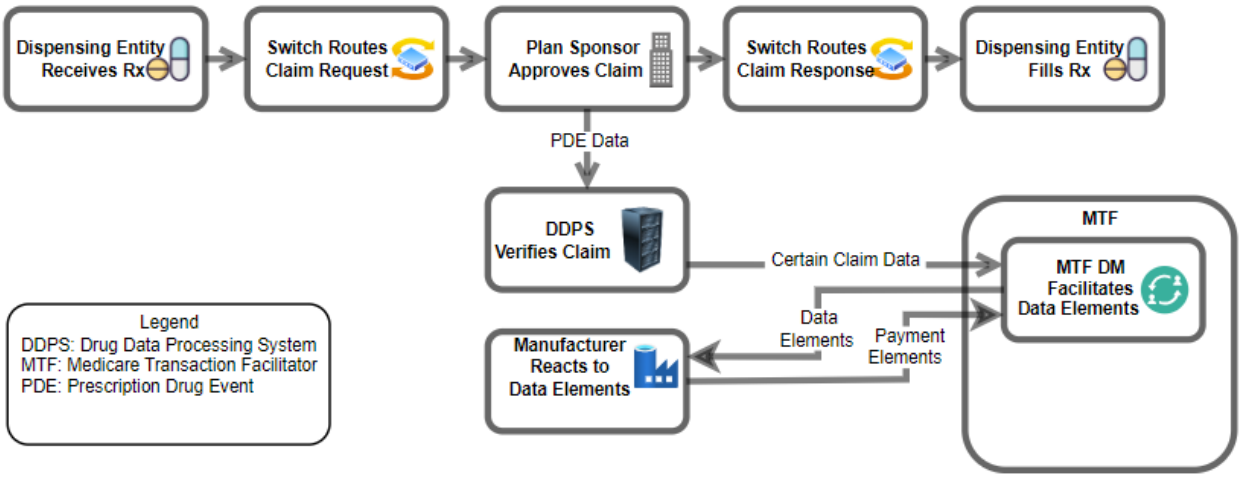


*Figure 2 has been updated from the version that appeared in the draft guidance.

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 will require all Primary Manufacturers to register with the MTF DM by a deadline to be specified by CMS and 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 data use, privacy, and security agreements with CMS and comply with data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF. 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 described in section 40.4.3 of this final guidance or the Primary Manufacturer may choose to establish its own method of payment facilitation).

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 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. However, 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 such 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, in which case no ERA or remittance will be produced). 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 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 original MTF ICN	MTF

MTF DM Data Elements List	Purpose	Data Source
Process Date	Identifies MTF processed date	MTF
Transaction Code	Indicates original claim, adjustment, reversal, etc.	MTF
Medicare Source of Coverage	Identifies coverage under Medicare Part B or Part D	MTF
Date of Service	Verifies MFP eligibility	PDE Record
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 Part D Claim	Provides list price on claim date of service	MTF
Maximum Fair Price (MFP) Per Unit on Date of Service of Part D 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

MTF DM Data Elements List	Purpose	Data Source
Service Provider Payment Method Preference	Indicates dispensing entity's specified preference for payment via electronic transfer of funds or paper check	MTF

* Denotes data elements that were not in the draft guidance

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 Part D Claim," and "MFP per unit on Date of Service of Part D Claim." Beginning January 1, 2025, the "Submission Clarification Code" value of "20" and the "Submission Type Code" value of "AA" will be added to the PDE record to indicate a 340B claim.[101] A dispensing entity may voluntarily apply these indicators to a Part D claim to indicate the claim is being billed for a 340B drug.[102] 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 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) or other identifier 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. The MTF will have additional data elements (i.e., "MTF internal claim number (ICN)," "Record ID," "MTF XRef ICN," "Process Date," "Transaction Code," 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.

Lastly, 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

[101] See: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.
[102] 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.

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. 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 CMS' Drug Data Processing System (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, the Part D plan sponsor verifies that the beneficiary listed on the claim paid by the Part D plan sponsor 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.[103]

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 the claim for transmittal to the applicable Primary Manufacturer.[104] Therefore, because MFP eligibility status has been twice validated 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. To identify appropriate claims, the MTF DM will send the Primary Manufacturer all claims for NDCs identified on the MFP file in the CMS HPMS that are validated by DDPS. CMS recognizes that certain DDPS edits may delay claims that could otherwise be earlier identified as a dispense to an MFP-eligible individual and intends to monitor the flow of claims and DDPS edits to ensure efficiency in the flow of claims for MFP-eligible individuals. 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

[103] Currently, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. CMS intends to propose in future rulemaking to shorten the current 30-day window for plans to submit PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities.

[104] 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.

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 CGDP, 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, 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 payment of an amount that provides access to the MFP when an MFP refund is appropriate and 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. 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 this final guidance). 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 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 requirement	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 claims-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 intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to enroll 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 making available remittances or ERAs, maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered Part D drugs, 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 electronic 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 will develop 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.[105] 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 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 were provided as a reimbursement mechanism. CMS intends to publish the Medicare Transaction Facilitator for Initial Price Applicability Year 2026 and 2027 ICR for a 60-day public comment period in Fall 2024. The ICR will include details on information that dispensing entities will be required to provide.

In response to the draft guidance, 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, CMS is concerned that this challenge will be most acute in the transition

[105] CMS will issue an information collection request in the future to solicit 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.

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 dependent on Medicare beneficiaries' access to selected drugs through dispensing entities, which in turn necessitates that dispensing entities—particularly those who 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 September 1, 2025 and September 1, 2026 deadlines for the submission of MFP effectuation plans for 2026 and 2027, respectively, 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 2026 and 2027. For example, CMS expects dispensing entities of the types that have raised material concerns about 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 to execute an agreement package during the MTF enrollment process, which, for example, may include an MTF agreement with CMS and a participation agreement with CMS' MTF Contractor. These agreements will include provisions such as data use, privacy, and security requirements for engaging with the MTF DM. These agreements also will include requirements for collecting, using, sharing, and safeguarding financial information. CMS is evaluating the data privacy and security implications of collecting, holding, and, if applicable, sharing interested parties' financial and securities information for purposes of data exchange and making an ERA or remittance available, and may incorporate

these considerations in the terms of MTF DM participation agreements. 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, NCPDP will provide instruction to Part D plan sponsors on including SDRAs on all Part D claims for selected drugs with a negotiated MFP in effect. The new message 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 will furnish additional direction to plan sponsors on implementing the SDRA on the claim response. This amount (SDRA) is only 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 (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 draft guidance, 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.

Interested parties made clear in their feedback that they generally support CMS establishing a process to facilitate manufacturer effectuation of MFP refund payments through the MTF, as described as "Option 2: MTF Pass Through of Primary Manufacturer Funds to Dispensing Entities" (Option 2) in the draft guidance. CMS will engage with the MTF Contractor to develop MTF functionality through the MTF PM as a mechanism to facilitate the transfer of MFP refund payments from participating Primary Manufacturers to dispensing entities, building on the approach described as Option 2 in the draft guidance. 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, CMS clarifies that 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.

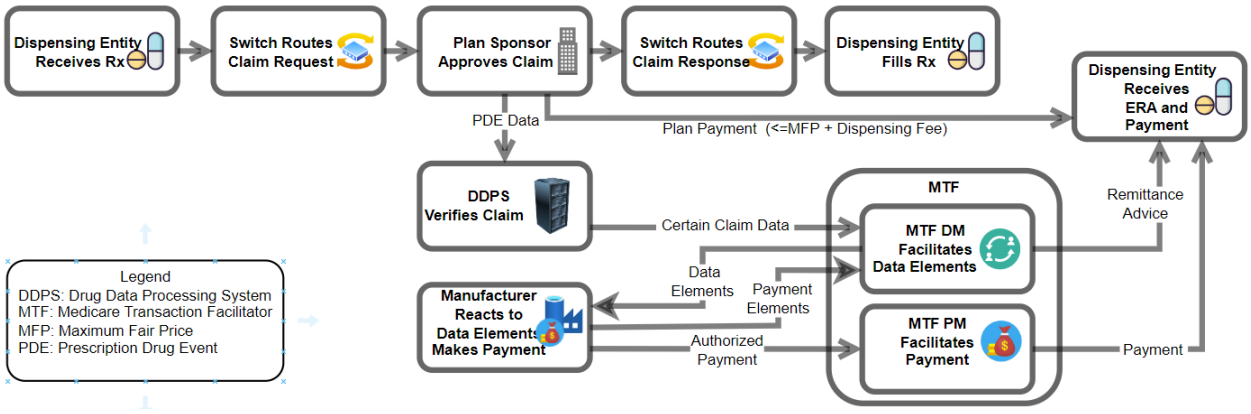
The provision of voluntary MTF payment facilitation services through the MTF PM does not supersede or alter the Primary Manufacturer's obligation under section 1193(a)(3)(A) of the Act to provide access to the MFP to dispensing entities for MFP-eligible individuals who are dispensed selected drugs. While 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 to not 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.

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. 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 will 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 described scenario, unclaimed funds will be returned to the Primary Manufacturer. As part of the MTF agreement for the MTF PM, CMS will provide additional information in the future to inform the handling of these situations. Any disputes related to unclaimed funds will be reconciled directly between the affected parties.

Primary Manufacturers that elect to use the MTF PM to pass through payments will be required to execute MTF agreements with the MTF PM outlining each party's rights, responsibilities, and potential liabilities associated with the transfer and receipt of funds through the MTF PM. CMS intends to publish these MTF agreements prior to the start of enrollment in the MTF DM and MTF PM. Issues that may arise from the operational work of facilitating MFP refund payments between the parties will be resolved between the MTF Contractor and interested parties subject to the terms of their MTF agreement. 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,[106] 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 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 to the MTF Contractor and agree to the MTF PM terms and conditions as

[106] 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.

outlined in the MTF 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 described in section 40.4.3.1, 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 to 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 addresses what is required of a Primary Manufacturer that elects to pass payments through the MTF PM and section 40.4.4 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. Each section (40.4.3 and 40.4.4) discusses the Primary Manufacturer's reporting requirements under each scenario.

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 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 will make available to the dispensing entity for Primary Manufacturers that pass payments through the MTF PM (unless the Primary Manufacturer indicates that the dispensed drug was prospectively purchased at MFP or the MFP is effectuated between parties outside of the MTF PM, in which case the MTF PM 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 was 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. Claim-level payment elements will include method for determining the MFP refund amount, the NPI of the entity receiving the MFP refund, 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. 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.

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 on MTF PM payment processing will be available as CMS continues to evolve technical specifications. CMS will prioritize expeditious pass through of payment to the dispensing entity as it builds the MTF PM and engages an MTF 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 this final guidance).

Table 4: Example Manufacturer Claim-Level Payment Elements List for Primary Manufacturers Passing Payment through the MTF PM[107]

[107] These elements are representative examples only, and CMS will provide the exact claim-level payment elements in forthcoming technical instructions as operations develop.

Payment Elements	Purpose
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5).
NPI of the Entity Receiving the MFP Refund	Documents the recipient of MFP refund.
Quantity of Selected Drug	Documents the number of units of selected drug included in MFP refund paid.
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.
MFP Refund Adjustment (Yes or No)	Indicates if the MFP refund payment was adjusted to a new MFP refund payment amount.

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.[108] 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 for Primary Manufacturers to establish efficient processes to provide such information to the MTF. CMS will 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 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[109]

[108] 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.

[109] CMS will maintain the exact codes to be used in future 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

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.
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.

through the MTF PM and will 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.

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.

By transmitting the claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, the Primary Manufacturer will authorize the electronic funds transfer of payment equal to the total refunds to be paid to 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, 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 that 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.

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 paper check, the MTF PM will issue a paper check using Primary Manufacturer's funds and on the behalf of the Primary Manufacturer, as described in 90.2.1 of this final guidance. 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. 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. 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.

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. 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 when the MTF PM is not used to make payment; maintaining generally accepted accounting principles (GAAP) compliant and auditable accounting of payments, credits and debits; maintaining appropriate documentation to support MFP refund amount; and issuing an ERA for electronic payments or remittance for payments issued by check.

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 payment is 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 issuance of an MFP refund payment, 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 each Primary Manufacturer that participates 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 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 MFP refund payment through the MTF PM or outside of the MTF PM through an alternative payment method, the MTF DM will transmit updated claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 2) of the original claim. For adjustments when a Primary Manufacturer participating in the MTF PM has already transmitted an MFP refund through the MTF PM, the Primary Manufacturer will identify and authorize the correct payment amount based on the reported claim adjustment in its response in the claim-level payment elements. CMS has included additional claim-level data elements (i.e., "MTF ICN," "Record ID," "MTF XRef ICN," "Process Date," "Transaction Code," 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 the 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. If the claim adjustment occurs within the 14-day prompt MFP payment window and the Primary Manufacturer has not already transmitted the MFP refund, the Primary Manufacturer may transmit the MFP refund based on the adjusted claim amount. The MTF PM may require additional authorization for fund transfer 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 MFP refund, the Primary Manufacturer will see the claim removed in its feed of claim-level data elements. For claims designated as a full reversal after the MFP refund has been transmitted, the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid MFP refund payment. 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.

As part of MFP effectuation, the Primary Manufacturer participating in the MTF PM will authorize the MTF PM, through transmittance 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 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 provided MFP refund payment, the MTF PM will credit the Primary Manufacturer and the MTF PM will indicate to the MTF DM that, for impacted claims, an accrued credit was applied. The MTF DM will use this information to inform the ERA or remittance, as applicable, 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 Manufacturer access to the disposition of each data element claim line to which they responded with claim-level payment elements and the status of MFP refunds will be available to Primary Manufacturers 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.

40.4.3.3 Pass Through Payment to Dispensing Entity When Primary Manufacturer Participates in the MTF PM

Under Option 2 in the draft guidance, it was contemplated that the MTF PM's payment facilitation functionality would be available only if both the Primary Manufacturer and the dispensing entity opt into the MTF PM. Upon review of comments from interested parties and further consideration of the nature of the MTF PM, CMS recognizes that the original concept of the MTF PM as a two-party platform requiring the dispensing entity's "participation" was inconsistent with the MTF PM's intended ministerial role as a mechanism through which Primary Manufacturers could transmit MFP refund payments to be passed through to dispensing entities. 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 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. If the Primary Manufacturer participates in the MTF PM and transmits MFP refund payments to 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 to 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 will issue detailed 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 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.

40.4.4 MFP Refund Payments When Primary Manufacturer Makes Payment Outside of the MTF PM

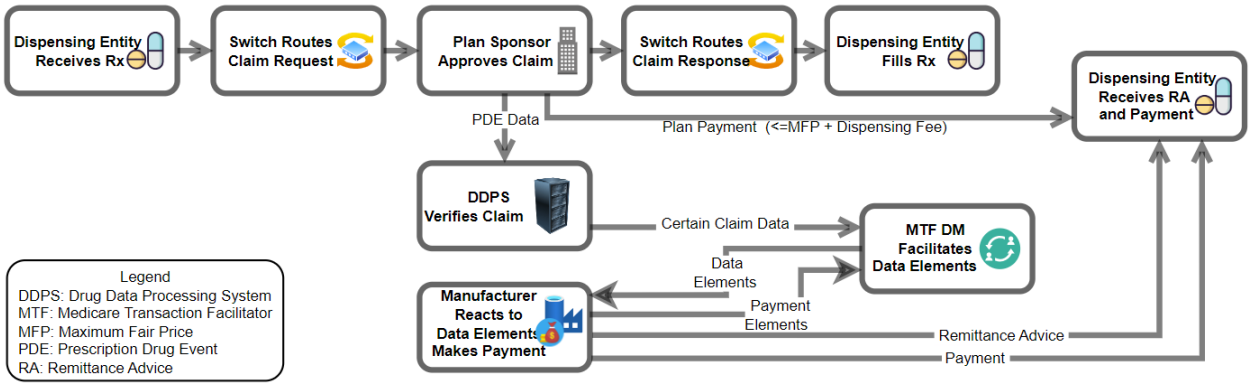
As discussed in section 40.4.3 of this final guidance, the Primary Manufacturer may choose not to pass payment through the MTF PM for facilitation of MFP refund payments. If the Primary Manufacturer chooses not to pass payment through the MTF PM, then the Primary Manufacturer is responsible for paying 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.

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 reports with claim-level payment elements to the MTF DM that detail MFP refund payments made directly to dispensing entities, which CMS will 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 includes 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 was 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.

Table 6: Example Manufacturer Claim-Level Payment Elements List when Primary Manufacturers Make Payment Outside of the MTF PM[110]

Payment Elements	Purpose
MFP Refund Transmission Date and Time	Indicates when the MFP refund was transmitted by the Primary Manufacturer.[111]

[110] These elements are representative of examples and CMS will provide the exact payment elements in forthcoming technical instructions as operations develop.
[111] 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

Payment Elements	Purpose
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5 in section 40.4.3.1 of this final guidance).
NPI of the Entity Receiving the MFP Refund or Prospective Sale	Documents the recipient of the MFP refund or prospective sale.
Quantity of Selected Drug	Documents the number of units of selected drug included in MFP refund paid.
Amount of Payment Transmitted as the MFP Refund	Documents the amount of MFP refund transmitted. Payment element should be populated with the final MFP refund amount if payment was an adjustment to a previous claim.
MFP Refund Adjustment (Yes or No)	Indicates if the MFP refund payment was adjusted to a new MFP refund payment amount.

Claim-level payment elements in common with required elements for payments made through the MTF PM include the "Method for Determining MFP Refund Amount," "NPI of the Entity Receiving the MFP Refund or Prospective Sale," "Quantity of Selected Drug," and "Amount of Payment Transmitted as the MFP Refund." "MFP Refund Transmission Date and Time" is an additional claim-level payment element that is 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.

An additional claim-level payment element that is required for MFP refund payments made outside of the MTF PM is "MFP Refund Adjustment." 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 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

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electronic payment was transmitted to the dispensing entity. For MFP refunds paid via paper check, the Primary Manufacturer report the date on which the paper check was mailed to the dispensing entity.

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 this final guidance). While the claim-level payment elements will serve as the record of a Primary Manufacturer's response to the claim-level data elements 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.[112] Examples of these justification codes, listed in 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 for Primary Manufacturers to establish efficient processes to provide such reports to the MTF. CMS will work with interested parties to add justification codes, if necessary, to 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.

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[112] 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.

The MTF DM will maintain a record of the execution of MFP refund payment, 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.

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 will take the steps outlined in section 90.2.2 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
CMS has received many requests to provide clarification on how MFP refunds will be reconciled when payment outside of the MTF PM occurs 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 engaged with the Primary Manufacturer's approach.

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. 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 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 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.[113] 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

[113] 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(a)(1) of the PHS Act regarding proper identification of 340B-eligible patients and covered outpatient drugs dispensed to such patients.

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 ingredient cost component of all Part D prescriptions filled 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.

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, 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 discount 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 an NPI alone (whether a prescriber NPI or a hospital/provider NPI) 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.

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.[114]

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 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 exploring 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.

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, 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,[115] the MTF would pass along the 340B indication data as applicable to the Primary Manufacturer when the MTF shares the 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

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[114] 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.

[115] 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 will be 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.

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 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 (HRSA) requirements for manufacturers to make the 340B ceiling price available 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 will establish 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 anticipates engaging 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 intends to 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. Based on the statutory deadlines for initial price applicability year 2027, which provide about one month less between the date of the Primary Manufacturer's submission of data and the date by which CMS must share initial offers compared to initial price applicability year 2026 (for initial price applicability year 2026, four months, October 2, 2023 through February 1, 2024, were given under the statute for this process; for initial price applicability year 2027, three months, March 1, 2025 through June 1, 2025, are given for this process), and the initial price applicability year 2026 experience of the average time used by Primary Manufacturers to submit any suggestions of error and by CMS to review and respond to any received suggestions of error, CMS believes it is necessary and feasible to shorten the period for each stage of the suggestion of error process (i.e., time from submission of data to provision of CMS' calculations described earlier in this paragraph, time from receipt of files to submission of a suggestion of error, and time from receipt of suggestion of error to provision of a response) for initial price applicability year 2027 compared to initial price applicability year 2026. 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.

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

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 CGDP 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 on sales of the selected drug during defined periods that are dispensed, furnished, or administered to individuals under the terms of Medicare. 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 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[116], 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

[116] The CGDP, established under section 1860D-14A of the Act, remains in place through December 31, 2024. Because the CGDP will sunset at this time, 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 and remain in place until the program sunsets.

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).[117] 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 beginning with 2028, for which guidance will be forthcoming for future years of the Negotiation Program.

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 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 termination notice 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 or section 1860D-14C and thus facilitate an expedited Termination Date.

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 termination notice that complies with the requirements in this section 40.6, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request for its applicable agreements under the Manufacturer Discount Program, as applicable. 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; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

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[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.

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 manufacturer or CMS must be sent in writing via email to CMS- and 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 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, academic experts, clinicians, caregivers, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS will be best positioned to identify all available, relevant evidence for the factors described at section 1194(e)(2) of the Act.

CMS published the Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS-10849, OMB 0938-1452) (hereinafter the "Negotiation Data Elements and Drug Price Negotiation Process ICR")[118] in the Federal Register for a 60-day public comment period on July 2, 2024 and intends to publish a revised version of the ICR for a 30-day comment period during Fall 2024. The Negotiation Data Elements and Drug Price Negotiation Process ICR for initial price applicability year 2027 will describe how CMS will 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 year 2026.[119]

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) and 1194(e)(1) of the Act are specified in Appendix A of this final guidance.

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[118] CMS has included the Negotiation Data Elements ICR for initial price applicability year 2027 in the same Federal Register 60-day notice as the Drug Price Negotiation Process ICR (CMS-10849, OMB 0938-1452) (see section 60.4.3 of this final guidance) for purposes of initial price applicability year 2027. CMS believes that combining these ICRs in one notice will streamline the review of these documents for interested parties.

[119] The Negotiation Data Elements ICR for initial price applicability year 2026 was approved as CMS-10847, OMB 0938-1449.

In accordance with sections 1194(b)(2)(A) and 1193(a)(4)(B) 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 2027 must be submitted to CMS by March 1, 2025. CMS' intention to require public submission on the same date as manufacturer submission (i.e., March 1, 2025) 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.

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.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by March 1, 2025:

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. 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.

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 Negotiation Data Elements 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.

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 be collecting these data through the Negotiation Data Elements and Drug Price Negotiation Process ICR described above. Specifically, under section 1194(c)(1)(C)(ii) of the Act, for initial price applicability year 2027, 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 2024 (i.e., the calendar year prior to the statutorily defined selected drug publication date, February 1, 2025). 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 will 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 2024, the non-FAMP reported by the 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) 2023 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 Negotiation Data Elements and Drug Price Negotiation Process 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, herein referred to as "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, academic experts, 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.[120] 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 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 requires respondents submitting information 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. CMS also requests that respondents submitting information under section 1194(e)(2) of the Act 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.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties, may submit information on selected drugs and their therapeutic alternatives (specifically pharmaceutical

[120] Some uses of QALY 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.

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 revised the Negotiation Data Elements and Drug Price Negotiation Process ICR to, for example, CMS grouped questions related to the topics listed above within the following categories: manufacturer input, patient or caregiver experience, clinical experience, and health research (e.g., economic and health equity data). CMS believes this format would improve the data collection process with information more closely aligned to a respondent's areas of expertise, although any interested party would be invited to respond to all questions regardless of area of expertise or question grouping. CMS also revised questions within these categories; for example, pertaining to patients' conditions. In addition, CMS requested a description about what it is like to live with a medical condition treated by the selected drug or its therapeutic alternative(s) and the factors a patient cares about most when assessing the value of a drug. Finally, CMS also requested section 1194(e)(2) evidence specific to the FDA-approved indications[121] and off-label uses for a selected drug and its therapeutic alternative(s).

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 will 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 on individuals with disabilities, patients with end-stage renal disease (ESRD), and Medicare-

[121] For purposes of the Negotiation Data Elements and Drug Price Negotiation Process ICR, Appendix A of this final guidance defines "indication" as: 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 nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. 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, if appropriate, may also choose not to report on certain FDA-approved indications or off-label uses.

aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS will 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 2027 must be submitted to CMS by March 1, 2025.

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.

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.

60.1 Establishment of a Single MFP for Negotiation 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, 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.

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 will 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), 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) back into per unit (e.g., tablet) prices at the dosage form and strength level and per package (e.g., bottle) for the purposes of publishing per-unit and per-package MFPs for the different dosage forms and strengths of the selected drug at the NDC-9 and NDC-11 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 or NDCs, including those added during the negotiation period or after any agreement upon MFP is reached, and NDCs with insufficient PDE or WAC data in calendar year 2024 to apply the MFP across that dosage form and strength during the negotiation period. 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 and package 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 and per package 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 a selected drug with respect to initial price applicability year 2027, 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 2027, 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, an amount equal to the sum of the plan-specific enrollment weighted amounts; or
- As described in section 60.2.3 of this final guidance, an amount equal to the applicable percent, with respect 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 2024;[122] 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, 2025, which for initial price applicability year 2027 is 2024.

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan-

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

specific enrollment weighted amounts and for 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 whether the sum of the plan-specific enrollment weighted amounts or the applicable percent of the average non-FAMP 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 calculate a single ceiling per 30-day equivalent supply (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology) 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. Sections 60.2.2 and 60.2.3 of this final guidance describe the process for calculating the sum of the plan-specific enrollment weighted amounts and for calculating the applicable percent of the average non-FAMP, respectively, and section 60.2.4 describes the selection of the ceiling for the single MFP.

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. Sample package NDC-11s will be excluded from the ceiling calculation.

- Sum of the plan-specific enrollment weighted amounts for the most recent year for which data is available (calendar year 2023 for initial price applicability year 2027): (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 2023; and (4) CMS observes any associated Direct and Indirect Remuneration (DIR) amounts for the NDC-11 for calendar year 2023.
- 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 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 2024: (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 2024; and (4) CMS observes any PDE days' supply and PDE quantity dispensed in calendar year 2024.

CMS will use the above methodology for initial price applicability year 2027 to account for the possible increased variation in NDC-11s of the selected drug over time arising from the additional consideration of the applicable percent of the average non-FAMP for calendar year 2024 as a possible ceiling. For initial price applicability year 2027, the set of NDCs used to calculate the sum of the plan-specific enrollment weighted amounts and the annual average non-FAMP for calendar years 2021 and 2024 may differ because CMS is concerned that using only the same set of NDCs would restrict the entire set of NDC-11s used in the calculations too narrowly, given the difference in the years of data used in the calculations of each amount and the degree to which NDC-11s change over time. CMS believes that, despite the potential differences in the set of NDC-11s for which data is used in each calculation, the above methodology will still allow for an accurate comparison of the sum of the plan-specific enrollment weighted amounts and the average non-FAMP amounts for the applicable calendar years for purposes of determining the ceiling and is consistent with section 1194(c) of the Act.

PDE data will be included in the ceiling calculation for the included NDC-11s of the selected drug when the PDE record meets the following requirements: (1) the PDE record is associated with a prescription filled between January 1 and December 31 of the calendar year of interest for the calculation;[123] (2) total gross covered prescription drug costs on the PDE record is greater than $0; (3) the PDE record is considered final action;[124] (4) the drug coverage status code indicates the PDE record is for a covered Part D drug; and (5) and the compound code indicates the PDE record is not for a compounded drug. An additional sixth requirement specific to the sum of the plan-specific enrollment weighted amount calculation for calendar year 2023 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 2023 DIR data (discussed further in section 60.2.2 of this final guidance).[125]

60.2.2 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 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 2023, 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 for initial price applicability year 2027.

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[123] The year used for average non-FAMP for calendar year (CY) 2021 is CY 2021, CY 2023 is used for sum of the plan-specific enrollment weighted amounts, and CY 2024 is used for average non-FAMP for CY 2024 as stated in the bulleted criteria above in this section.

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

[125] 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.

CMS will include all Part D plans[126] found in the PDE data that meet the criteria for inclusion detailed in section 60.2.1 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 2023.[127]

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 2023 using the criteria described in section 60.2.1 of this final guidance.
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 rebate at point-of-sale amounts (ERPOSA), and units dispensed.
3. For each Part D plan and each NDC-9, CMS will sum the total DIR amounts found in the 2023 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 2023 and the total number of individuals enrolled in each Part D plan in that same month, for each NDC-9 of the selected drug.[128] 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.

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[126] CMS will identify Part D plans based on the combination of the Part D contract identifier and the plan benefit package identifier.

[127] 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.

[128] 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.

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 2023 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 2023 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 2023 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.

60.2.3 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 to determine the ceiling for each selected drug for initial price applicability year 2027, 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,[129] 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 2024;[130] or
2. The calculated amount equal to the applicable percent of the average non-FAMP price for the selected drug for calendar year 2024.

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.

[129] If there is not a non-FAMP (or an average non-FAMP can't be calculated) for such drug for calendar year 2021, CMS will 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.

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

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 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 2024. The methodology will use the manufacturer-reported non-FAMP for 2024 and calendar year 2024 PDE quantity dispensed and days' supply data in the calculation for NDC-11s that meet the criteria to be included in the 2024 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 2027, 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 2024.

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 (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 2024 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 (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology).

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 2024.

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 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 two amounts (average non-FAMP and sum of the plan-specific enrollment weighted amounts) represent the same quantity of the selected drug.[131]

[131] 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.

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 quantity dispensed for that NDC-11 by the total quantity dispensed for all applicable NDC-11s of the same NDC-9 (both respectively determined using the applicable 2021 or 2024 PDE data identified in section 60.2.1 of this final guidance) and multiply this quotient by the average non-FAMP per unit for the calendar year calculated in step 4.
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 2024 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 2024.
    - Note: For initial price applicability year 2027, 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 2024.
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 2024 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 2027. 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 2027

Monopoly Type	Definition	Applicable Percent	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[132]	For initial price applicability year 2027, 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, 2011, and before February 1, 2018. The first 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, 2011, and before February 1, 2014 for drugs, or before February 1, 2014 for vaccines.

[132] 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 2027, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

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 first 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, 2011.

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 as calculated in step 8 by the quotient of the total quantity dispensed 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) calculated from 2021 or 2024 PDE data (as applicable) 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 from 2021 or 2024 PDE data (as applicable), 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 2024 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 step 10 of section 60.2.2 of this final guidance (sum of the plan-specific enrollment weighted amounts) 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 purposes of determining an initial offer, CMS will: (1) identify therapeutic alternative(s), if any, for the selected drug, as described in section 60.3.1 of this final guidance; (2) use the lower of Part D total gross covered drug cost (TGCDC) net of DIR and CGDP payments (hereinafter the "Net Part D Plan Payment and Beneficiary Liability"[133]) for the therapeutic alternative(s), and/or the ASP for the therapeutic alternative(s) that is covered under Part B, or the MFP for initial price applicability year 2026 selected drugs that are therapeutic alternatives to determine a starting point for developing an initial offer as described in section 60.3.2 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 the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need, the selected drug's impact on specific populations, and the extent to which the selected drug represents a therapeutic advance as compared to 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

[133] Once CGDP is phased out and the Medicare Part D Manufacturer Discount Program takes effect, 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 available.

For initial price applicability year 2027, for the purpose of identifying indications[134] for the selected drug, CMS will identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, 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 nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia.[135]

For each indication of the selected drug, CMS will identify a pharmaceutical therapeutic alternative(s). CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, for initial price applicability year 2027, CMS will only consider therapeutic alternatives that are drugs or biological products covered under Part D or Part B. 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 will use data submitted by the Primary Manufacturer and the public, FDA-approved indications, drug classification systems commonly used in the public and commercial sector for formulary development, CMS-recognized Part D compendia, widely accepted clinical guidelines, the CMS-led literature review, drug or drug class reviews, and peer-reviewed studies. In addition to brand name drugs and biological products, CMS will consider generic drugs and biosimilars when identifying a potential therapeutic alternative(s) to a selected drug. CMS may consider off-label use for therapeutic alternatives when identifying indications if such use is included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia.

CMS will begin by identifying 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 based on CMS' review of the sources noted above. 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 nationally recognized, evidence-based 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 approved therapies for the same indication. CMS may also consult with clinicians, patients or patient organizations, and/or academic experts, to ensure that appropriate therapeutic alternatives are identified. CMS may

[134] For purposes of this section of the final guidance and the Negotiation Data Elements and Drug Price Negotiation Process 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 will use "indication" for purposes of determining the initial offer as discussed in this final guidance.

[135] CMS-recognized Part D compendia are described in Chapter 6, § 10.6 of the Prescription Drug Benefit Manual.

also consider clinical evidence available through a literature search 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(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[136] (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 will identify 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 will also consider the CGDP payments 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 is itself a selected drug from initial price applicability year 2026. Reducing the TGCDC by both DIR and CGDP payments is appropriate because a drug with an MFP will be exempt from CGDP's successor program, the Manufacturer Discount Program, so removing CGDP payments (or Manufacturer Discount Program payments, as applicable) from TGCDC will permit an appropriate accounting of the price paid by the plan and beneficiary. Therefore, for selected drugs in initial price applicability year 2027, 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 either: (1) the Net Part D Plan Payment and Beneficiary Liability, which reflects TGCDC net of DIR and CGDP payments, or (2) the MFP for initial price applicability year 2026 selected drugs, if applicable. When determining the Net Part D Plan Payment and Beneficiary Liability of a

[136] 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.

therapeutic alternative, CMS will exclude PDE records for which a compound code indicates the PDE record is for a compounded drug.

In taking this approach, CMS acknowledges that the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit, however, using Net Part D Plan Payment and Beneficiary Liability, ASP, or MFP of therapeutic alternatives 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 for calculating a 30-day equivalent supply as appropriate for the therapeutic alternative(s). For example, because Part B claims data do not contain a "days' supply" field similar to PDE data, CMS may use an alternative methodology to calculate the price per 30-day equivalent supply for the therapeutic alternative(s) covered under Part B.

If there is one therapeutic alternative for the selected drug, CMS will use the lower of Net Part D Plan Payment and Beneficiary Liability or MFP for initial price applicability year 2026 selected drugs (regardless of whether the agreed-upon MFP for such selected drug has become effective), and/or ASP, as applicable, of the therapeutic alternative (if such price is lower than the ceiling) as the starting point to develop CMS' initial offer for the MFP for initial price applicability year 2027. If there are multiple therapeutic alternatives, CMS will consider the range of Net Part D Plan Payment and Beneficiary Liability, MFP(s) for initial price applicability year 2026 selected drugs, and/or ASPs, including the prices of generic and biosimilar therapeutic alternatives, as well as the utilization of each therapeutic alternative relative to the selected drug, to determine the starting point within that range. As part of its consideration of the utilization of therapeutic alternatives, CMS may consider the utilization of therapeutic alternative(s) across multiple indications or other patterns of use for the therapeutic alternative(s) 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 Agency"[137] price ("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.

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[137] 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. See section 8126 of title 38 of the U.S. Code.

60.3.3 Adjusting the Starting Point Based on Section 1194(e)(2) Factors[138]
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 clinical evidence, including data received from the public and manufacturers as described in section 50.2 of this final guidance, and data 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, academic experts, 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, 2025, 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 flexibility for CMS to consider multiple perspectives on the section 1194(e)(2) factors for the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to use of the selected drug, safety, and patient experience.

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 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. CMS will use a qualitative approach to preserve flexibility in negotiation, including the ability to consider nuanced differences between different 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 Selected Drugs with Therapeutic Alternative(s)
To consider comparative effectiveness between a selected drug and its therapeutic alternative(s), CMS will identify outcomes to evaluate for each indication of the selected drug. CMS will

[138] The change to this subsection title and several uses of "clinical benefit" in this subsection to refer to "section 1194(e)(2) factors," or similar phrasing, as compared to phrasing used in the revised guidance for initial price applicability year 2026, is intended to more clearly reflect CMS' policy and practice of considering section 1194(e)(2) factors holistically and qualitatively when adjusting the starting point to determine the initial offer.

consider the identified outcomes, including patient-centered outcomes,[139] and patient experience data, when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s). 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 such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients and patient-reported outcomes may also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug, including patient-centered outcomes when available. 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 Negotiation Data Elements and Drug Price Negotiation Process ICR described in section 50 of this final guidance, as well as in the patient-focused events described in section 60.4.1.

In all cases, CMS will consider applicable evidence and other input collectively, within the context of the course of care for the condition(s) or disease(s) that the selected drug is indicated to treat, and in accordance with section 50 of this final guidance. As noted previously, this approach provides flexibility to consider multiple perspectives on the section 1194(e)(2) factors for the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

CMS will also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations as required by section 1194(e)(2)(C) of the Act. In doing so, CMS will evaluate health outcomes for specific populations, including through an access and equity lens. To do so, CMS will seek to identify studies focused on the impact of the selected drug and its therapeutic alternative(s) on individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries. Specific populations may include underserved and underrepresented populations. Further, CMS will consider the extent to which the selected drug and its therapeutic alternatives address an unmet medical need. 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. 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

[139] 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.)

nonbinding recommendations in the FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics,"[140] 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.

CMS will determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by examining improvements in outcomes 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 such therapeutic alternative(s). CMS may consider the extent to which a selected drug represents a therapeutic advance by examining the extent to which the selected drug provides a substantial improvement in outcomes compared to the selected drug's therapeutic alternative(s) for an indication(s). CMS understands that a selected drug can be first in class,[141] 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 at the time the section 1194(e)(2) data is submitted. In accordance with section 1194(e)(2)(A) of the Act, CMS will review the analyses detailed above for each 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).

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) as well as the patient population(s) taking the selected drug. For each selected drug, the applicable starting point will first 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 (and then subsequently it will be adjusted by the manufacturer-submitted data described in section 60.3.4). 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).

60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives

Similar to a selected drug with at least one therapeutic alternative, the starting point for a selected drug without a therapeutic alternative will be adjusted based on the totality of relevant information and evidence as detailed above, such as outcomes and impact on specific populations, submitted through the Negotiation Data Elements and Drug Price Negotiation Process ICR and gathered through CMS' analysis of the section 1194(e)(2) factors for the selected drug.

CMS will consider the extent to which the selected drug addresses an unmet medical need separately for each indication. CMS will define unmet medical need as a circumstance in which

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[140] 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.

[141] 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.

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 may consider the extent to which a selected drug represents a therapeutic advance by examining the extent to which the selected drug provides a substantial improvement in outcomes for an indication(s).

60.3.3.3 Preliminary Price

After the starting point has been adjusted, as appropriate, based on section 1194(e)(2) data submitted by manufacturers and the public through the Negotiation Data Elements and Drug Price Negotiation Process 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 Manufacturer-Specific Data

Under section 1194(e)(1) of the Act, CMS must also consider manufacturer-specific data reported by the Primary Manufacturer, as described in section 50.1 of this final guidance. The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or downward, as needed to account for these manufacturer-specific data elements. These data elements 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 elements 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. To do this, CMS may consider each factor in isolation or in combination with other factors. 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 element (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. total lifetime 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 Negotiation Data Elements and Drug Price Negotiation Process ICR and in Appendix A of this final guidance to adjust the preliminary price.

In considering element (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 element (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 element (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 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 element (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.

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 2027, February 28, 2025. 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.

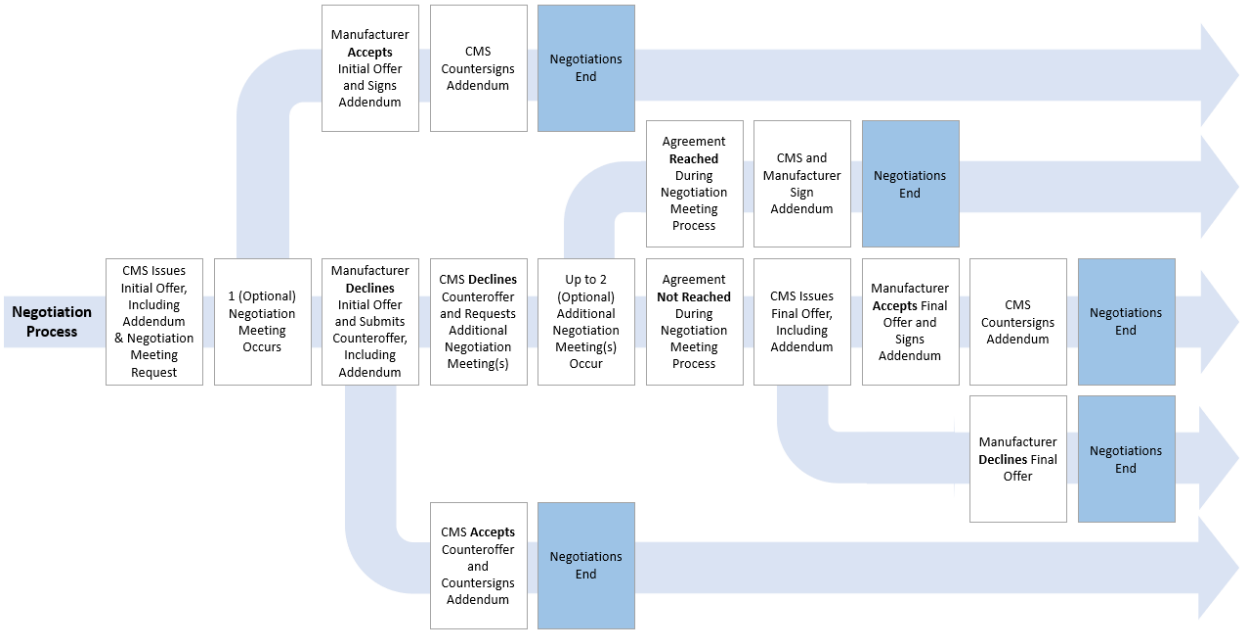
The negotiation process may include the following steps, as discussed in detail in the subsections of this section:

(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 2027 no later than June 1, 2025. 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 will also 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 (referred to herein as 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 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 in-person, virtual, or hybrid (where a portion of attendees are in-person and a portion of attendees are virtual) 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 one week before final offers are due to be sent by CMS (October 15, 2025), 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, 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 2027, subject to the conditions and timing described in section 70 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[142]



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. Section 90.3 and section 100 of this final guidance further describe possible actions to address noncompliance.

[142] Mention of the "negotiation meeting process" in this figure is inclusive of the additional price exchange functionality described in section 60.4.5.

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, 2025, 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 2025 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. 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 2027, CMS intends to 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 aggregate selected drugs by condition when appropriate. CMS will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. 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 2025. 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 up to 15 patient-focused roundtable events will not be livestreamed; however, CMS will make public the transcripts 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,[143] as well as omit identifying information for patient advocacy organization representatives and family members/caregivers. CMS will use an intentional process to select speakers for the patient-focused roundtable events and for the town hall meeting. 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, 2025, 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

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

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 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 NDC-11 package price level to demonstrate how this initial offer price will apply to the dosage forms and strengths as identified on the list of National Drug Codes 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 earlier in the negotiation period compared to initial price applicability year 2026. 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. 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 follow the same standards around meeting length and number of attendees as the post-statutory written counteroffer negotiation meetings described in section 60.4.4 of this final guidance. 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 Negotiation Data Elements and Drug Price Negotiation Process ICR for initial price applicability year 2027 in the Federal Register for a 60-day public comment period on July 2, 2024. 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 2024, 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 2027 must end prior to November 1, 2025, i.e., an agreement on MFP for the selected drug must be reached no later than October 31, 2025, 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 rejects the Primary Manufacturer's statutory written counteroffer, CMS will extend an invitation to the Primary Manufacturer for an optional negotiation meeting. If agreement upon an MFP is not reached in that meeting, CMS will extend an invitation for an additional optional meeting. This reflects a change in process from the initial price applicability year 2026 negotiation process, where each party could request an additional meeting and where all negotiation meetings took place after the Primary Manufacturer's statutory written counteroffer. These changes are intended to make the negotiation process more efficient and to provide clarity to Primary Manufacturers, based on the initial price applicability year 2026 negotiation experience, that all meetings can occur if necessary and if desired by the Primary Manufacturer.

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 towards 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 six 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. Additionally, a maximum of six attendees per side is in line with requirements for similar meetings between government entities and manufacturers. Each meeting will last no more than two hours and may be conducted in-person at CMS or Department of Health and Human Services (HHS) facilities in the Washington-Baltimore area. CMS believes two hours per negotiation meeting (of which there can be up to three meetings) is sufficient for a fruitful discussion and is appropriate considering time and scheduling constraints. If necessary, due to distance or scheduling challenges, meetings may be held virtually or may accommodate a hybrid arrangement. 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. As feasible, CMS will share a meeting agenda with the Primary Manufacturer via email approximately two weeks or more before the

meeting. The Primary Manufacturer may request additions or edits to the agenda as long as they are in scope, as discussed in the paragraph above. Such requests must be submitted 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 20 pages (or a combination of pages, slides, and/or charts and graphs totaling 20 pages), 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. 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 30, 2025. As described in section 60.4.2, 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 about two months' time between CMS' rejection of the Primary Manufacturer's statutory written counteroffer (approximately July 31, 2025), if applicable, and the deadline for negotiation meetings to conclude (September 30, 2025). CMS requires that all negotiation meetings end no later than September 30, 2025, the last business day that is 15 days prior to October 15, 2025, 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 October 15, and allow the Primary Manufacturer time to consider the final offer and accept or reject the final offer by October 31, 2025, as all negotiations must be concluded prior to November 1, 2025. These dates assume that a Primary Manufacturer is timely in entering into an Agreement, submitting information, and meeting deadlines related to the Negotiation Program.

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.

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 one week before final offers are due to be sent by CMS (October 15, 2025), 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 one week before CMS intends to issue final offers to provide CMS the time necessary for adequate consideration of any outstanding counteroffers. 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, 2025, for initial price applicability year 2027 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 October 15, 2025. 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 October 15, 2025, 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,

2025. Table 8 details CMS' timing for the negotiation process for initial price applicability year 2027.

Table 8: Negotiation Process Milestones for Initial Price Applicability Year 2027

Date[144]	**Milestone**
June 1, 2025	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, 2025)	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, 2025)	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, 2025 and manufacturer statutory written counteroffer is made on July 1, 2025)	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 September 30, 2025 (the last business day that is 15 days prior to October 15, 2025) or the day an MFP is agreed upon, whichever is earlier	Optional negotiation meetings (in-person, virtual, or hybrid; maximum of two possible meetings), if applicable
Date that the Primary Manufacturer's statutory written counteroffer is not accepted by CMS through October 8, 2025 (the last business day that is 7 days prior to October 15, 2025) or the day an MFP is agreed upon, whichever is earlier	Additional price exchange, if applicable

[144] 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 will 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.

October 15, 2025	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, 2025	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, 2025	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, 2025
November 1, 2025	Statutory end of negotiation period

In all instances, to formalize agreement on an MFP, CMS and the Primary Manufacturer both 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 Negotiation Data Elements and Drug Price Negotiation Process 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 or via the additional price exchange functionality described in section 60.4.5, 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, or can meet the statutory criteria for the suspension of tax or may terminate its Agreement in the manner described in section 40.6 of this final guidance, which includes sending a notice terminating all of their 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 pharmacies, mail order services, or other dispensing entities, with respect to such MFP-eligible individuals), however, CMS will publish the MFP at the per-unit (e.g., tablet) level for each NDC-9 and at the package (e.g., bottle) level for each NDC-11 associated with the selected drug based on the list of NDCs 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 to ensure accuracy (e.g., in the event of partial package dispense).

The following methodology will be used to apply the single MFP across NDC-9s for a 30-day equivalent supply and to calculate an MFP per unit for each NDC-9 of the selected drug. CMS will use a methodology that scales the MFP per unit based on price differentials across different dosage forms and strengths. For initial price applicability year 2027, CMS will use the WAC of the selected drug in this calculation. CMS will first calculate annual calendar year 2024 WAC per unit cost for each of the NDC-11s for the selected drug 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 2024 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)), so that the WAC will be comparable to the negotiated single MFP. CMS will 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 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 2024 in the CMS HPMS (see section 40.2 of this final guidance). For such NDCs, CMS would use calendar year 2024 PDE records where (1) the PDE record is associated with a prescription filled between January 1, 2024, and December 31, 2024; (2) total gross covered prescription drug costs on the PDE record are greater than $0; (3) the PDE record is considered final action; (4) the drug coverage status code indicates the PDE record is for a covered Part D drug; and (5) the compound code indicates the PDE record is not for a compounded drug. CMS also will apply the MFP to any new NDCs or NDCs with

insufficient PDE or WAC data in calendar year 2024 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, 2024, and ending December 31, 2024, for purposes of this calculation because it is 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 quantity dispensed by the total 30-day equivalent supply, both calculated from 2024 PDE data, to calculate the average number of units per 30-day equivalent supply.
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 by the total 30-day equivalent supply across all applicable NDC-11s within an NDC-9 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).

CMS will include the MFP per-unit price for each NDC-9 of the selected drug, calculated in step 11 above, along with corresponding NDC-11 package prices (determined by multiplying the NDC-9 unit price by the number of units per NDC-11 package), 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 2027 and CMS may consider additional policies for future years of the Negotiation Program.

60.5.1 Application of the MFP to New NDAs / BLAs or NDCs and NDCs with Insufficient PDE or WAC Data in Calendar Year 2024

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 a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient as the selected drug, CMS will include such NDCs, 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. Similarly, after the drug is selected, 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, CMS will include such NDCs, 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. Additionally, an NDC 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 or WAC data in calendar year 2024 to apply the MFP across that dosage form and strength during the negotiation period as described above.

For such NDCs described above, CMS will determine whether there is an existing, comparable NDC 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 quantity dispensed to 30-day equivalent supply (adjusted as necessary to reflect dosing 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 quantity dispensed to 30-day equivalent supply using sources such as the FDA-approved label and other sources associated with the NDC that lacks sufficient PDE and/or WAC data but will use a WAC ratio of 1.0 to apply the MFP to the NDC that lacks sufficient PDE and/or WAC data.[145]

As described in section 40.5 of this final guidance, as feasible, CMS intends to 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

[145] While this guidance is focused on initial price applicability year 2027, CMS notes that in future years, renegotiation of the MFP might be appropriate in the event of certain new NDCs that represent material changes to the selected drug, such as where the new NDC is sought due to changes in the selected drug that result in the addition of a new indication. CMS will provide additional information in the future on renegotiation, which will be implemented for initial price applicability year 2028 and subsequent years, in accordance with the statute.

suggestion of error process. For example, comments on calculation methodology will be considered out of scope.

CMS intends to address, in future guidance, how the MFP application could be adjusted by updating the quotient of total quantity dispensed to 30-day equivalent supply based on observed PDE data for existing NDCs that lacked sufficient WAC or PDE data in calendar year 2024 to be included in the initial calculation of WAC ratios (described in section 60.5, step 9), and new NDCs launched after the initial calculation of WAC ratios. CMS intends that any such process for updating the application of MFP to dosage forms and strengths based on observed PDE data would apply for years in a selected drug's price applicability period.

60.6 Publication of the MFP

In accordance with section 1195(a)(1) of the Act, CMS will publish by November 30, 2025, the MFP for each drug selected for initial price applicability year 2027 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[146] will contain the single MFP for a 30-day equivalent supply of the selected drug, the NDC-9 per unit price, and NDC-11 per package 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 NDC-11s are added or removed for the selected drug, or if the NDC-9 per unit price or NDC-11 per package 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, 2025, CMS will publish on the CMS website updated amounts for any MFPs for initial price applicability year 2026 selected drugs for which a manufacturer agreement is in effect. Those updated MFPs will take effect in 2027 and will be equal to the initial price applicability year 2026 MFP for the selected drug increased by the percent increase in CPI-U from July 2024 to July 2025. 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—is bona fide

[146] 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.

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). Guidance about MFPs for drugs subject to renegotiation will be forthcoming in future years of the Negotiation Program.

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, 2026, for initial price applicability year 2027. CMS will strive to publish these public explanations earlier than March 1, 2026, if feasible. The public 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 public explanations of the MFPs 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 a public explanation for the MFP 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 the public explanation for the MFP 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 2027 by November 1, 2025 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. Guidance about the renegotiation process will be forthcoming for future years of the Negotiation Program.

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) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or the 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 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. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing of that drug or product.

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 2025, and repeated each month thereafter, 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 2027.

Second, if CMS determines that a generic drug or biosimilar has been approved or licensed, CMS will begin by reviewing the PDE and AMP data 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 2025, CMS will use PDE data with dates of service from March 2024 through February 2025 and AMP data with sales from February 2024 through January 2025 (submitted to CMS by February 28, 2025). When CMS performs this assessment in April 2025, CMS will use PDE data with dates of service from April 2024 through March 2025 and AMP data with sales from March 2024 through February 2025 (submitted to CMS by March 31, 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 selected drug, 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 2027, if CMS makes this determination between the date that the selected drug list for initial price applicability year 2027 is published and November 1, 2025, the drug will remain a selected drug through 2027, 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, 2025 and March 31, 2027, for a drug selected for initial price applicability year 2027, then the drug will cease to be a selected drug on January 1, 2028 and the MFP will apply for 2027. If CMS makes this determination between April 1, 2027 and March 31, 2028, then the selected drug will cease to be a selected drug on January 1, 2029, and the MFP will apply for 2027 and 2028. 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 2027 is published through November 1, 2025 (the end of the Negotiation Period for the initial price applicability year 2027)	Selected drug remains a selected drug for initial price applicability year 2027, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2028.
November 2, 2025 through March 31, 2027	Selected drug remains a selected drug and MFP applies for initial price applicability year 2027; selected drug ceases to be a selected drug on January 1, 2028.
April 1, 2027 through March 31, 2028	Selected drug remains a selected drug and MFP applies for initial price applicability year 2027 and calendar

	year 2028; selected drug ceases to be a selected drug on January 1, 2029.

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, or to transfer ownership of the selected drug as discussed in section 40.7, 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 competition are met for a selected drug, CMS will publish such information on the CMS website.

80. MFP-Eligible Individuals in 2026 and 2027

For 2026 and 2027, in accordance with section 1191(c)(2) of the Act, the term "maximum fair price 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,[147] and for whom no PDE record is produced for the claim. For 2026 and 2027, CMS does not expect 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 an MA plan.

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. Following the publication of selected drugs for each initial price applicability year, CMS will provide information about the negotiation process 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.

[147] 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.

During the negotiation period, 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. Only one extension, if determined to have a reasonable basis, will be granted for each request.

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 Plans, 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 100.4 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 ending 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 100.4 of this final guidance.

90.2 Monitoring of Access to the MFP in 2026 and 2027

In accordance with section 1193(a)(3)(A) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP 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, and to the pharmacy, mail order service, or other dispensing entity with respect to such MFP-eligible individuals who are dispensed 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 to MFP-eligible individuals, 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 to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities 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 pharmacies, mail order services, and other dispensing entities that are providing the selected drug to an MFP-eligible individual, as discussed in section 80 of this final guidance.

If CMS determines through audits, investigations, or complaints from dispensing entities or other market participants, that the Primary Manufacturer has not consistently fulfilled its obligation to make MFP available by transmitting payment of an amount that provides access to the MFP within the 14-day prompt MFP payment window (unless the dispensing entity's acquisition cost for the selected drug is equal to or less than the MFP), CMS will notify the Primary Manufacturer of its noncompliance and encourage the Primary Manufacturer to adopt process changes to address MFP refund payment discrepancies as soon as possible. Failure to make MFP available promptly may result in CMS imposing the appropriate CMPs as set forth in section 100 of the revised guidance for initial price applicability year 2026 or this final guidance, as applicable. 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 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, in 2026 and 2027, CMS will engage 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 will also engage an MTF Contractor for the MTF PM to provide optional facilitation of retrospective MFP refund payment 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 or this final guidance, as applicable, for additional details). Under section 1191(d)(6) of the Act, the

MFPs for selected drugs for initial price applicability year 2026 must be published by September 1, 2024, and under section 1195(a)(1) of the Act, the MFPs for selected drugs for initial price applicability year 2027 must be published by November 30, 2025.[148] 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. This includes the reasons considered in section 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.

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 dispensed 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, the Primary Manufacturer is required to provide access to the MFP to the 340B covered entity in a nonduplicated amount to the 340B ceiling price.

CMS recognizes that the data elements transmitted by the MTF to Primary Manufacturers may include claims that should be subject to a different refund amount than the SDRA, 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 section 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.

For claims identified as paid at a refund amount other than the SDRA, 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

[148] Section 40.2 of the revised guidance for initial price applicability year 2026 and of this final guidance describe 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 and of this final guidance describe 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 and section 60.6 of this final guidance describe CMS' publication of and updates to the MFP file. Section 60.8 of the revised guidance for initial price applicability year 2026 and section 60.8 of this final guidance describe the MFP publication timeline that CMS will follow in the event of late action from the Primary Manufacturer.

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 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 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 claim was 340B-eligible. CMS notes that an NPI alone (whether a prescriber NPI or a hospital/provider NPI) 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 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 dispensing 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 dispensing 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 report of 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.

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 report of claim-level payment

elements. 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, 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 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) providing access to the MFP through prospective sale of selected drugs at prices no greater than the MFP; or (3) using some combination of these two approaches.

CMS requires that a Primary Manufacturer submit its plan for making the MFP available in writing to CMS at least four months before the start of the first initial price applicability year for the selected drug. CMS understands that this deadline is sooner than stated in the revised guidance for initial price applicability year 2026, which indicated that plans were due one month prior; however, CMS believes that an earlier deadline will allow for evaluation of a Primary Manufacturer's plan prior to the start of 2026 and allow CMS time to conduct outreach to Primary Manufacturers if important information, as discussed throughout this section, is missing from the written plan.

To provide a clear, concise method of collecting the requested information, CMS plans to request Office of Management and Budget approval for an ICR for manufacturer plan submission and plans to seek comments on criteria interested parties identify as important to ensure that MFP is made available consistent with the Act. CMS intends to consolidate this public comment feedback in conjunction with the requirements of sections 40.4 and 90.2.1 of this final guidance to develop a standardized method of data collection to promote the Primary Manufacturer's development of a robust plan for making MFP available. CMS is exploring a standardized method of data collection existing within the MTF DM that could be populated by a Primary Manufacturer during its enrollment.

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 is revising this deadline to September 1, 2025 in this final guidance. For selected drugs with a first initial price applicability year of 2027, written submission of the plan will be due by September 1, 2026. 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 plan for making the MFP available 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 participation 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 does so at least 90 days before the start of 2027. If a Primary Manufacturer elects to terminate use of the voluntary passing of payments through the MTF PM at any time after submission of its MFP effectuation plan, then it must provide notice at least 90 days before withdrawing from participation and provide its alternative method for making MFP available if it differs from any alternative payment methods outlined in its current plan. A Primary Manufacturer may amend its plan to begin voluntarily passing payments through the MTF PM at any time.

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 would collect, maintain, and deliver to CMS, if requested, for the purposes of auditing

and compliance with the requirement to make the MFP available. Each Primary Manufacturer's written submission 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 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, all Primary Manufacturer plans 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.

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 and 2027 and will provide updates to the list on an ongoing basis as other dispensing entities enroll in the MTF DM and self-identify as having material cashflow concerns or 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 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 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 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 written submission must indicate whether it will participate in the MTF PM. If a Primary Manufacturer chooses to use the MTF PM, then the written submission 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 MFP 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 dispensing entity's selected payment method preference 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 written submission 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 it chooses not to participate in the MTF PM or has an alternative arrangement with certain dispensing entities even if the Primary Manufacturer ordinarily uses 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 written submission within 90 days of the creation of the new unique arrangement. If a Primary Manufacturer fails to provide an updated written submission 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 each dispensing entity's own standard business practices, 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, to the extent that alternative arrangements with a Primary Manufacturer outside of the MTF PM are private contracts between the Primary Manufacturer and the dispensing entity, 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. By submitting its written plan to effectuate MFP, the Primary Manufacturer acknowledges it will use the processes outlined in the plan to effectuate MFP consistent with the statute. A Primary Manufacturer's written submission describing its plan to ensure MFP availability is considered in effect until it is superseded by the submission of a new plan with the required 90 day notice, 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.

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 selected 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. Primary Manufacturers and dispensing entities will be able to access the complaint and dispute process directly from the MTF DM user interface. Those outside the MTF will be able to access the complaints process via a publicly accessible portal.

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 timely receipt of a reported issue, an initial triage will be conducted to route the concern to the appropriate track, as described below. 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 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, 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 system and process (e.g., claims included as potentially requiring an MFP refund). A dispute will warrant CMS review and issuance of a non-appealable finding and will be assessed 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.

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 system originating from MTF system 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 helpdesk 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 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 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 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. 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 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 MTF complaint and dispute process.

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. CMS understands the Department of the Treasury has established regulations that govern the administration of the excise tax.[149]

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 2027 because 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 drugs or biosimilars that CMS determined are 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 selected drug.

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[149] 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*, 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.

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 selected drug 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 selected drug 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.

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 for MFP-eligible individuals and pharmacies, mail order services, and other dispensing entities that dispense 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 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.

Category	Example of Substantive Violations
	• Omissions or inaccuracies of manufacturer-submitted information that are critical to the negotiation 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 MTF 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). • Knowing submission of false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception. • Knowing provision of false information under procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Act of the Biosimilar Delay.
MFP Availability	• Failure to make the MFP available to MFP-eligible individuals, and to pharmacies, mail order services, or other dispensing entities (see section 100.1 of this final guidance). • Failure to process timely and complete reimbursement under a retrospective reimbursement structure as described in section 40.4 of this final guidance.

Broadly, CMS is establishing a structure for enforcement actions that:

1. Is within CMS' statutory authority;
2. Is not punitive in response to immaterial 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 of SBE and the Biosimilar Delay. This final guidance does not address failure to pay a rebate for a biological product pursuant to section 1192(f)(4) of the Act, as this topic will be addressed in future guidance. CMS provides details about the process for CMP imposition in section 100.4 of this final guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP

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 pharmacies, mail order services, or other dispensing entities with respect to MFP-eligible individuals who are dispensed 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 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. 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 will send the Primary Manufacturer a Notification of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS will 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 will 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 (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 pharmacies, mail order services, and other dispensing entities that dispense 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, CMS will use the amount that is equal to the required pass through of the MFP described in section 40.4 of this final guidance. 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.

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 may be subject to a statutorily specified CMP for each day of such violation. The amount of $1,032,410 a day is applicable for any CMP that may be assessed, related to either initial price applicability year 2026 or initial price applicability year 2027 drugs, in 2024 and will be updated yearly per the Federal Civil Penalties Inflation Adjustments

Improvements Act of 2015.[150] 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 Negotiation Data Elements and Drug Price Negotiation Process 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, 2025 for initial price applicability year 2027. In this example, when the Primary Manufacturer failed to timely submit 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 will 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, 2025) 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 information is submitted. 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)).

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 will 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 100.4 of this final guidance.

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[150] 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 Adjustments Act Improvements Act of 2015. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. 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-24-07, "Implementation of Penalty Inflation Adjustments for 2024, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015," the cost of living multiplier for 2024 is 1.03241.

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 under the procedures to apply 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 under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Act of the Biosimilar Delay, such manufacturer may be subject to a statutorily specified CMP for each item of such false information. The amount of $103,241,000 per item is applicable for any CMP assessed in 2024 related to either the initial price applicability year 2026 or initial price applicability year 2027 and will be updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.[151]

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 will 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 Notice and Appeal Procedures
Where CMS makes a determination to assess a CMP, CMS will 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 will send the

[151] 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.

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 will 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 42 C.F.R. § 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 CGDP. 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. § 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, 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.[152] For contract year 2027, CMS will continue the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 (described further below in this section). At this time, CMS does not have sufficient information to determine whether changes to the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 are warranted. Multiple IRA Part D redesign provisions take effect in 2025 that impact Part D plan sponsors' benefit and formulary design choices.[153] CMS is assessing Part D plan sponsors' benefit and formulary design decisions for contract year 2025 to determine whether policy changes are warranted. Additionally, the formulary inclusion requirement in section 1860D-4(b)(3)(I) of the Act has not taken effect yet, and plan sponsors will not submit their formularies for the first contract year in which MFPs are in effect (i.e., contract year 2026) until 2025. For these reasons, CMS will continue monitoring

[152] As required by section 1860D-4(b)(3)(I)(ii) of the Act, 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).

[153] See: Final CY 2025 Part D Redesign Program Instructions, https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.

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 2027, 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 2027, 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 requires 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, 42 C.F.R. § 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, 42 C.F.R. § 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, 42 C.F.R. § 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 tier than non-selected 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 (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected 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 2027 Part D formulary review and approval process, CMS will expect Part D sponsors to provide a reasonable justification to support the submitted plan 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 package complies with those requirements.

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.[154]

Given that the application of the MFP for initial price applicability year 2027 is limited to drugs for which there is Part D utilization, this final guidance describes the interaction between the Negotiation Program and the Part D Drug Inflation Rebate Program. CMS will address the application of Part B inflation rebates to selected drugs in future guidance for initial price applicability year 2028.

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 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

[154] CMS published revised guidance on both Part B and Part D inflation rebates on December 14, 2023, which includes more specific details on the operation of the Part B and Part D inflation rebate programs. 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.

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 Part D drug inflation rebate calculation is based on changes in the AMP over time.[155] MFP is excluded from AMP and thus does not affect the rebate calculation.[156]

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 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) 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) for drugs first approved or licensed after October 1, 2021.

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.

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[155] 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.

[156] Section 1927(k)(1)(B)(i)(VI), as amended by section 11001(b)(3) of the IRA.

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

For the purposes of describing the data at sections 1194(e)(1), 1194(e)(2), and 1193(a)(4)(A) of the Act to be collected for use in the Negotiation Program, as described in sections 40.2, 50.1, and 50.2 of this final guidance, CMS applies the following definitions and standards. As described in section 50 of this final guidance, CMS published the Negotiation Data Elements and Drug Price Negotiation Process ICR for a 60-day public comment period on July 2, 2024, and CMS intends to publish the Negotiation Data Elements and Drug Price Negotiation Process ICR for a 30-day public comment period in Fall 2024. The ICR will include instructions on how Primary Manufacturers and members of the public may submit relevant data for initial price applicability year 2027, including the optional data described in this Appendix (relating to Evidence About Alternative Treatments).

General

- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment.[157] If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount should be used.

Selected Drug Information

- Average Manufacturer Price (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.
- 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 (21 U.S.C. § 353(c)(1)).
- 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.

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

[157] Most studies on research and development (R&D) costs apply a cost-of-capital adjustment to each company's R&D spending to reflect the lag between investment and return on investment. The use of 8.1 percent is consistent with assumptions used by the Congressional Budget Office (CBO), see "Research and Development in the Pharmaceutical Industry," CBO (April 2021), available at https://www.cbo.gov/publication/57126.

38 U.S.C § 8126(h)(5)) for the four calendar quarters of the year involved.[158] For initial price applicability year 2027, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and 2024 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2025). 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 2024, 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) 2024 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585.[159] 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).

Research and Development (R&D) Costs

R&D costs mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the five categories below, and excluding (a) prior Federal financial support, (b) costs associated with applying for and receiving foreign approvals, and (c) costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Acquisition Costs
2. R&D: Basic Pre-Clinical Research Costs
3. R&D: Post-Investigational New Drug Application (IND) Costs
4. R&D: Abandoned and Failed Drug Costs
5. R&D: All Other R&D Direct Costs

CMS is calculating recoupment of R&D costs using both the global and U.S. total lifetime net revenue for the selected drug:

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[158] 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).

[159] See: https://www.va.gov/opal/docs/nac/fss/pl102585-2024-pbm-fcp-guidance-for-new-covered-drugs.pdf.

6. Recoupment: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

The definitions and associated time periods for these terms are included below.

Definitions for 1. R&D: Acquisition Costs

- For the sole purpose of data collection under section 1194(e)(1)(A) of the Act, acquisition costs are defined as costs associated with the Primary Manufacturer's purchase from another entity of the rights to hold previously approved or future NDA(s) / BLA(s) of the selected drug.

Definitions for 2. R&D: Basic Pre-Clinical Research Costs

- Basic pre-clinical research costs are defined as all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses (defined below).
- For each FDA-approved indication of the selected drug, the basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that FDA-approved indication of the selected drug went into effect.[160, 161] The basic pre-clinical research period may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications that went into effect, use the date of the first IND application that went into effect as the end date for the 52-month period.[162]
- 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.

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[160] CMS acknowledges that the exact date of initial discovery might not be known, but Primary Manufacturers should use their best estimate.

[161] For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug, use the earliest date of acquisition for any NDA / BLA of the selected drug.

[162] CMS believes that 52 months represents a solid average across studies. For example, one study reported that the pre-clinical phase takes 52 months on average. See DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 2003, https://fds.duke.edu/db?attachment-25--1301-view-168. Another study estimated that the pre-clinical phase can take 31 months on average. See DiMasi, J, Grabowski, H, Hansen, R. Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, 2016, as cited by the Congressional Budget Office in Research and Development in the Pharmaceutical Industry, April 2021, https://www.cbo.gov/publication/57126. Other estimates have found that the pre-clinical phase ranges from three to six years. See PhRMA, "Biopharmaceutical Research & Development: The Process Behind New Medicines," 2015.

- Indirect basic pre-clinical research costs and relevant general and administrative costs 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 biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[163, 164] For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs for that period of time, then *indirect* costs should be allocated proportionally. Thus, for the selected drug, they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

Definitions for 3. R&D: Post-IND Costs

- Post-IND costs are defined as all 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 for each FDA-approved indication. Post-IND costs also include all direct costs associated with completed FDA-required, postmarketing trials that are conducted after the FDA has approved a product. Post-IND costs exclude FDA-required, postmarketing trials that were not completed.
- 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 during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, 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.
- The post-IND period begins on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required postmarketing trial was completed for the selected drug.

Definitions for 4. R&D: Abandoned and Failed Drug Costs

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not receive FDA approval.

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[163] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166.
[164] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

- Failed or abandoned product costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
    - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
    - Direct research expenses include personnel (monetary and non-monetary compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned product costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not receive FDA approval.
    - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
    - Direct post-IND costs include 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 drug, and facility costs that are directly related to conducting dosing and clinical trials for the drug. Personnel, patient recruitment, and per-patient costs include monetary and non-monetary compensation.

Definitions for 5. R&D: All Other R&D Direct Costs

- All other R&D direct costs are any other allowable costs that do not align with R&D definitions 1-4. For example, other R&D direct costs may include direct costs associated with conducting FDA-required postmarketing trials and other FDA postmarketing requirements and commitments that were not completed, Phase IV postmarketing studies for FDA-approved indications that were not required by FDA, post-IND costs for indications that did not receive FDA approval, acquisition costs for failed or abandoned products, and costs associated with generating real-world evidence that was submitted to FDA to support the safety or effectiveness of a selected drug or to support or satisfy a postmarketing requirement or commitment.

Definitions for 6. Global and U.S. Total Lifetime Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.

Definitions for 6a. Global, including U.S., Total Lifetime Net Revenue for the Selected Drug

- Global, total lifetime 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.
- Global, total lifetime net revenue period is defined as the date the drug or biological product was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.

- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.
- Global, total lifetime net revenue for the selected drug must be in nominal U.S. Dollars (USD).

Definitions for 6b. U.S. Lifetime Net Revenue for the Selected Drug

- U.S. lifetime 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.
- U.S. lifetime net revenue period is defined as the date the drug or biological product was first sold in the U.S. through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If U.S. lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.
- U.S. lifetime net revenue for the selected drug must be in nominal USD.

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 (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS).[165] 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 production 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 distribution are defined as all (direct and allocation of indirect) costs related to:
    - Packaging and packaging materials;

[165] 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);
    - Average unit costs during the 12-month period ending December 31, 2024;
    - 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 are defined not to 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, 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

For the purposes of describing prior federal financial support for novel therapeutic discovery and development to be collected for use in the Negotiation Program with respect to the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this final guidance, CMS adopts the definitions described in this subsection.

- "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" refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, whichever is later, to the day through the date the most recent NDA / BLA was approved for 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.

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), as of February 1, 2025, 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 related 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 related 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;[166] 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.

[166] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.

- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays and prohibitions on the approval of competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[167]
    - New Chemical Entity Exclusivity (NCE);[168]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[169]
    - New Clinical Investigation Exclusivity (NCI);[170]
    - Pediatric Exclusivity (PED);[171] and
    - Reference Product Exclusivity for Biological Products.[172]
- 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[173] 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 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.
- 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.[174] The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in 38 U.S.C. § 8126. The Big Four price is reported at the NDC-11 level.

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[167] Section 527 of the FD&C Act.
[168] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[169] Section 505E(a) of the FD&C Act.
[170] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[171] Section 505A(b) & (c) of the FD&C Act.
[172] Section 351(k)(7) of the PHS Act.
[173] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.
[174] See: https://department.va.gov/administrations-and-offices/acquisition-logistics-and-construction/freedom-of-information-act-requests/#toc_Historical_VA_Pharmaceutical_Prices.

- 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 group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Part A and Part B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The U.S. commercial average net unit price includes 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 purchasers. The U.S. commercial average net unit price excludes 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 U.S. commercial average net unit price─ net of patient assistance includes 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 includes 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 purchasers. 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 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 U.S. commercial average net unit price─ best includes 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 U.S. commercial average net unit price─ best excludes 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.
- 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. This manufacturer net Medicare Part D average unit price would include specific data, including coverage gap discounts and other supply chain concessions (e.g., wholesale discounts) 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 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. This manufacturer net Medicare Part D average unit price – best would include specific data, including coverage gap discounts and other supply chain concessions (e.g., wholesale discounts) 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 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 will 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 will 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.
- Therapeutic Advance: CMS will determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by examining improvements in outcomes compared to its therapeutic alternative(s) and may consider the extent to which a selected drug represents a therapeutic advance by examining the extent to which the selected drug provides a substantial improvement in outcomes for an indication(s). CMS will consider the extent to which a selected drug represents a therapeutic advance at the time of submission of evidence related to 1194(e) factors through the Negotiation Data Elements and Drug Price Negotiation ICR.
- Outcomes: Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients and patient-reported outcomes may also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug, including patient-centered outcomes when available. The caregiver perspective will 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.[175]
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries including those that may experience disparities in access to care, health outcomes, or other factors that impact health equity.
- Health equity: The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[176]
- 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.[177] Unmet medical need is determined at the time of submission of this information. Under section 1194(e)(2) of the Act, CMS will 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 nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. 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, if appropriate, 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 nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia.

[175] 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).

[176] See: https://www.cms.gov/pillar/health-equity.

[177] 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.