CENTER FOR MEDICARE

DEPARTMENT OF HEALTH & HUMAN SERVICES
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DATE: May 3, 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SUBJECT: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair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

Draft Guidance on the Medicare Drug Price Negotiation Program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)[1] for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereinafter "the Act"), as added by sections 11001 and 11002 of the IRA.

The Centers for Medicare & Medicaid Services (CMS) is committed to actively engaging with interested parties for the successful implementation of the IRA. Through this draft guidance, CMS seeks to gather input from a broad range of interested parties regarding the implementation of the Negotiation Program for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027. Public feedback on all aspects of the negotiation process and manufacturer effectuation of the MFP is critical to the success of the Negotiation Program. CMS is committed to learning from, collaborating with, and engaging the public, including patients, consumer advocates, health and data experts, and pharmaceutical supply chain entities in the policy-making process.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the Department of Health and Human Services (hereinafter "the Secretary") to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with

[1] 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.

the law, CMS is issuing this draft guidance for implementation of the Negotiation Program for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027. CMS is also voluntarily soliciting comment on the topics in this draft guidance, except section 90.3.[2] Please send comments pertaining to this draft guidance to IRARebateandNegotiation@cms.hhs.gov with the subject line "Medicare Drug Price Negotiation Program Draft Guidance." Comments received by 11:59 PM Pacific Time (PT) on July 2, 2024 will be considered. After considering the public comments received in response to this draft guidance, CMS will issue final guidance for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027.

This draft 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 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.

This draft guidance describes how CMS intends to 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: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." This draft 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. CMS will issue final guidance later this year setting forth CMS' final policies on the issues discussed in this draft guidance. In the final guidance, CMS may make changes to any policies discussed in this draft guidance in response to comments received or based on the agency's further consideration of the relevant issues.

If any provision in this guidance, once finalized, is held to be invalid or unenforceable, it shall be severable from the remainder of the final guidance, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances.

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[2] CMS is not soliciting comment on section 90.3 because 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 (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-procedural-requirements 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).

The table of contents for this draft guidance is as follows:

20. Overview

This draft guidance describes how CMS intends to 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 draft guidance also sets forth additional policies regarding manufacturer effectuation of the MFP in 2026 and 2027, including the use of a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data and payment between pharmaceutical supply chain entities. Given the timing overlap between the development of this draft guidance and the negotiation period for initial price applicability year 2026, CMS may make 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 is voluntarily soliciting comments on all sections of this 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). More specific comment solicitations are included in various sections of this draft guidance.

Topics that are not relevant to Negotiation Program implementation for initial price applicability year 2027 or for MFP effectuation in 2026 and 2027 will not be 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

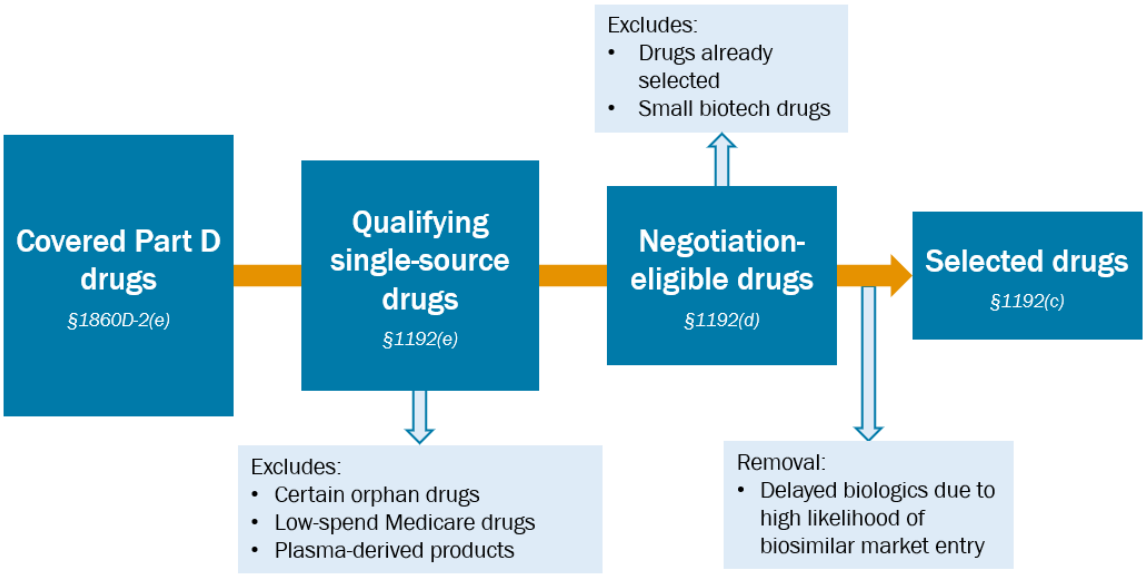
Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-

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 draft 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[3] 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 draft guidance (in this step, CMS will also exclude certain drugs in accordance with sections 1192(d)(2) and (3) of the Act).

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 draft 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 for negotiation for initial price applicability year 2027 (described in section 30.3 of this draft guidance) and publish a list of up to 15 selected drugs not later than February 1, 2025 (described in section 30.4 of this draft 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.

[3] For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) 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.

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 draft 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[4] 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),[5] 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, CMS may further investigate whether such NDAs 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[6] that are marketed pursuant to such NDA(s), (2) authorized generic drugs that are marketed pursuant to such NDA(s), or (3) multi-market approval (MMA)[7] products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);[8]
- 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),[9] 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, CMS may further investigate whether such BLAs 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

[4] Throughout this draft 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 draft guidance.
[5] As described in section 505(c) of the FD&C Act.
[6] For purposes of the Negotiation Program, the terms "repackage" and "relabel" have the meaning specified in 21 C.F.R. § 207.1.
[7] See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-and.
[8] If the holder of the NDA manufactures one or more dosage forms and strengths of the drug with the same active moiety distributed by a private label distributor, that dosage form and strength will also be aggregated in the potential qualifying single source drug of that holder of the NDA.
[9] As described in section 351(a) of the PHS Act.

> 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).[10]

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

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

[10] If the holder of the BLA manufactures one or more dosage forms and strengths of the biological product with the same active ingredient distributed by a private label distributor, that dosage form and strength will also be aggregated in the potential qualifying single source drug of that holder of the BLA.

product, a product that has been licensed under section 351(a) of the PHS Act[11] 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.

If a drug is a fixed combination drug[12] 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:

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.

[11] 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.

[12] 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, 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[13] and Purple Book,[14] to determine whether a generic drug or biosimilar biological product[15] 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 available on January 16, 2025, as well as Average Manufacturer Price (AMP)[16] 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 draft 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 draft guidance.

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[13] See: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[14] See: https://purplebooksearch.fda.gov/.

[15] 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 draft 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.

[16] "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.

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 draft 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 draft 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 ("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)[17] 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 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 draft guidance must meet the criteria for exclusion. CMS will use the FDA Orphan Drug Product designation database[18] 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[19]) 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 needed, 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

[17] 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).

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

[19] 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/.

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.

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)[20] for the period beginning on June 1, 2023 and ending on September 30, 2024,[21] 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 service described above that have been submitted no later than 30 days[22] after October 31, 2024, i.e., by November 30, 2024. 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 draft 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.[23] 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

[20] 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/).

[21] 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.

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

[23] For the purposes of this draft 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.

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 draft guidance ("the Plasma-Derived Product Exclusion"). For purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. CMS will refer to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[24] and will refer to databases such as FDALabel and the FDA Online Label Repository[25] to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA as needed.

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 draft guidance. CMS will exclude any drugs that qualify for the exclusions listed in sections 30.1.1 through 30.1.3 of this draft guidance.
- CMS will identify PDE data for each 11-digit National Drug Code (NDC-11)[26] 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 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 draft guidance; (3) rank the remaining qualifying single source drugs by Total Expenditures under Part D during the applicable

[24] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[25] FDALabel: https://nctr-crs.fda.gov/fdalabel/ui/search; FDA Online Label Repository: https://labels.fda.gov/.
[26] 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.

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 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.[27] 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 (IRC) of 1986 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 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 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

[27] 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.

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 draft 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.[28] Because the earliest effective date for this limitation is January 1, 2025 for acquisitions prior to January 1, 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.[29] 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 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), with a revised title of "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 May 3, 2024, for a 60-day public comment period that will close on July 2, 2024.[30]

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[28] See section 50.1 of the Manufacturer Discount Program Final Guidance, and, see also, the November 17, 2023 HPMS memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers" for more information.

[29] 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.

[30] To view the SBE and Biosimilar Delay ICR Forms available for a 60-day public comment period, and a summary of changes made to the proposed SBE ICR Form for initial price applicability year 2027 in comparison to the SBE ICR Form approved for initial price applicability year 2026 (CMS-10844, OMB 0938-1443), *see* https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016. The 60-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 draft guidance). CMS believes that combining these ICR Forms into one notice will streamline review of these documents for interested parties.

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.[31]

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 no later than mid-December 2024.[32] CMS believes that a mid-December 2024 deadline 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

[31] For purposes of the SBE and implementing section 1192(d)(2)(B)(ii) of the Act to determine whether the acquiring entity meets the definition of a specified manufacturer under section 1860D-14C(g)(4)(B)(ii) of the Act, CMS will use the determination made by CMS under the Manufacturer Discount Program as to whether the acquiring entity is a "specified manufacturer." The Part D Manufacturer Discount Program ICR (CMS-10846, OMB control no. 0938-1451) is available for viewing at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003 (select "all" to see full details).

[32] As specified in the SBE and Biosimilar Delay ICR Forms available for a 60-day public comment, CMS anticipates opening the CMS HPMS for SBE request submissions in late 2024. 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 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," 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 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.[33] 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:

1. CMS will rank the 50 negotiation-eligible drugs identified, as described in section 30.2 of this draft 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 draft 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 draft 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

[33] 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.

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 IPAY 2027 and will be covered in future guidance or rulemaking, as applicable. CMS is 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 to inform CMS' policy development for this issue.

CMS is releasing the SBE and Biosimilar Delay ICR on May 3, 2024 for a 60-day comment period that will close on July 2, 2024. As specified in the SBE and Biosimilar Delay ICR Forms available for a 60-day public comment, CMS anticipates that a Biosimilar Manufacturer will submit an Initial Delay Request using the CMS HPMS by no later than mid-December 2024.[34] 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)).

[34] As specified in the Supporting Statement for the SBE and Biosimilar Delay ICR Forms, available for a 60-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 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.

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 draft 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 draft guidance.

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 draft 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 draft 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 draft 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 is still determining the appropriate date by which this determination should be made. CMS is considering making this determination by late-2025 to allow for sufficient notice prior to the publication of the selected drug list for initial price applicability year 2028. CMS is soliciting comments from interested parties regarding the date by which CMS will inform a Biosimilar Manufacturer if the Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. The timing of this notification will be specified in the final guidance for initial price applicability year 2027.

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 either:
   - 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 draft 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.[35]
   - For Initial Delay Requests submitted with respect to initial price applicability year 2027, the Biosimilar's application for licensure must be approved or

[35] 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.

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 has 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.

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. 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 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.[36] CMS will deny all Initial Delay Requests for Biosimilars that do not meet this requirement with respect to at least one reference product included in the Reference Drug. However, active litigation related to another reference product included in the Reference Drug that is not applicable to the Biosimilar will not be disqualifying.

[36] As described in section 30.3.1.1 of this draft 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.

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.

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 draft 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 Directory and NDC Structured Product Labeling (SPL) Data Elements file (NSDE) 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).[37] 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 draft guidance.[38] 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 draft 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 draft 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 (a "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

[37] 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.

[38] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

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.

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), 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 draft 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 draft 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 dispensers. 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 dispensers that are providing a selected drug to an MFP-eligible individual, as described in section 80 of this draft 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 draft 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 draft guidance;
3. Negotiates an MFP with CMS, as described in section 40.3 of this draft guidance;
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to those individuals, as described in section 40.4 of this draft 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 dispensers, as described in section 40.5, section 90, and section 100 of this draft guidance.

Termination of an Agreement for the Negotiation Program is described in section 40.6 of this draft guidance, and other relevant provisions from the Agreement are described in section 40.7. of this draft 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.[39]

CMS recommends, but does not require, that within five days following publication by CMS, no later than February 1, 2025, of the list of selected drugs for initial price applicability year 2027, 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 manufacturer could be exposed to potential excise tax liability. Instructions and a template of the Agreement are available on the CMS IRA website.[40] CMS voluntarily invites comment from interested parties on those documents.

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

[39] See: https://hpms.cms.gov/app/ng/home/.
[40] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

Medicaid Drug Rebate Program, the CGDP,[41] 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 CGDP and 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 under the Medicaid Drug Rebate Program, the CGDP, and the Manufacturer Discount Program.[42] 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 CGDP and the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14A(b)(4)(B)(i) and 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-14A or 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 CGDP and/or 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 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 section 8126(h)(5) of title 38, United States Code), as described in section 50.1.1 and Appendix A of this draft 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 draft guidance. This information must be submitted by the Primary Manufacturer to CMS no later than March 1, 2025 for initial price applicability year 2027.

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[41] The CGDP, established under section 1860D-14A of the Act, remains in place through December 31, 2024. CGDP requirements are codified in Subpart W of 42 C.F.R. Part 423 and remain in place until the program sunsets.

[42] 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.

The Agreement must be fully executed, meaning both the Primary Manufacturer and CMS have signed the Agreement before the Primary Manufacturer may submit the data elements described in this section. While these data elements may not be submitted prior to execution of the Agreement, Primary Manufacturers will be able to access the data elements template in the CMS HPMS, and CMS believes Primary Manufacturers will be able to gather these data elements prior to the Agreement being executed. By signing the Agreement, a Primary Manufacturer agrees to use the CMS HPMS and comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system.

Certain data, as described in section 50.1 and Appendix A of this draft guidance, must reflect any products 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 draft 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, 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 the list to the Primary Manufacturer of the selected drug. In connection with the data submission described in section 50.1 of this draft 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 private label NDC-11s,
- 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 draft 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-9s and NDC-11s for each selected drug maintained on the CMS HPMS as well as information published pursuant to section 30.4 of this draft 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 draft 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 draft 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 draft 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 private label 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 draft 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 draft 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. Primary Manufacturers should timely notify CMS of any NDC-11 changes via the IRA Mailbox at IRARebateandNegotiation@cms.hhs.gov with the subject line "NDC-11 changes for [name of selected drug]".

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)).[43]

[43] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

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.

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 applications and approvals 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 draft 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) 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 draft 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.

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 draft 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. If warranted, CMS may issue a Notification of Potential Noncompliance 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. 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.

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 failure to engage in timely corrective action may result in the Primary Manufacturer being subject to CMPs as authorized under section 1197(c) for failure to submit required information.

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 offer and justification, and to receive any 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 draft 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 written counteroffer, the Primary Manufacturer will populate an Addendum in the CMS HPMS containing the MFP identified in the counteroffer and sign the Addendum; if CMS wishes to accept the 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[44] 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 draft 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, including 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 draft 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).

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, but is not obligated to make sales of the selected drug. As described in section 40.2 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable, the Primary

[44] In sections 40.2-40.5, 40.7, 50, 60-60.6, 60.8, 90, 100-100.2, and 100.4 of this draft guidance, all references to a "Primary Manufacturer" refer to any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program.

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 draft 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.[45] 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 safeguards 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 draft guidance. CMS defines "providing access to the MFP" as ensuring that the net amount paid by the dispensing entity for the selected drug 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 (the requirements for which are further described in sections 40.4.1 and 90.2 of this draft guidance), or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (the requirements for which are further described in section 40.4.3 of this draft guidance). 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 40.4.2 of this draft guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, CMS requires that the Primary Manufacturer ensure the dispensing entity receives reimbursement in an amount that provides access to the MFP within

[45] 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.

14 calendar days of when the MTF, described further below, 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"). CMS notes that the 14-day prompt MFP payment window aligns with the timing requirement in the longstanding prompt pay rules in Part D.[46] However, 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 Part D 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)(1)(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). Commercial and other payers continue to have discretion to consider Medicare payment rates, including the MFP, in establishing their own payment policies.

CMS continues to work with interested parties to identify existing processes and any new processes that would be feasible for the supply chain to operationalize to ensure that pharmacies, mail order services, and other dispensing entities have access to the MFP for a selected drug during a price applicability period. In the revised guidance for initial price applicability year 2026, CMS stated that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to support the verification that the selected drug was dispensed to an MFP-eligible individual. To conduct market research on the availability and potential technical ability of health care related organizations to provide MTF services, CMS issued on October 18, 2023 a Request for Information (RFI) on the Medicare Transaction Facilitator (MTF) for the Medicare Drug Price Negotiation Program, for which responses were due by November 13, 2023.[47] In addition to its consideration of the RFI responses received, CMS continues to consult with pharmacies, mail order services, and other dispensing entities, as well as with industry standard development organizations (e.g., National Council for Prescription Drug Programs (NCPDP)), 340B covered entities and related organizations, pharmaceutical and biotechnology manufacturers, and other supply chain participants to understand existing data flows and identify opportunities for increased connectivity and data sharing.

Based on CMS' continuous engagement with and extensive feedback from interested parties, for 2026 and 2027, CMS will engage with an MTF 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 40.4.1 of this draft guidance. CMS has initiated the MTF data exchange acquisition

[46] See 42 C.F.R. § 423.520, Prompt Payment by Part D Sponsors, which requires Part D sponsor payment to pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.
[47] See: https://sam.gov/opp/f9765a945b8b4aa08b263c7ccc53ae24/view.

process concurrent with publication of this draft guidance and is considering if additional MTF supporting acquisitions are needed. As described in section 40.4.1 of this draft guidance, CMS believes mandatory participation for Primary Manufacturers in the MTF's data exchange functionality is necessary to administer the Negotiation Program and promote compliance consistent with the Primary Manufacturer's responsibility in accordance with section 1193(a) of the Act to provide access to the MFP for the selected drug to the dispensing entity.

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. CMS is soliciting comments on two options for potential voluntary facilitation of retrospective payment, provided by the MTF, for participating Primary Manufacturers and participating dispensing entities to help effectuate access to the MFP, as described in section 40.4.4 of this draft guidance.

40.4.1 Medicare Transaction Facilitator Data Facilitation

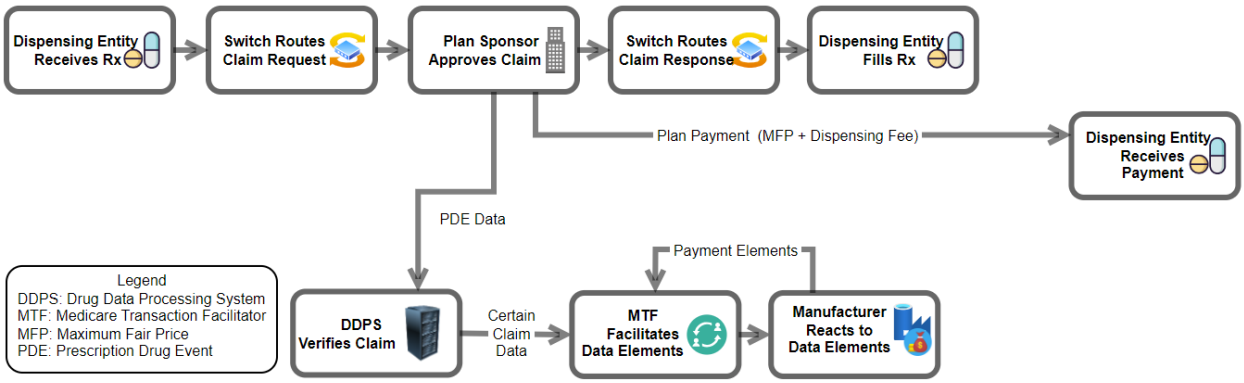
As discussed in section 40.4 of this draft guidance, CMS will engage the MTF to facilitate the exchange of certain claim-level data elements and payment elements for selected drugs. Under this construct, the data exchange component of the MTF would involve both the transmission of certain claim-level data elements to the Primary Manufacturer and receipt of payment-related data elements from the manufacturer. CMS acknowledges that a Primary Manufacturer may choose to contract with one or more third parties to perform the designated operations on behalf of the Primary Manufacturer as discussed in this section (related to MTF data exchange) and in section 40.4.4 of this draft guidance (related to options for voluntary retrospective payment facilitation). However, the Primary Manufacturer remains responsible for compliance with all Negotiation Program requirements notwithstanding any actions that third parties may perform on the Primary Manufacturer's behalf.

The MTF data exchange is intended to accomplish the following tasks in the administration of the Negotiation Program: (1) to support verification that the selected drug was dispensed to an MFP-eligible individual and to furnish the manufacturer with certain claim-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual and identifying which dispensing entity dispensed the selected drug to the MFP-eligible individual, (2) to initiate the 14-day prompt MFP payment window for effectuating the MFP refund for each claim for a selected drug, and (3) to collect payment-related data elements for each claim for a selected drug from Primary Manufacturers indicating whether a refund was paid and the amount of the refund paid to make the MFP available. 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 data exchange is mandatory. All Primary Manufacturers will be required to register with the MTF and maintain the functionality necessary to receive certain claim-level data elements from the MTF. 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. Additionally, all Primary Manufacturers will be required to report to the MTF whether and how (e.g., via retroactive reimbursement) the Primary Manufacturer has made the MFP available for

each claim for which the Primary Manufacturer received data from the MTF, or why no refund payment has been made on a claim (e.g., because access to the MFP had been provided prospectively, or the manufacturer determined the claim to meet the requirements of section 1193(d)(1) of the Act) (the "report with payment-related data"). These data exchange requirements will 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 a potential MTF payment functionality, options for which are described in section 40.4.4 of this draft guidance). CMS intends to leverage existing Part D claims data in this data exchange and does not envision dispensing entities separately transmitting claims data to Primary Manufacturers.

For illustrative purposes, Figure 2 depicts a basic conceptual overview of the currently anticipated mandatory MTF data flow for 2026 and 2027. CMS may revisit the data flow for such years in the future and anticipates technical specifications to evolve as development of the MTF's data functionality moves through acquisition and information system development.

Figure 2: Diagram of MTF Data Flow



Requiring Primary Manufacturers to exchange such data with the MTF is necessary to administer a uniform approach to the start of the 14-day prompt MFP payment window for each claim for a selected drug, and to monitor the extent to which Primary Manufacturers have made MFP available, pursuant to CMS' obligation under section 1196(b) of the Act to monitor compliance of Primary Manufacturers with the terms of the Agreement. Failure by the Primary Manufacturer to register with the MTF or failure to meet the MTF data exchange requirements, including maintaining functionality to receive certain claim-level data elements from the MTF and transmission of payment-related data elements to the MTF within 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(b) of the Act (see section 100.2 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable).

The claim-level data elements for Part D claims for NDCs of a selected drug that the MTF will send to the Primary Manufacturer are listed in Table 2. These data will be exclusively transmitted through the MTF to the Primary Manufacturer. In selecting the MTF 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, prescriber identifiers, and claim reimbursement amounts. CMS believes that the selected data elements provide the minimum necessary information to the Primary Manufacturer that verifies 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.

Table 2: MTF Claim-Level Data Elements

MTF Data Elements List	Purpose	Data Source
Record ID	Used to identify the type of record, such as new claim, adjustment, reversal, etc.	MTF
MTF Internal Claim Number (ICN)	Used to identify the internal unique MTF ID to support claim adjustments	MTF
MTF XRef ICN	Used to link an adjustment to original MTF ICN	MTF
Process Date	Used to identify MTF processed date	MTF
Transaction Code	Used to indicate original claim, adjustment, reversal, etc.	MTF
Medicare Source of Coverage	Used to identify coverage under Medicare Part B or Part D	MTF
Date of Service	Used to verify MFP eligibility	PDE Record
Service Provider Identifier Qualifier	Used to verify MFP eligibility	PDE Record
Service Provider Identifier	Used to verify MFP eligibility	PDE Record
Prescription/Service Reference Number	Used to verify MFP eligibility	PDE Record
Fill Number	Used to verify MFP eligibility	PDE Record
Product /Service Identifier	Used to verify MFP eligibility	PDE Record
Quantity Dispensed	Used to assist the manufacturer in calculating a refund	PDE Record
Days' Supply	Used to verify MFP eligibility	PDE Record
340B Claim Indicator (as voluntarily reported by dispensing entity)	Used to verify MFP eligibility	PDE Record
Contract Number	Used to verify MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) at time of dispensing	Used to calculate the Standard Default Refund Amount	MTF
Maximum Fair Price (MFP) at time of dispensing	Used to assist the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (WAC-MFP)	Used to assist the manufacturer in calculating a refund	MTF
Service Provider MTF Enrollment Status	Used to indicate if dispensing entity opted in to MTF payment facilitation	MTF

The combination of Date of Service, Service Provider Identifier Qualifier, Service Provider Identifier, Prescription/Service Reference Number, and Fill Number identify unique Part D claims. Other data elements listed in Table 2 will provide additional information about each claim to the Primary Manufacturer that may be useful in calculating the retrospective refund, if applicable, including Product/Service Identifier, Quantity Dispensed, Days' Supply, Contract Number, WAC at time of dispensing, and MFP at time of dispensing. Beginning January 1, 2025, the Submission Clarification Code value of "20" and the Submission Type Code field with a value of "AA" will be added to the PDE record to indicate a Section 340B claim.[48] These indicators may be voluntarily applied to a Part D claim by the dispensing entity to indicate a Part D claim is being billed for a Section 340B drug.[49] The MTF will also include the field Service Provider MTF Enrollment Status to indicate to Primary Manufacturers if the dispensing entity responsible for the claim is enrolled for payment facilitation services that may be provided through the MTF (see section 40.4.4 of this draft guidance for potential services that may be provided by the MTF to facilitate the transfer of funds between Primary Manufacturers and dispensing entities). 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 Claim Type) that will assist in the facilitation of information on claim adjustments and reversals.

Lastly, the claim-level data elements that the Primary Manufacturer will receive from the MTF will include a Standard Default Refund Amount that will reflect the difference between the WAC and the MFP of the selected drug at time of dispense based on the quantity dispensed. Regardless of whether the Primary Manufacturer uses the potential MTF payment facilitation functionality, the Primary Manufacturer bears responsibility for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP. The MTF's provision of the Standard Default Refund Amount claim-level data element does not supersede that responsibility or indicate that payment of such an amount will be sufficient for the Primary Manufacturer to meet its statutory obligation to make the MFP available. Rather, this claim-level data element is intended to provide an additional data point to assist the Primary Manufacturer in determining and paying an amount sufficient to make the MFP available consistent with the statute. See sections 40.4.3 and 40.4.4 of this draft guidance for additional detail regarding retrospective refunds and any potential payment facilitation services that may be provided through the MTF.

The MTF will provide Primary Manufacturers with data that has been verified by both the Part D plan sponsor and CMS' Drug Data Processing System (DDPS), resulting in dual verification for each claim being transmitted of both an individual's eligibility for Part D and Part D coverage of the selected drug. 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 will pay the dispensing entity for dispensing the selected drug. Then,

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[48] See: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.

[49] 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.

the Part D plan sponsor sends the data on the claim as a PDE record to DDPS, a CMS system used to process all Medicare PDE records and related data. CMS, using DDPS, also performs verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim and will identify if the claim is not related to a Medicare-eligible individual. 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, which will prepare the file of claim-level data elements listed in Table 1 for the claim where there was a plan-approved payment for transmittal to the applicable Primary Manufacturer. Therefore, because MFP eligibility status has been twice validated before the data elements are sent from the MTF 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. The Primary Manufacturer's receipt of the claim-level data elements starts the 14-day prompt MFP payment window in which the Primary Manufacturer must provide access to the MFP and transmit reports with payment-related data with regard to the claim identified in the MTF data; failure to meet these obligations may cause the Primary Manufacturer to be subject to CMPs (see section 100 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable).

Manufacturers have requested many data elements in order to verify that the selected drug was dispensed to an MFP-eligible individual, including requests for detailed beneficiary-level data. Providing additional patient information (such as an encrypted Medicare Beneficiary Identifier) would be neither necessary nor helpful to the Primary Manufacturer to verify the selected drug was dispensed to an MFP-eligible individual because the Primary Manufacturer would also need access to the individual's Medicare eligibility status to verify eligibility. That information is stored with the Medicare plans and DDPS. As stated above, the claim-level data elements will have been 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 manufacturer. In addition, providing additional specific information on individual beneficiaries that constitutes personally identifiable information (PII) or protected health information (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 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, which will trigger the start of the 14-day prompt MFP payment window for effectuating the MFP of the selected drug. If a Primary Manufacturer believes that there is an error with the claim-level data received, it can submit a dispute following the process outlined in section 90.2.2 of this draft guidance. Currently, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. The MTF would send Primary Manufacturers regular transmissions of data from all claims received through DDPS. CMS is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. CMS is also evaluating options for the process, timing, and frequency by which

files containing these claim-level data elements will be transmitted from the MTF to Primary Manufacturers. CMS is considering transmission of these files on either a daily or bi-weekly frequency and is soliciting comments on the process, timing, and frequency of these file transmissions. These files will include the previously described claim-level data elements for each dispense of an NDC of a selected drug with a published MFP in the MFP file to an MFP-eligible individual.

The Primary Manufacturer will be the sole manufacturer authorized to receive this claim-level data directly from the MTF with regard to 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 Secondary Manufacturers complies with applicable privacy and security laws, regulations, and CMS requirements to protect the claim-level data elements received from the MTF. Claim-level data will be batched across all claims available to the MTF as received for all NDCs for the selected drug and regularly transmitted to the Primary Manufacturer. The Primary Manufacturer must ensure any activity by Secondary Manufacturer(s) of a selected drug to make MFP available to dispensing entities complies with applicable privacy and security laws, regulations, and CMS requirements to adequately protect the claim-level data elements received from the MTF and the requirements for the Primary Manufacturer to provide access to MFP and transmit reports with payment-related data within the 14-day prompt MFP payment window.

If the MFP is not made available to a dispensing entity or the report with payment-related data is not provided to the MTF within the 14-day prompt MFP payment window in accordance with section 1193 of the Act and this draft guidance, the Primary Manufacturer may be liable for CMPs (see section 100 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable). 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 in its report with payment-related data to the MTF 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. Such reporting is necessary for CMS to administer the Negotiation Program and to monitor compliance with the requirements of the program, including to verify that access to the MFP has been timely provided by the Primary Manufacturer to the dispensing entity. Among other things, this report with payment-related data will be used to confirm compliance with the 14-day prompt MFP payment window. Due to the anticipated high volume of claims for selected drugs, CMS anticipates that Primary Manufacturers may engage a third party and/or automate the submission of reports with payment-related data to the MTF.

Primary Manufacturers, inclusive of any of the Primary Manufacturer's contracted parties, will be required to include in the report with payment-related data the corresponding data elements previously transmitted by the MTF in addition to the payment elements listed in Table 3 for all claims that are transmitted by the MTF to the Primary Manufacturer regardless of whether a refund was paid and submit these payment elements to the MTF with the corresponding

information from the MTF claim-level data elements file. Payment elements will include the MFP refund transaction date, the method for determining the MFP discount/refund amount, the NPI of the entity receiving the MFP refund, and the amount of payment sent as the MFP refund. CMS is soliciting comments on the required payment elements to be reported to the MTF by the Primary Manufacturer, including whether to add other specific categories. Primary Manufacturers will be responsible for reporting payment elements for all claims for their selected drugs for which the Primary Manufacturer received data from the MTF, regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer. Payment elements must be submitted to the MTF within 14 calendar days of receipt of the original MTF claim-level data elements (i.e., within the 14-day prompt MFP payment window). As discussed previously, CMS anticipates that Primary Manufacturers and their contracted third parties may automate the process of reporting payment elements and welcomes comment on any data needs or limitations to facilitate such operations. Failure by the Primary Manufacturer to transmit all claim-level payment elements in its report with payment-related data to the MTF within 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(b) of the Act.

Table 3: Payment Elements List

Payment Elements	Purpose
MFP Refund Transaction Date	Used to indicate when the MFP refund was sent to the recipient. Payment element should be left blank if the claim was prospectively purchased or a refund was not sent.
Confirmation of MFP Refund to Dispensing Entity	Used to indicate if payment was successful or not. Payment element should be left blank if the claim was prospectively purchased or a refund was not sent.
Method for Determining MFP Discount/Refund Amount	Used to indicate the basis on which MFP discount or refund amount was determined (refer to Table 4)
NPI of the Entity Receiving the MFP Discount/Refund	Used to document recipient of MFP discount or refund
Quantity of Selected Drug	Used to document number of units of selected drug included in MFP refund paid
Amount of Payment Sent as the MFP Refund	Used to document amount of MFP refund paid. Payment element should be left blank if the claim was prospectively purchased or a refund was not sent.

While Primary Manufacturers of selected drugs may have multiple payment mechanisms they utilize to refund dispensing entities within the 14-day prompt MFP payment window, as described in more detail within sections 40.4.3 and 40.4.4 of this draft guidance, they will always be required to report payment elements to the MTF regardless of the payment process used. While reporting of payment elements will serve as the record of payments made and the instances in which a Primary Manufacturer did not make payment following receipt of a claim

from the MTF, the Primary Manufacturer will also be required to maintain documentation for each claim received from the MTF of either: (1) the retrospective MFP refund payment, or (2) the explanation of why the Primary Manufacturer did not provide a retrospective MFP refund. The Primary Manufacturer must make this information available to CMS upon request.

CMS understands there are several reasons why a given claim provided to the Primary Manufacturer may not receive a retrospective MFP refund. For example, the Primary Manufacturer and the dispensing entity may have an arrangement in place where the selected drug is prospectively purchased at or below the MFP. Among other elements, the Primary Manufacturer will be required to report a mandatory payment element "Method for Determining MFP Discount/Refund Amount" to be populated with one of several pre-identified justification codes for indicating whether the MFP refund payment was at the Standard Default Refund Amount, a different amount, or the reason an MFP refund payment was not provided. Examples of anticipated justification codes include codes for the drug being prospectively purchased at or below the MFP, the manufacturer and dispensing entity having a separately negotiated refund amount distinct from the Standard Default Refund Amount, and the claim being excluded from MFP refunds under section 1193(d)(1) of the Act (refer to Table 4). CMS believes that identifying standardized justifications for the report with payment-related data would allow for Primary Manufacturers to establish efficient processes to provide such reports to the MTF. CMS is soliciting comments on the codes included for the "Method for Determining MFP Discount/Refund Amount" payment element.

Table 4: Example of Codes and Values for the "Method for Determining MFP Discount/Refund Amount" Payment Element Displayed in Table 3

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this draft guidance)
1	Standard Default Refund Amount Paid	Invoices from the dispensing entity and proof of successful payment.
2	Amount Other than Standard Default Refund Amount Paid	Documentation 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, and proof of successful payment.
3	No Refund Paid – Prospective MFP Access	Invoice documentation of the drug sold at or below MFP, or an agreement between the Primary Manufacturer and dispensing entity establishing prospective purchasing of the selected drug.

4	No Refund Paid – 1193(d)(1) Exception	• At a minimum, either records from the Primary Manufacturer's process for deduplicating 340B claims and the conclusion reached for the claim, or confirmation from a 340B covered entity, or any vendor the 340B covered entity employs to determine 340B status, that the claim was processed as 340B eligible. • Documentation that the 340B ceiling price is less than MFP.
5	No Refund Paid – Payment Attempted but Unsuccessful	This code would be available in the event a Primary Manufacturer attempts to make an MFP refund available to a dispensing entity but is unable to complete the transaction. 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 Paid – Other	CMS is soliciting comment on any additional specific categories that may be necessary in addition to or in place of a general "other" category.

When Primary Manufacturers report a code other than "1" for the "Method for Determining MFP Discount/Refund Amount" payment element, they will be required to maintain supporting documentation demonstrating why MFP refunds were provided at an amount other than the Standard Default Refund Amount, or were not provided, for applicable claims. This documentation is described in further detail in section 90.2 of this draft guidance. Upon CMS' request, Primary Manufacturers must provide evidence of MFP refund payments, which could include any number of items including 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 reported 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 draft guidance. Regardless of the payment approach(es) used, the Primary Manufacturer must ensure that the required payment elements are reported to the MTF within the 14-day prompt MFP payment window, so that CMS can verify that such payments have been made to dispensing entities and that the MFP has been effectuated in compliance with all applicable requirements.

After the Primary Manufacturer makes payment to the dispensing entity and sends the report with payment-related data to the MTF, CMS is considering having the MTF generate an electronic remittance advice to the dispensing entity for purposes of reconciling manufacturer retrospective MFP refunds. CMS welcomes comment from interested parties on the concept of

the MTF creating and sending an electronic remittance advice to dispensing entities to reconcile the payment provided by the Primary Manufacturer's retrospective refund payments. Additionally, CMS welcomes feedback on other methods for electronic remittance advice, including Primary Manufacturer electronic remittance advices, and specific data elements for such electronic remittance advices to ensure that accounts receivables can be closed for dispensing entities. CMS anticipates the introduction of new NCPDP values on claim responses from Part D plan sponsors that will allow dispensing entities to be made aware of specific claims that were priced at or below the MFP amount and therefore be able to create an accounts receivable for anticipated manufacturer retrospective refund payments, as applicable.

CMS is considering how to address claim adjustments and reversals. As noted earlier, CMS plans to explore shortening the time in which Part D plan sponsors submit PDE data to DDPS to facilitate timely payment. CMS expects some time to elapse between the dispensing entity billing the Part D plan and submission of clean PDE data to the MTF, and this time could allow for timely adjustments to submitted claims, such as reversals. However, CMS recognizes that adjustments and reversals could occur after the 14-day prompt MFP payment window has concluded. CMS envisions claim adjustments or reversals would entail transmission of additional data elements and reports with payment-related data when a change to original payment is warranted, based on an adjustment claim. These elements would inform the Primary Manufacturer of payments it owes or that are due based on claim adjustments. CMS has included these additional data elements (i.e., MTF internal claim number (ICN), Record ID, MTF XRef ICN, Process Date, Transaction Code, and Medicare Claim Type) in Table 1 above, and believes they will assist in the facilitation of information on claim adjustments and reversals. CMS invites comments on whether CMS should recognize a certain timeframe for paying or collecting claim adjustments, whether these should be considered as offsets to future claims to a dispensing entity that was overpaid, and any additional approaches commenters may wish to see from the MTF data functionality for addressing claim adjustments.

40.4.2 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.[50] Under section 1193(d)(2) of the Act, the Primary Manufacturer is required to provide access to the MFP to

[50] Hereinafter, and solely for the purpose of this draft 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.

340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.

A Primary Manufacturer that provides access to the MFP for a selected drug (whether via prospective discount or retrospective refund) is not required to provide a 340B ceiling price on that same selected drug claim if the MFP is lower than the 340B ceiling price. That is, these price concessions are not cumulative, but manufacturers must ensure that the appropriate price concession is honored, consistent with their obligations under section 1193 of the Act, and inclusive of their agreements under section 340B(a)(1) of the PHS Act. CMS expects that the 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 340B drugs, such as separate physical drug inventories or a virtual replenishment model.

To illustrate how the 340B nonduplication provision would apply, we first reiterate the MFP prompt pay requirement under section 40.4.1 of this draft guidance, that the MFP must be passed through to the dispensing entity 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 Primary Manufacturer indicates 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 provide 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 section 40.4.1 of this draft 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 1193(d)(1) of the Act, the Primary Manufacturer would indicate so when reporting payment elements to the MTF and declining to pay the refund within the 14-day prompt MFP payment window. 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 draft guidance.

CMS has received requests from numerous interested parties for CMS to assume responsibility for "deduplicating" the 340B ceiling price and the MFP. CMS understands that these requests for CMS to undertake deduplication 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), and 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.[51]

In light of numerous factors such as those outlined below, CMS will not, at this time, assume responsibility for deduplicating 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 payment elements to the MTF, as described in section 40.4.1 of this draft 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 will continue to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under 1193(d)(1) into MTF processes in the future and welcomes comment on this approach.

If it is subsequently determined that the individual who is dispensed a selected drug was a 340B-eligible patient and received access to the MFP, and the 340B ceiling price for the selected drug is determined to be lower than the MFP, then the Primary Manufacturer will need to promptly provide to the 340B covered entity dispensing the 340B drug the difference between the MFP (which was already provided by the Primary Manufacturer to the dispensing entity) and the 340B ceiling price. In this instance, the Primary Manufacturer will not need to report to the MTF that it provided the 340B covered entity the difference between the MFP and the 340B ceiling price. The Primary Manufacturer would not be required to also replenish that full stock for the 340B covered entity or contract pharmacy at the 340B ceiling price, as the Primary Manufacturer already provided the MFP to the dispensing entity. To the extent dispensing entities choose to voluntarily and proactively indicate on a submitted claim that the claim is 340B-eligible,[52] the MTF would pass along the 340B indication to the 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 a 340B-eligible claim. A Primary Manufacturer continues to be responsible for statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. A Primary Manufacturer also continues to have potential 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.

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[51] The deduplication function described here would be primarily proactive in nature and, for purposes of this discussion, is separate and distinct from any functions that may be performed in the context of the dispute or complaint process or in the enforcement context.

[52] 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 draft 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.

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 (i.e., 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. CMS is soliciting comments on the policies in this section requiring Primary Manufacturers to make the MFP available in a nonduplicated amount to the 340B ceiling price.

40.4.3 Retrospective Refund Amount to Effectuate the MFP

As described previously in this draft guidance, the 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 providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP within the 14-day prompt MFP payment window. In calculating the retrospective refund amount, CMS recognizes the significant challenges that manufacturers and dispensing entities face in attempting to establish a reliable acquisition cost for a selected drug that could be used to determine the difference between the MFP and the dispensing entity's acquisition cost.

For example, using each individual dispensing entity's actual acquisition cost for each particular dispensed unit of a selected drug would 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 parties. As discussed in section 40.4.1 of this draft guidance, CMS will provide Primary Manufacturers with a Standard Default Refund Amount 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. CMS recognizes, however, that this standardized pricing metric may not apply universally and that the Primary Manufacturer is ultimately responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP.

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 Standard Default Refund Amount), 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. CMS is considering approaches to allow parties to notify each other and CMS that they agree a retrospective payment of the Standard Default Refund Amount is sufficient to provide access to MFP on a particular claim or category of claims.

To calculate the retrospective MFP refund amount owed by the Primary Manufacturer to a dispensing entity, the parties may use a reasonable, standardized pricing metric as the dispensing entity's acquisition cost in the MFP refund amount payment calculation (as reflected below).

MFP Refund Amount = Standardized Pricing Metric – MFP

In this draft guidance, CMS intends for the MTF to use WAC, as published in pharmaceutical pricing database compendia on the date of dispensing, as the standardized pricing metric to calculate the Standard Default Refund Amount. As described in section 40.4.1 of this draft guidance, the MTF will provide the Primary Manufacturer with the Standard Default Refund Amount (i.e., WAC minus MFP) as part of the transmitted data elements. The Primary Manufacturer may elect to use the Standard Default Refund Amount, as appropriate, to calculate and make the retrospective MFP refund payment to dispensing entities. WAC, as defined by section 1847A(c)(6)(B) of the Act, is the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. WAC is a widely available pricing metric, published and regularly updated in large pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process, and that does not require the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates between parties.

In response to the Medicare Drug Price Negotiation Program Initial Memorandum for initial price applicability year 2026,[53] 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. 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 development of this draft guidance, CMS considered other options for a standardized pricing metric to calculate the Standard Default Refund Amount, including National Average Drug Acquisition Cost (NADAC), Average Wholesale Price (AWP), and Average Sales Price (ASP). CMS maintains that WAC is the best

[53] 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 https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

option to calculate the Standard Default Refund Amount for the MTF payment facilitation functionality for the reasons stated above and due to the support expressed by interested parties.

As discussed in section 40.4.1 of this draft guidance, the obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP rests with the Primary Manufacturer. A Primary Manufacturer can choose to refund an amount different than the Standard Default Refund Amount if the Primary Manufacturer determines some other amount is appropriate to make the MFP available (e.g., the dispensing entity purchased the selected drug at a cost above WAC). The Primary Manufacturer will need to indicate on the report with payment-related data that an MFP refund was made and indicate the "Method for Determining MFP Discount/Refund Amount" used to determine the MFP refund amount, as described in section 40.4.1 of this draft guidance. For any claim for which the Primary Manufacturer refunds an amount different than the Standard Default Refund Amount, the Primary Manufacturer will also need to maintain documentation, as described further in section 90.2 of this draft guidance, regarding its basis for determining the amount refunded and how it meets the Primary Manufacturer's obligation to make the MFP available to the dispensing entity. 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 payment elements provided by the Primary Manufacturer to the MTF.

For example, as mentioned above, the Standard Default Refund Amount may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug. In this case, payment of the Standard Default Refund Amount would 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. The Primary Manufacturer could address these circumstances by making MFP refund payments that reflect the dispensing entity's higher acquisition costs for the claims. CMS is soliciting comments from interested parties on which dispensing entities may be impacted by this scenario, when the described scenario may occur, and evidence a manufacturer and dispensing entity might review to determine acquisition costs higher than WAC.

As set forth in section 90.2.1 of this draft 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 applicable dispensing entity's actual acquisition cost or a reasonable proxy for such a cost, such as WAC (e.g., the Standard Default Refund Amount). Additionally, as described in section 40.4.1 of this draft guidance, the Primary Manufacturer would be required to indicate that a different amount was made available by indicating the correct justification code under the "Method for Determining MFP Discount/Refund Amount" payment element and indicating the distinct "Amount of Payment Sent as the MFP Refund" when reporting payment elements to the MTF. In section 40.4.4 of this draft guidance, CMS provides details on ways the MTF may be able to facilitate payments by the Primary Manufacturer.

40.4.4 Options for Medicare Transaction Facilitator Payment Facilitation

CMS has received many requests from a wide variety of interested parties to support payment facilitation. Interested parties have presented CMS with a range of views on why MTF payment facilitation is important, including standardization, predictability, and limitation of burden to involved parties. Section 1193(a)(3)(A) of the Act makes it the sole responsibility of the Primary Manufacturer to provide access to the MFP. However, while the statute does not provide CMS with an express role to support manufacturer effectuation of the MFP, CMS has considered what role the MTF could fill in facilitating transactions between Primary Manufacturers and dispensing entities. Thus, CMS is considering how the MTF could offer some form of a voluntary payment facilitation functionality.

The purpose of a voluntary MTF payment facilitation functionality would be to connect the Primary Manufacturer to the dispensing entity, so that the Primary Manufacturer could provide a retrospective refund to the dispensing entity as required to make the MFP available in accordance with section 1193(a)(3) of the Act and within the 14-day prompt MFP payment window.

CMS is soliciting comment on two distinct payment facilitation options that are outlined in this section of draft guidance. The first option would involve the MTF collecting banking information from participating dispensing entities and providing that information to Primary Manufacturers electing to receive such information in order for the Primary Manufacturer to provide payment to those accounts. The second option would involve the MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating dispensing entities. CMS anticipates technical specifications of both options to evolve as voluntary payment facilitation operations move through acquisition and information system development.

CMS reiterates that the Primary Manufacturer must participate in the MTF for the purposes of data exchange with the MTF, as discussed in section 40.4.1 of this draft guidance, to receive certain claim-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual, initiate the 14-day prompt MFP payment window, and provide reports with payment-related data to the MTF confirming whether MFP refunds have been issued. Separately, any potential payment facilitation functionality of the MTF would be voluntary for dispensing entities and Primary Manufacturers, and neither party would have to pay any fees to participate as CMS would bear the cost of operationalizing the MTF. To participate in the MTF's payment facilitation functionality, dispensing entities and Primary Manufacturers would need to opt-in by agreeing to the terms of an MTF payment facilitation participation agreement. As discussed in section 90.2.1 of this draft guidance, the Primary Manufacturer would also need to indicate whether it would participate in the MTF payment facilitation functionality in its written plan for making the MFP available.

Regardless of which option CMS may choose to pursue for the MTF's voluntary payment facilitation functionality, participating dispensing entities would be required to furnish the MTF with banking information and maintain the accuracy of that information over time. The Primary Manufacturer would be the sole manufacturer authorized to participate in MTF payment facilitation for its selected drug, and it would be the sole manufacturer permitted to authorize

contracted third-party vendors to act on its behalf to support payment delivery to dispensing entities for that selected drug.

Information collected from the participating dispensing entity in order to facilitate payment between the Primary Manufacturer and the dispensing entity could include but would not be limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or National Provider Identifier (NPI); (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) depositor account number with financial institution; and (6) type of registered financial account. Participating dispensing entities would need to certify that information provided is accurate and up to date. CMS would further outline contractual requirements for collecting, using, sharing, and safeguarding financial information in the effectuation of MFP refund payments for parties who voluntarily elect to participate in MTF payment facilitation and would protect interested parties' data in accordance with applicable laws. 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 MTF payment facilitation. CMS is soliciting comments on what information would be required by interested parties in either of the two options in order to efficiently facilitate payments.

In instances where a dispensing entity believes that a refund provided through use of the optional MTF payment facilitation functionality was not made or was not sufficient to provide access to the MFP, CMS encourages the dispensing entity to work with the Primary Manufacturer to resolve any issues with payment. 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 draft guidance. If a complaint is filed, CMS will take the steps outlined in section 90.2.2 and may issue a decision regarding whether or not the MFP was made available to the dispensing entity. In a circumstance where CMS determined that MFP was not made available, CMS may decide to assess CMPs, as discussed in section 100.1 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable. In a circumstance where CMS has elected Option 2 below for MTF payment facilitation, and a dispensing entity and Primary Manufacturer determine that additional payment needs to be made through the MTF payment functionality in order to make the MFP available, then the Primary Manufacturer must inform the MTF so the original claim can be adjusted.

Nothing in this section precludes a Primary Manufacturer and a dispensing entity from reaching agreements outside of the MTF on the effectuation of the MFP, even if both utilize the MTF voluntary payment facilitation functionality for other payment arrangements (e.g., a Primary Manufacturer uses the MTF voluntary payment facilitation functionality to pay refunds to some dispensing entities but not others). A dispensing entity could work directly with a Primary Manufacturer outside of the MTF to establish an adjusted refund amount based on the dispensing entity's acquisition costs. In these cases, as described in section 40.4.1 of this draft guidance, the Primary Manufacturer would indicate on the report with payment-related information that the MFP refund was made and the method for determining the MFP refund amount, ensuring that the dispensing entity has access to the full MFP and that the Primary Manufacturer fulfills the

statutory requirements to make the MFP available. The following discussion describes in detail the two MTF payment facilitation functionality options CMS is considering.

Option 1: MTF Collects and Shares Banking Information to Facilitate Private Transactions

Through CMS' engagement with interested parties, both manufacturers and dispensing entities have expressed the concern that they typically do not have direct financial relationships with one another. That is, manufacturers do not typically sell goods directly to dispensing entities, and dispensing entities typically purchase from pharmaceutical wholesalers, not directly from manufacturers. In considering the range of potential options for MTF payment facilitation, CMS, through the MTF, could address the resulting challenge to interested parties by serving as a repository for participating dispensing entities' up-to-date bank account information that would be shared and used by Primary Manufacturers to provide MFP refund payments to participating dispensing entities' registered bank accounts.

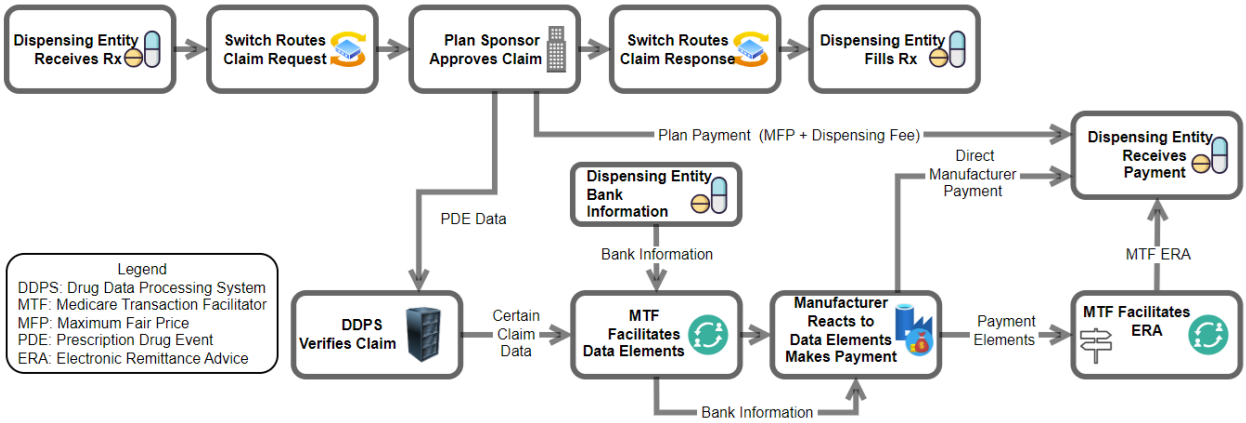
This first option for payment facilitation being considered by CMS, referred to throughout this draft guidance as Option 1, is an attempt to address the lack of connection between Primary Manufacturers and dispensing entities. Under Option 1, the MTF would not transfer funds between parties directly. Instead, the MTF would collect and share participating dispensing entities' bank account information with participating Primary Manufacturers as part of the data elements transmitted by the MTF to facilitate the Primary Manufacturer's direct transfer of funds itself (or through a contracted third-party) to participating dispensing entities. Dispensing entities would only be required to provide bank account information, such as account numbers and bank routing information, to the MTF if they elected to opt-in to the MTF payment facilitation.

Examples of the type of bank account information that would be required for collection are referenced earlier in this section 40.4.4. To operationalize this information transfer, CMS would create a portal where dispensing entities would voluntarily create a profile with their contact and financial account information, and the MTF would share this account and contact information with Primary Manufacturers volunteering to receive the information, along with the file of MTF data elements for each MFP-eligible claim that all Primary Manufacturers will receive according to section 40.4.1 of this draft guidance, and transmission of which initiates the 14-day prompt MFP payment window. The provided data elements also would include a distinct data element indicating to the Primary Manufacturer which dispensing entities participate in this option of MTF payment facilitation.

To provide up-to-date bank account information under this approach, the CMS portal would require participating dispensing entities to share and update, as necessary, their bank account information with the MTF. The dispensing entity would sign an agreement with the MTF contractor allowing the MTF to share this information with Primary Manufacturers to facilitate MFP refund payment. Under Option 1, participating Primary Manufacturers would have to create their own arrangements for establishing MFP refund payment issuance mechanisms (or contract with a third-party solution) to pay dispensing entities. Under this option, neither CMS nor the MTF would receive and distribute funds between parties. An illustration of the described operational flow of Option 1 is in Figure 2 below**.**

CMS recognizes the limitations of Option 1. Due to the high volume of claims for selected drugs, compounded by the number of dispensing entities across the country (roughly greater than 60,000 community pharmacies and other dispensing entities), Option 1 would require Primary Manufacturers to make a high number of direct transactions either themselves or through a contracted third party. Further, dispensing entities would need to track and receive a high number of transactions from a variety of different Primary Manufacturers or their contracted entities. Moreover, the number of Primary Manufacturer transactions would be expected to increase over time as the number of drugs selected for negotiation increases. However, CMS also believes that Option 1 provides Primary Manufacturers with the greatest flexibility in how to operationalize payments across a highly variable dispensing entity landscape and addresses interested parties' concerns that Primary Manufacturers would not be able to identify dispensing entities for timely payment. Combined with the reporting of payment framework outlined in section 40.4.1 of this draft guidance, under Option 1, the MTF would provide Primary Manufacturers with all minimum necessary information to provide refunds to participating dispensing entities and could foster a wide variety of market-driven payment solutions. CMS is soliciting comments on Option 1, including how interested parties would utilize the information provided under this option and what additional details or considerations might be necessary to ensure efficient transfer of refunds from Primary Manufacturers to dispensing entities.

Figure 2: Diagram of MTF Payment Flow Option 1



Option 2: MTF Pass Through of Primary Manufacturer Funds to Dispensing Entities

In the second option, referred throughout this draft guidance as Option 2, CMS would receive aggregated MFP refund amount payments from participating Primary Manufacturers and pass through such payments to participating dispensing entities utilizing bank account information collected by the MTF. In addition to concerns from interested parties that manufacturers typically do not interface directly with dispensing entities, both dispensing entities and manufacturers have expressed interest in a single platform for transmitting refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments. To the extent possible, Option 2 would attempt to address this interest.

CMS reiterates that while the MTF payment facilitation functionality may be useful in assisting a participating Primary Manufacturer in making refund payments to participating dispensing

entities, the statute places the responsibility to make the MFP available solely on the Primary Manufacturer. Under Option 2, the MTF's facilitating role in passing through any refund payments from the Primary Manufacturer to participating dispensing entities would not supersede or alter the Primary Manufacturer's statutory obligation to effectuate the MFP. Moreover, the MTF's transfer of the Primary Manufacturer's authorized payment to a dispensing entity does not in any way indicate or imply that the MTF or CMS agrees that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity.

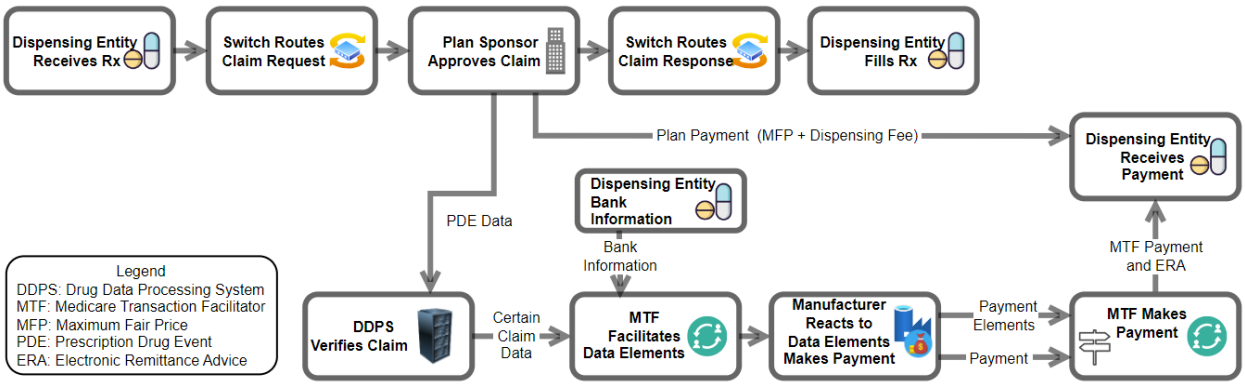
Under Option 2, to the extent dispensing entities choose to participate in the MTF payment facilitation functionality, the participating Primary Manufacturer would authorize a payment amount to those dispensing entities through the MTF interface, subject to a payment facilitation participation agreement, to comply with the 14-day prompt MFP payment window for MFP-eligible claims.

Contemporaneous with the Primary Manufacturer providing the report with payment-related data to the MTF, the Primary Manufacturer would also authorize a lump sum payment equal to the total refunds to be paid in the report with payment-related data and any necessary payment adjustments, to be paid through the MTF. Once the Primary Manufacturer uploads payment elements to the MTF and authorizes payment, the MTF would route the payment provided from the Primary Manufacturer to the corresponding bank account registered by the participating dispensing entities. The MTF would then forward a payment confirmation to both the dispensing entity and the Primary Manufacturer to demonstrate effectuation of the payment and close out the open transaction. Additionally, under Option 2, the MTF would maintain a record of the execution of payment within the 14-day prompt MFP payment window for every transaction facilitated through the MTF payment functionality to further assist in the dispute and complaint resolution process between interested parties, as described in section 90.2.2 of this draft guidance. Figure 3 provides an illustration of the operational flow of Option 2. Under Option 2, Primary Manufacturers and dispensing entities that voluntarily choose to participate in the MTF payment facilitation functionality would be required to execute participation agreements outlining each party's rights, responsibilities, and potential liabilities associated with the transfer of funds through the MTF. Primary Manufacturers would be responsible for ensuring that reported payment element information is accurate.

The establishment of an MTF payment facilitation functionality has been requested by dispensing entities, manufacturers, and other interested parties to provide a means to effectuate payment between parties in a reliable, predictable, and consistent manner without significant burden or cost to interested parties. As discussed above, the MTF payment facilitation functionality would be optional for both the Primary Manufacturer and the dispensing entity. In the event one or both parties choose not to utilize the MTF payment functionality under Option 2, then any MFP refund payments by the Primary Manufacturer to the dispensing entity would be provided outside of the MTF through a process agreed to by the Primary Manufacturer and the dispensing entity. Thus, there likely would still be some contracting between Primary Manufacturers and dispensing entities outside of the MTF for payment. It should be noted that the Primary Manufacturer has ultimate responsibility to make the MFP available under section

1193(a)(3) of the Act to a dispensing entity regardless of participation in any payment facilitation functionality. However, CMS would expect that a majority of Primary Manufacturers and dispensing entities would opt-in, given prior interested party feedback requesting such functionality, creating a single platform for the majority of MFP-eligible claims nationally and reducing burden on Primary Manufacturers and dispensing entities. CMS is soliciting comments from interested parties on Option 2, including any specific operational concerns with Option 2 and additional details or considerations that might be necessary to streamline operations. CMS is also soliciting comments on the likelihood that Primary Manufacturers and dispensing entities would utilize such functionality if provided by the MTF.

Figure 3: Diagram of MTF Payment Flow Option 2



General Requirements of Payment Facilitation

CMS reiterates that the statute places the responsibility to make the MFP available solely on the Primary Manufacturer. The options under consideration for MTF payment facilitation functionality are intended only to provide a mechanism to assist the Primary Manufacturer in making the MFP available to the dispensing entity; the MTF's facilitating role would not supersede or alter the Primary Manufacturer's statutory obligation to effectuate the MFP. Neither CMS nor its contractor administering the MTF would be responsible for funding or paying the refund amount 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.).

Given the range of potential issues that may arise under either payment facilitation option and the importance of establishing robust processes and safeguards when facilitating the transfer of funds, the rights, responsibilities, and potential liabilities of participating parties as well as the third-party vendors contracted to provide MTF payment services would be subject to participation agreements executed and maintained through an enrollment process. Because the MTF payment facilitation functionality would be intended only to facilitate transactions between Primary Manufacturers and dispensing entities, under no circumstances would federal funds be used to resolve or make payment related to disputes that may arise between parties participating in the MTF, including with respect to nonpayment or insufficient payment by a particular party.

The MTF payment facilitation functionality would serve only to transfer funds of the Primary Manufacturer to dispensing entities as directed by the Primary Manufacturer in the amounts authorized by the Primary Manufacturer and would not collect funds for any other use. Under either MTF payment facilitation option, a Primary Manufacturer that elects to participate would need to opt in for each selected drug it manufactures and pay MFP refunds to dispensing entities that elect to opt into MTF payment, unless a process to provide MFP access is agreed upon by both parties outside of the MTF.

Under both MTF payment facilitation options under consideration, as set forth in section 90.2.1 of this draft guidance, a Primary Manufacturer would indicate to CMS its intention to use the MTF payment facilitation functionality as part of the Primary Manufacturer's written submission describing its plan to make the MFP available.

As discussed in section 40.4.1 of this draft guidance, the MTF would provide Primary Manufacturers with information on which dispensing entities have elected to participate in the MTF payment facilitation and identify any dispensing entities that have dispensed the selected drug to MFP-eligible individuals but have not elected to participate in MTF payment facilitation. This does not absolve the Primary Manufacturer of its responsibility to make MFP available to that dispensing entity.

CMS is soliciting comments on which MTF payment facilitation option interested parties believe would be preferable based on the discussion provided in this section of guidance. CMS is also soliciting comments on any other functionality interested parties believe would help facilitate timely refunds between Primary Manufacturers and dispensing entities to effectuate the MFP.

40.4.5 Medicare Transaction Facilitator Dispensing Entity Participation Requirements

Under either MTF payment facilitation functionality option under consideration in section 40.4.4 of this draft guidance, the Primary Manufacturer and the dispensing entity each may choose not to utilize the MTF for facilitation of retrospective refund payments. However, even if the Primary Manufacturer chooses not to utilize the MTF for payment facilitation, it is still required to utilize the MTF for data exchange as discussed in section 40.4.1 of this draft guidance.

In the event that one or both parties has elected not to participate in the potential payment facilitation services that may be provided through the MTF, then any 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, as described in the Primary Manufacturer's MFP availability plan required under section 90.2.1 of this draft guidance, and will be subject to the 14-day prompt MFP payment window and other applicable requirements for MFP effectuation in this draft guidance. Selected drugs that are prospectively purchased at or below the MFP will not require a retrospective refund.

If a dispensing entity chooses to utilize the MTF for payment facilitation, and CMS pursues either of these options, the dispensing entity would register with the MTF and provide information to enable accurate payment facilitation, including account information to receive payments as detailed in section 40.4.4 of this draft guidance. CMS notes that in either option,

dispensing entities that elect to participate would be required to register with the MTF and furnish certain information, including account information as discussed in section 40.4.4 of this draft guidance. Dispensing entities that utilize the MTF for payment facilitation would be encouraged to do so for all selected drug claims where Primary Manufacturers offer access to the MFP through the MTF. Neither Primary Manufacturers nor their contracted entities shall charge dispensing entities any transaction or other fees for the data exchanges facilitated through the MTF.

Dispensing entities, whether choosing to utilize any potential MTF payment facilitation functionality or not, are encouraged to use the MTF complaint and dispute process, as described in section 90.2.2 of this draft guidance, so that CMS is alerted to situations where MFP may not have been made available.

As discussed in section 40.4.1 of this guidance, CMS is contemplating a method to send an electronic remittance advice to dispensing entities. CMS envisions that it would provide electronic remittance advices to dispensing entities because these remittances would serve as the most comprehensive tool for a dispensing entity to track money owed from Primary Manufacturers. CMS expects that dispensing entities would maintain records accounting for any refunds owed by a Primary Manufacturer should they engage in the dispute or complaint resolution process envisioned in section 90.2.2 of this draft guidance. As the approach for creating and sending electronic remittance advices to dispensing entities is developed, additional participation requirements for dispensing entities may be necessary to support the transmission of this information.

If a dispensing entity chose to utilize the MTF payment facilitation functionality and later decides to no longer utilize it or modifies the selection of drugs for which it will use the MTF payment facilitation, the dispensing entity must notify CMS of this decision at least 90 calendar days prior to the effective date of the change. In addition to soliciting comments on participation requirements presented in this section, CMS is soliciting comments on other potential considerations for facilitation services that may be provided through the MTF for dispensing entities, such as circumstances that might constitute a breach of the dispensing entity's participation agreement or timing requirements to initiate a dispute.

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.

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 in the subsequent 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 draft 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 imply that a Primary Manufacturer need not comply with Negotiation Program requirements and will not affect 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 draft 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 draft 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 9 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 draft 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 CGDP 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 CGDP and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(A)(i), and (2) an attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer (a) shall not seek to enter into any subsequent agreement with any such program and (b) shall not seek

coverage for any of its drugs under the CGDP under section 1860D-14A of the Act or 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).[54] A Primary Manufacturer later seeking to re-enter any applicable agreement or obtain coverage for any of its drugs under the CGDP or 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 CGDP or 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 draft 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 CGDP or 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 CGDP 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 CGDP and the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14A(b)(4)(B)(i) and 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-14A or section 1860D-14C and thus facilitate an expedited Termination Date.

Moreover, consistent with the process described in section 40.1 above, 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 CGDP and 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.

[54] 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. Those steps 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 pursuant to the preceding paragraph, such that an 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 draft 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 (e.g., not treated as part of the same employer under subsections (a) and (b) of section 52 of the IRC of 1986) 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 draft 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 draft 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 draft 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) 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).

CMS intends to publish the Negotiation Data Elements ICR for initial price applicability year 2027, to be titled 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")[55] in the Federal Register for a 60-day public comment period during summer 2024, followed by a revised version of the ICR with a 30-day comment period. The 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 will incorporate lessons learned pertaining to the collection process, question format, and content received from respondents for initial price applicability year 2026.[56]

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 draft guidance.

In accordance with sections 1191(d)(5)(A), 1194(b)(2)(A), and 1193(a)(4)(B) of the Act, the data described in sections 50.1 and 50.2 of this draft guidance for drugs selected for initial price

[55] CMS intends to include 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 60.4.2 of this draft 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.

[56] The Negotiation Data Elements ICR for initial price applicability year 2026 was approved as CMS-10847, OMB 0938-1449).

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 draft 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 draft 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 draft 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 draft 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 Drug Price Negotiation Data Elements and 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 draft guidance. Details on how CMS defines the parameters of the non-FAMP data collection are included in Appendix A of this draft guidance and will be included in the Drug Price Negotiation Data Elements and Drug Price Negotiation Process ICR for initial price applicability year 2027.

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.[57] 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), as well as with section 1182(e) of Title XI of the 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)[58]), 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 therapeutic alternatives, as described in detail in section 60.3.1 of this draft 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),

[57] 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.

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 intends to improve upon the collection process, question format, and content received for initial price applicability year 2026 with the forthcoming Negotiation Data Elements and Drug Price Negotiation Process ICR for initial price applicability year 2027. For example, CMS may group 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 is also considering revising questions within these categories; for example, pertaining to patients' conditions, CMS is considering requesting 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 is considering requesting section 1194(e)(2) evidence specific to the FDA-approved indications[59] 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 draft 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-aged populations, as particularly important. In considering impact on specific populations and

[59] For purposes of the ICR, Appendix A of this draft 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.

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 draft 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 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 counteroffer, the potential for up to three negotiation meetings between CMS and the Primary Manufacturer, 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), 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 draft 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 draft 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 draft 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 draft 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 to 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 draft 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 draft 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 draft guidance, an amount equal to the sum of the plan-specific enrollment weighted amounts; or
- As described in section 60.2.3 of this draft 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;[60] 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-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

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

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 draft 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 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 draft 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 we are 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;[61] (2) total gross covered prescription drug costs on the PDE record is greater than $0; (3) the PDE record is considered final action;[62] and (4) the drug coverage status code indicates the PDE record is for a covered Part D drug. An additional fifth 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 draft guidance).[63]

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.

[61] 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.
[62] A PDE record is considered final action based on the final action indicator for the claim and claim line.
[63] 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[64] found in the PDE data that meet the criteria for inclusion detailed in section 60.2.1 of this draft 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.[65]

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 draft 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 draft 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 draft 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.[66] The Part D plans included in both calculations of step 5 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.

[64] CMS will identify Part D plans based on the combination of the Part D contract identifier and the plan benefit package identifier.

[65] 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.

[66] 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,[67] 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;[68] 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 draft 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 draft guidance) for each quarter of calendar year 2021 to calculate an annual average non-FAMP per unit for calendar year 2021.

[67] 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.
[68] 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, we 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 draft guidance. As described in section 60.2.1 of this draft 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 draft 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 draft 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 draft 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.[69]

[69] 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 draft 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 draft 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 draft 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 50.1.1 of this draft 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 draft 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 percentage are described below 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 4: Monopoly Types and Applicable Percentage for Initial Price Applicability Year 2027

Monopoly Type	**Definition**	**Applicable Percentage**	**Note**
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[70]	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.

[70] 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)	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 draft 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 would 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. The lower amount will be compared against the sum of the plan-specific enrollment weighted amounts to determine the ceiling for each selected drug for initial price applicability year 2027, as described in section 60.2.4 of this draft guidance.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS would compare the lower amount of the applicable percent of the average non-FAMP as determined in section 60.2.3 of this draft guidance to the amount calculated in step 10 of section 60.2.2 of this draft guidance (sum of the plan-specific enrollment weighted amounts) to determine the lower amount, which would 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 draft 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) 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 draft 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"[71]) for the therapeutic alternative(s), and/or the Average Sales Price (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 draft 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 draft 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 draft 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

[71] Once CGDP is phased out and the Medicare Part D Manufacturer Discount Program takes effect, the Net Part D 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[72] 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.[73]

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 draft 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

[72] For purposes of this section of the draft guidance and the Negotiation Data Elements and 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 draft guidance.

[73] 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 draft guidance), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule[74] (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 or ASP 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). 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 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.

[74] 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.

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, ASPs, or MFPs 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 initial offer 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. 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 draft 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"[75] 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, this starting point will not exceed the statutory ceiling and will be subject to adjustments as described further below.

60.3.3 Adjusting the Starting Point Based on Section 1194(e)(2) Factors[76]

[75] 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.

[76] 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

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 draft guidance, and data identified through a CMS-led literature review. CMS may also analyze Medicare claims or other datasets, or request 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 the FDA. As described in section 60.4 of this draft 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 of this draft 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 consider the identified outcomes, including patient-centered outcomes,[77] and patient experience

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.

[77] 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.)

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), 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 draft guidance, as well as in the patient-focused events described in section 60.4.

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 draft 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 nonbinding recommendations in the FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics,"[78] as well as any updates that may be issued by FDA

[78] 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.

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 a selected drug to represent a therapeutic advance if evidence indicates that the selected drug represents 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,[79] however, other drugs may have become available since the selected drug's initial approval. In accordance with section 1194(e)(2)(A) of the Act, CMS will review the analyses detailed above for each indication for the selected drug and its therapeutic alternative(s) and determine, based on the relevant information and evidence, what the difference in clinical benefit is between the selected drug and the 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 the clinical benefit the selected drug provides (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 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. A selected drug may be considered a

[79] 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.

therapeutic advance when the selected drug represents 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 draft 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 data reported by the Primary Manufacturer, as described in section 50.1 of this draft 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 draft 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 draft 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 whether 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 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 draft 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 draft 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 draft 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.

After the submission of the section 1194(e) data by 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 and other interested parties. 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 will also host patient-focused events to seek verbal input from patients and other interested parties. These events will be intended to bring together patients, beneficiaries, caregivers, and consumer and patient organizations as well as other interested parties to share patient-focused feedback with CMS on patient experiences with the conditions or diseases treated by the selected drugs as well as 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 intends to improve upon the design of the patient-focused listening sessions from initial price applicability year 2026 and is soliciting comments from interested parties on event format, scope, and logistics. For patient-focused events for initial price applicability year 2027, CMS is considering events where there is discussion among speakers and in which CMS may ask clarifying questions. CMS is also weighing different event formats, such as round table sessions on broader topics with a mix of speaker types (e.g., patients, providers, and health data experts) or focus groups on targeted topics with one speaker type (e.g., patients or caregivers), and CMS is particularly interested in comments on events that promote discussion versus listen-only events. CMS is also considering combining events for selected drugs that treat like condition(s) / disease(s), instead of having drug-specific events, or organizing events based on another factor.

Instead of livestreaming these events, CMS is considering publishing an event summary or, as CMS provided following the initial price applicability year 2026 patient-focused listening sessions, sharing a redacted transcript afterwards. A redacted transcript would omit names and other identifying data for patients, patient advocacy organization representatives, and family members/caregivers according to the Safe Harbor de-identification method under the HIPAA Privacy Rule.[80] Furthermore, CMS understands that patient-focused listening sessions conducted by FDA are not livestreamed. However, CMS is soliciting feedback on the tradeoff between maximizing participation in events and promoting access and transparency for these events by enabling livestreaming functionality, including the option of audio-only livestreaming. CMS would appreciate comments on methods to mitigate any barriers to participation for patients and other interested parties.

[80] See: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#safeharborguidance.

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

In accordance with section 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the 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.

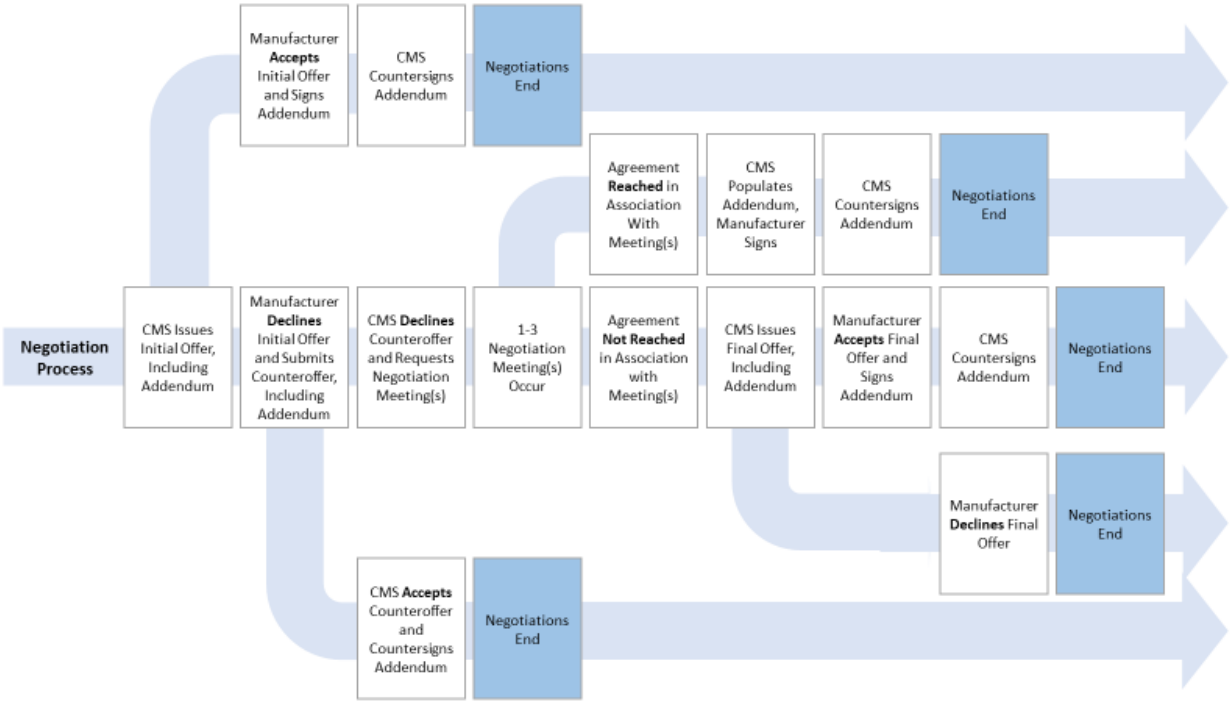
After the written initial offer from CMS is sent to the Primary Manufacturer, the negotiation process may include the following steps, depending on when and whether agreement on the MFP is reached and an offer is accepted:

(1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer, including an Addendum populated with the counteroffer price as described in section 60.4.2 of this draft guidance, from the Primary Manufacturer (if CMS' written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer from CMS;
(2) in accordance with section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written manufacturer counteroffer, which CMS will provide within 30 days of receipt or within 60 days of sharing the initial offer, whichever is later;
(3) if the Primary Manufacturer's written counteroffer is not accepted by CMS, pending input from the comment solicitation in section 60.4.3 of this guidance, possible 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; and
(4) a final written offer, including an Addendum containing the final offer price as described in section 60.4.4 of this draft guidance, made by CMS to the Primary Manufacturer, if no agreement is reached before the end of the negotiation meetings.

Every offer and counteroffer will include an Addendum populated with the offered/counteroffered price. If an agreement is reached at any point during the negotiation process by the Primary Manufacturer accepting CMS' written initial offer or final offer (as described in section 60.4.4 of this draft guidance), CMS accepting the Primary Manufacturer's counteroffer, or an agreement being reached in association with the negotiation meetings, the Addendum to the Agreement, as described in section 40.3 of this draft guidance, will be executed by both parties and will constitute agreement on the MFP. Section 60.4.4 of this draft guidance describes how and when the Addendum will be created and signed. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2027 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 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 4: Possible Negotiation Paths[81]



During the entire negotiation process, CMS cannot offer or agree to any manufacturer counteroffer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and as described in section 60.2 of this draft 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 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 draft guidance further address possible actions to address noncompliance.

60.4.1 Provision of an Initial Offer and 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 draft guidance. The justification will include a qualitative

[81] This graphic depicts possible negotiation paths and may be revised in final guidance in response to the comment solicitation regarding the negotiation process in section 60.4.3.

description of the factors from section 1194(e) (further described in sections 50 and 60.3 of this draft guidance) and a description of the methodology that CMS used to determine the initial offer. 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) that CMS found compelling during the development of the initial offer, thereby providing the Primary Manufacturer with information to build a 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 information, PHI / PII, other information that is protected from disclosure under other applicable law, or the starting point.

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 draft 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 draft guidance. As described in section 40.2.3 of this draft guidance, CMS may reach out to the Primary Manufacturer for clarity on its data submission if CMS determines the information is not complete or accurate. In situations when additional outreach to the Primary Manufacturer is required to clarify the submitted data such that there are delays in CMS receiving necessary data, CMS may be delayed in providing information on the calculation of the statutorily-determined ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer. In these situations, CMS will aim to provide this information as close to 45 days from the subsequent submission of data necessary to perform these calculations, as feasible. As described in section 40.5 of this draft 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 price and the provision of these NDC-level price applications does not constitute a separate offer.

60.4.2 Required Components of a Counteroffer

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 written counteroffer and providing a justification for such counteroffer based on the data described in section 50 of this draft guidance. Any counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the elements described in section 1194(e) 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 alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS. Primary Manufacturers may also include in their counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) that supports the counteroffer price.

The Primary Manufacturer should provide a suggested counteroffer price for the selected drug in its written counteroffer. As described in section 60.1 of this draft guidance, the counteroffer price should be made consistent with the manner that CMS' written initial offer was made; that is, a single price 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 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 draft guidance.

CMS intends to publish a Negotiation Data Elements and Drug Price Negotiation Process ICR for initial price applicability year 2027, as described in section 50 of this draft guidance. The 60-day notice for this ICR will be published in summer 2024. CMS will publish the Negotiation Data Elements and Drug Price Negotiation Process ICR for 60-day comment to capture information related to the counteroffer that a Primary Manufacturer may submit after receiving CMS' initial offer. The Negotiation Data Elements and Drug Price Negotiation Process ICR will include instructions and a form for a Primary Manufacturer to submit a written counteroffer in the case where CMS' written initial offer price for a selected drug is not accepted.

In order for a written counteroffer to be considered complete, a Primary Manufacturer must complete an Addendum in the CMS HPMS in addition to filling out the Counteroffer Form in the CMS HPMS, as described in section 40.3 of this draft guidance. A completed Addendum would include, but is not limited to, the MFP the Primary Manufacturer is counteroffering and a signature by an authorized representative.

60.4.3 Negotiation Process After Manufacturer Counteroffer

In accordance with section 1194(b)(2)(D) of the Act, CMS will respond in writing to a written counteroffer made by the Primary Manufacturer. Although the statute does not specify a timeframe for CMS' response to the 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, 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 written counteroffer, CMS will consider the counteroffer and either accept or reject it in writing within 30 days of receipt of the counteroffer or within 60 days of sharing the initial offer, whichever is later. When considering a 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. If CMS' written response to the counteroffer rejects the Primary Manufacturer's written counteroffer, CMS will extend an invitation to the Primary Manufacturer for a negotiation meeting. CMS will offer to hold a

minimum of one meeting between CMS and the Primary Manufacturer to discuss CMS' written initial offer, the Primary Manufacturer's written counteroffer, and data considered. After this initial meeting, CMS will give each party (CMS and the Primary Manufacturer) the opportunity to request one additional meeting, resulting in a maximum of three meetings between CMS and the Primary Manufacturer. Compared to initial price applicability year 2026, statutory requirements for initial price applicability year 2027 indicate that CMS will select up to 15 drugs, which represents a potential increase in the number of selected drugs, and provide for an approximately one-month shorter timeframe between the statutory deadline for the Primary Manufacturer to respond to CMS' initial offer and the statutory end of the negotiation period. Accordingly, CMS acknowledges that conducting up to three negotiation meetings between CMS and the Primary Manufacturer in time for CMS to issue a final offer, if needed, and for the Primary Manufacturer to review and respond to any final offer, may present challenges (and may become increasingly challenging as the number of potentially selected drugs increases in future years). CMS is considering changes to the number and format of these negotiation meetings and is soliciting comments from interested parties on the most efficient and effective approach to facilitating negotiation within the statutory deadlines, including whether three meetings are necessary and whether it would be preferable to contemplate an additional written offer to be made in lieu of one or more meetings.

The scope for these negotiation meetings will focus on the section 1194(e) data, including the therapeutic alternative(s) for the selected drug, and how they should inform the 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 HHS headquarters. 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 be 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 draft 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 via email at least one week ahead of the meeting. While the agency intends to limit substantive discussion to the negotiation meetings, we anticipate 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 counteroffer and before the end of the statutory negotiation period.

The meetings for initial price applicability year 2027 will occur between the time the Primary Manufacturer's written counteroffer is not accepted by CMS, which will be within 30 days of receipt of the counteroffer or within 60 days of sharing the initial offer, whichever is later, if applicable, and September 30, 2025. There would be about two months' time between CMS' rejection of the Primary Manufacturer's written counteroffer (approximately July 31, 2025) 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 in association with the negotiation meetings), 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 draft 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.

As described in section 60.6.1 of this draft 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 draft guidance.

60.4.4 Determination that Negotiations Have Finished

In accordance with section 1194(b)(2)(E) of the Act, all negotiations between CMS and the 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 that negotiation meetings occurred, and an MFP was not agreed to in association with the negotiation meetings, 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 in association with the negotiation meetings. 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 5 details CMS' timing for the negotiation process for initial price applicability year 2027.

Table 5: Negotiation Process Milestones for Initial Price Applicability Year 2027

Date[82]	**Milestone**
June 1, 2025	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer
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 written counteroffer to CMS
30 days after receipt of the manufacturer 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 counteroffer is made on July 1, 2025)	Date by which CMS will provide a written response accepting or rejecting the manufacturer counteroffer
Date that the Primary Manufacturer's written counteroffer is not accepted by CMS through September 30, 2025 (the last business day that is 15 days prior to October 15, 2025)	Negotiation meetings (in-person, virtual, or hybrid; maximum of three possible meetings), if necessary

[82] These dates are contingent on CMS and the Primary Manufacturer meeting the deadlines described in this draft 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 written counteroffer was not accepted and an MFP was not agreed upon in association with the negotiation meetings
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

To formalize agreement on an MFP, CMS and the Primary Manufacturer both sign an Addendum to the Agreement (described in sections 40.3 and 60.4 of this draft guidance) that sets forth the agreed-upon MFP. 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 written counteroffer is not considered complete unless the Primary Manufacturer submits a complete response to the Counteroffer Form (as described in the forthcoming Negotiation Data Elements and Drug Price Negotiation Process ICR) in the CMS HPMS, submits an Addendum for the MFP consistent with the counteroffer amount in the CMS HPMS, and signs that Addendum. If CMS accepts the written counteroffer, CMS will countersign the Addendum.

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 draft 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 draft 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-14A or 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 draft 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 draft 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 dispensers, 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 draft guidance.

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 draft 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; and (4) the drug coverage status code indicates the PDE record is for a covered Part D 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 draft 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 draft 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 draft 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 to NDCs with Insufficient PDE or WAC Data in Calendar Year 2024

Based on the definition of a qualifying single source drug described in section 30.1 of this draft 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 after the drug has been selected, CMS requires that the MFP apply to NDCs of the drug or biological products marketed pursuant to the new NDA or BLA. 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 requires that the MFP apply to the NDCs of such new drug or biological product and new NDC. Additionally, an NDC that has been marketed pursuant to an applicable NDA or BLA prior to drug selection 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, 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 NDC that lacked 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.[83]

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 draft guidance). The MFP file will contain the single MFP for a 30-day equivalent supply of the selected drug, the NDC-9 per unit price, and 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. 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.

[83] 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.

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 (until renegotiation), 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 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, a selected drug with an agreed-upon MFP may cease to be a selected drug and no longer subject to an MFP if a generic drug or a biosimilar for the reference drug is approved or licensed by the FDA and—as discussed in section 70 of this draft guidance—is bona fide marketed. CMS further recognizes that, in accordance with section 1194(f) of the Act, the MFP for a selected drug may also change due to renegotiation beginning in initial price applicability year 2028 (in the case of a renegotiation-eligible drug selected by the Secretary pursuant to section 1194(f)(3) of the Act). Guidance about MFPs for drugs subject to renegotiation will be forthcoming in future years of the Negotiation Program.

CMS requests comment on the potential MFP file layout, web file structure, and definitions document that have been posted to the CMS IRA website. CMS also requests comment on the following targeted considerations:

- Preferences on file maintenance to account for changes in MFPs and the addition of NDC-11s over time (e.g., a single file that maintains all historical information for each NDC-11 of a selected drug or a current file with an archived website where historical file versions can be found);
- Other data fields that would be necessary to successfully effectuate the MFP; and
- How potential revisions to file(s) should be handled to address situations where MFPs would need to be retroactively applied to reprocess selected drug claims.

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 will 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 draft 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 draft 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, 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 draft 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 draft 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 draft 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 draft 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), 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 draft 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 draft 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 draft 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 draft 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) 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 6.

Table 6: 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 (which includes 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 draft 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) 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 dispenser, 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,[84] 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 draft guidance for additional details). CMS anticipates this information will include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information.

During the negotiation period, CMS will track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. To facilitate successful Negotiation Program operations and support manufacturer compliance with Program requirements, CMS will issue reminder letters prior to manufacturer deadlines with warnings of potential applicability of the excise tax (see 26 U.S.C. § 5000D for additional information regarding the excise tax) or CMPs (see section 100 of this draft guidance). CMS may also provide written requests for clarifications, corrections, and/or additional information following data submissions; written requests for corrective action, as applicable (see section 40.2.3 of this draft guidance); written notification that a Primary Manufacturer may be subject to enforcement action, as applicable; and written confirmation that a Primary Manufacturer may no longer be subject to enforcement action, as applicable.

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). As described in section 100 of this draft guidance, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in CMPs.

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,

[84] 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.

or other dispensing entity with respect to such MFP-eligible individuals who are dispensed the selected drug. 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, but is not obligated to make 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 draft guidance, CMS requires that the Primary Manufacturer establish safeguards 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 draft guidance.

If CMS determines through audits, investigations, or complaints from dispensing entities or other market participants, that the Primary Manufacturer has not fulfilled its obligation to make MFP available within the 14-day prompt MFP payment window, CMS will encourage the Primary Manufacturer to address any payment discrepancies as soon as possible. Failure to take action in these cases may result in CMS issuing the appropriate CMPs as set forth in section 100.1 of the revised guidance for initial price applicability year 2026 or this draft 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 to use the complaint and dispute process set forth in section 90.2.2 of this draft guidance to alert CMS of any discrepancies.

As described in section 40.4 of this draft guidance, in 2026 and 2027, CMS will engage with an MTF 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. The MTF may also provide optional facilitation of retrospective payment from participating Primary Manufacturers to participating dispensing entities to help effectuate access to the MFP. CMS describes two potential options for MTF payment facilitation in section 40.4.4 of this draft guidance.

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 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 draft 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.[85] 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 and 40.4.3 of this draft guidance, the Primary Manufacturer is responsible for calculating a refund amount for each MFP-eligible claim and reporting payment elements with a justification code indicating the method of calculation of that refund amount. This includes the reasons considered in section 40.4.1 of this draft guidance for an MFP refund payment amount that differs from the Standard Default Refund Amount, 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 40.4.2 of this draft 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 Standard Default Refund Amount, were filled with selected drugs prospectively purchased at or below MFP, or meet the exception under section 1193(d)(1) of the Act. As noted in section 40.4.1 of this draft guidance, CMS expects Primary Manufacturers to indicate such claims in the reported payment elements, and to maintain documentation justifying the indication and payment.

For claims identified as paid at a refund amount other than the Standard Default Refund Amount, Primary Manufacturers will be required to maintain supporting documentation demonstrating why MFP refunds were provided at an amount other than the Standard Default Refund Amount or were not provided for applicable claims. CMS would expect Primary Manufacturers to maintain documentation that includes evidence reflecting the dispensing entity's actual acquisition cost or demonstrating a better approximation than WAC of the dispensing entity's acquisition cost. This could include, but would not be limited to, invoices from the dispensing

[85] Section 40.2 of the revised guidance for initial price applicability year 2026 and of this draft 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 draft guidance describes how CMS will apply the MFP if new NDCs are added for the selected drug list. Section 60.6 of the revised guidance for initial price applicability year 2026 and section 60.6 of this draft 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 draft guidance describe the MFP publication timeline that CMS will follow in the event of late action from the Primary Manufacturer.

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, CMS would expect 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. CMS is soliciting comments on what documentation interested parties feel should be necessary to demonstrate the need for a refund other than the Standard Default Refund Amount.

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 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 with payment-related data 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 has reasonable grounds to believe, 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 could include, at a minimum, either the Primary Manufacturer's process and conclusion from its 340B deduplication process, or confirmation from a 340B covered entity or any vendor the 340B covered entity employs to determine 340B status that the claim was processed as 340B-eligible. 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 Health & Human Services enforcement mechanisms outside of the complaint and dispute process described in section 90.2.2 of this draft guidance to pursue corrective action in order to receive the 340B ceiling price. CMS is soliciting comments on these documentation requirements.

In particular, CMS is interested in feedback on whether each documentation type listed above would, on their own, be sufficient to demonstrate 340B eligibility of a claim, as well as whether other documentation types should be added to this list. If the Primary Manufacturer submits the indication in the report with payment-related data and maintains adequate documentation to justify its nonpayment and promptly pays 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 promptly pay the dispensing entities with 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 Standard Default Refund Amount that the Primary Manufacturer identified in the report with payment-related data. Primary Manufacturers will maintain the documentation that justifies its

nonpayment, or its payment of a refund amount other than the Standard Default Refund Amount, and deliver documentation to CMS, if requested, for the purposes of auditing and monitoring compliance with the Negotiation Program. CMS will also monitor the status of claims paid at the Standard Default Refund Amount and may require documentation confirming 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 draft guidance, that the Primary Manufacturer has not made MFP available within the 14-day prompt MFP payment window, CMS will encourage the Primary Manufacturer to provide payment necessary to effectuate the MFP as soon as possible. Failure to take action in these cases may result in CMS issuing the appropriate CMPs as set forth in section 100.1 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable.

90.2.1 Manufacturer Plans for Effectuating MFP

Consistent with section 40.4 of this draft guidance, the Primary Manufacturer may make MFP available, including to 340B covered entities and their contract pharmacies consistent with section 40.4.2 of this draft 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, including its process for deduplicating 340B covered units (pursuant to section 1193(d) of the Act and section 40.4.2 of this draft guidance) for the selected drug, in writing to CMS at least seven 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. 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 draft guidance. Primary Manufacturers with plans that CMS identifies as having a greater risk of failing to make MFP consistently available will be subject to increased scrutiny through CMS' monitoring and oversight activities.

In addition to the items noted above, 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. To promote transparency and preparedness for MFP effectuation among pharmaceutical supply chain entities, CMS intends to publish these plans on the CMS IRA website and will redact proprietary information in those plans. 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 June 1, 2025 in this draft guidance. For selected drugs with a first initial price applicability year of 2027, written submission of the plan will be due by June 1, 2026. A Primary Manufacturer must notify CMS in writing of any changes to its plan for making the MFP available at least 90 days before the change goes into effect, 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 June 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 they do so at least 90 days before the start of 2027.

All plans submitted by Primary Manufacturers, whether using any potential MTF payment facilitation functionality or not, will be assessed for their consistency with the requirements set forth in sections 40.4 through 40.4.5 of this draft guidance. CMS expects 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 reimbursing dispensing entities, 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), and confirmation that it will submit verification of reimbursement to the MTF via the report with payment-related data discussed in sections 40.4.1 and 40.4.3 of this draft guidance, as required for purposes of administering and monitoring compliance with the Negotiation Program consistent with section 1193(a)(5) of the Act.

Specific examples of criteria CMS has identified as important to make MFP available include, but are not limited to, a Primary Manufacturer's data transmission method to return reports of payment to the MTF, frequency of report with payment-related data transmission if something other than 14 days after transmission, payment method, procedures for making payment of refunds, calculation of refund amounts for reimbursements not consistent with the Standard Default Refund Amount, and 340B deduplication method. 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.

The plan should also include how Primary Manufacturers will ensure that their process for making the MFP available will comply with all applicable data privacy and security laws, regulations, policies, and CMS requirements. Examples of other key areas that should be addressed in a Primary Manufacturer's plan include, but are not limited to, its method for addressing MFP refund obligations by Secondary Manufacturers (as applicable) and procedures for record keeping and reporting MFP availability. CMS plans to request Office of Management

and Budget approval for an Information Collection Request (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.

A Primary Manufacturer's written submission describing its plan to make the MFP available must include whether it will participate in the potential MTF payment facilitation functionality. If a Primary Manufacturer chooses to use the potential MTF payment facilitation functionality, 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 40.4.4 of this draft guidance and any applicable participation agreement with the MTF. Because participation in the potential MTF payment facilitation would be voluntary both for Primary Manufacturers and dispensing entities, the Primary Manufacturer's written submission also will need to indicate its general plan and procedures for contacting and reimbursing dispensing entities. Individual dispensing entities may also choose how they are reimbursed, and CMS would expect the Primary Manufacturer to work with dispensing entities to ensure functionality between the Primary Manufacturer's reimbursement mechanism and the dispensing entities' reimbursement acceptance mechanism in order to satisfy the Primary Manufacturer's statutory responsibility to make the MFP available. Consistent with standard business practices, dispensing entities should review their accounts receivable and determine whether a Primary Manufacturer has both paid all the claims the dispensing entity believes are MFP-eligible claims and in the amounts the dispensing entity believes are accurate to effectuate the MFP. Dispensing entities may use the complaint process described in section 90.2.2 of this draft guidance to raise any identified issues with the payment amount. In addition, a dispensing entity is expected to be responsive to a Primary Manufacturer's inquiries into their preferred payment method (e.g., account or process) if they are declining to use the MTF payment facilitation functionality. A Primary Manufacturer should maintain documentation of its attempts to contact nonresponsive dispensing entities and may use this documentation as part of the complaint and dispute process set forth in section 90.2.2 of this draft guidance.

For a Primary Manufacturer that chooses to utilize prospective purchasing, CMS will require the Primary Manufacturer to submit to the MTF, at a minimum, the NPIs of the dispensing entities that are prospectively purchasing and the effective date for when any prospective purchases will begin occurring (e.g., prospective purchases will begin on July 1, 2026, and the MTF should anticipate receiving data from that date forward). If a Primary Manufacturer were to cancel, significantly amend, or create new contracts related to the prospective purchasing of units, then the effective dates of such contracts should be no sooner than 90 days from the signature date. The Primary Manufacturer should immediately submit an amendment to its plan to make MFP available, consisting only of the changes to its prospectively purchased units. If a Primary Manufacturer is unable to provide the 90-day notice due to an issue specific to the contract for prospectively purchased units (e.g., cannot agree to an effective date 90 days later), then CMS will accept the amendment as soon as practicable. In the event that the Primary Manufacturer wishes to engage or disengage in allowing prospective purchasing at any time after the submission of their initial plan, the Primary Manufacturer must submit an updated plan to CMS at least 90 days prior to the engagement or disengagement.

If a Primary Manufacturer and dispensing entity maintain a reimbursement or purchasing arrangement that changes after the submission of the plan, CMS will require an update to the Primary Manufacturer's submission at least 90 days prior to the effective date of the new arrangement. If a Primary Manufacturer is unable to provide an updated reimbursement or purchasing arrangement within the 90-day notice due to a specific contracting issue, then CMS will accept the amendment as soon as practicable.

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. The Primary Manufacturer's written submission describing its plan to ensure MFP availability is considered to be the procedures it is actively using to ensure that MFP is made available, and would be superseded only when the Primary Manufacturer has submitted a new plan with the required 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 draft guidance.

90.2.2 Negotiation Program Complaints and Disputes

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 related to other HHS benefits programs will be directed to the appropriate review mechanism. While reports of difficulty using, or errors related to, MTF data and/or potential payment system functionality are also received in this process, the complaints and disputes process described in this section and referenced in this draft guidance is a distinct process that is available to parties notwithstanding their degree of participation in any aspect of the MTF.

The complaint and dispute system 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 manufacturers or dispensing entities regarding a technical aspect of the MTF process. The second track is a complaint process that will intake complaints, will be available to both 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.

Upon receipt of a reported issue, an initial triage will be conducted to route the concern to the appropriate track. While the MTF may be involved in facilitating the resolution of disputes and

complaints related to its data exchange and potential 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. CMS is exploring mechanisms to enable the appropriate handling and referral of disputes and complaints that present evidence of potential noncompliance so that these can be effectively and timely remediated by CMS.

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 participating dispensing entities suggesting an error in the calculation of their Standard Default Refund Amount. 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 interested parties participating in MTF data or potential payment facilitation functionality. For this type of complaint, CMS expects that the MTF contractor would provide helpdesk functions and resolve these types of issues promptly to ensure that the system operates smoothly without input or further evaluation from CMS, including communicating the solution to the submitting party. CMS envisions that the MTF helpdesk would be a way for the MTF contractor 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 retrospective refund payment that effectuates the MFP. 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. Complaints related to a lack of MFP availability would not necessarily require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability. Investigations may lead to enforcement action, as described in section 100 of the revised guidance for initial price applicability year 2026 or this draft 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 related to whether or not MFP was made available. CMS may request that the Primary Manufacturer provide documentation related to attempts to make the MFP available. If the Primary Manufacturer provides documentation showing that good faith attempts were made to make the MFP available, but the transaction was unable to be completed (e.g., because the dispensing entity provided inaccurate or out-of-date bank account information), CMS may take evidence of good faith into account when completing the investigation and deciding whether to pursue an enforcement action.

CMS is still exploring the limits on the scope of disputes and complaints that the agency may remediate in the context of an otherwise private transaction between the Primary Manufacturer and dispensing entity. In addition, CMS is currently exploring the most efficient way to receive reports of complaints and disputes and welcomes comment.

90.3 26 U.S.C. Section 5000D Excise Tax on Sale of Designated Drugs

The IRS will administer the excise tax. CMS understands the Department of the Treasury is in the process of rulemaking to establish regulations that govern the administration of the excise tax.[86] Accordingly, CMS is not soliciting comment on this section.

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 draft 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 draft 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

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[86] *See* Excise Tax on Designated Drugs; Procedural Requirements, 88 Fed. Reg. 67690, available at https://www.federalregister.gov/documents/2023/10/02/2023-21586/excise-tax-on-designated-drugs-procedural-requirements and Notice 2023-53; *See also*, 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.

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.

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 who 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, 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. Section 100.2 sets forth examples of such potential substantive violations.

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 draft 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 the Small Biotech Exception and the Biosimilar Delay Rule. This draft 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 draft 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 draft 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 (the requirements for which are further described in sections 40.4.1 and 90.2 this draft guidance); or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (the requirements for which are further described in section 40.4.3 of this draft guidance). 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. CMS will monitor the WAC in relation to other pricing metrics. Upon discovery and confirmation of a failure to make the MFP available, 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. CMS will establish an informal 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.

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 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

draft guidance. As described in section 40.5 of this draft 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) or fails to provide the information required under section 1193(a)(4) may be subject to a CMP of $1,000,000 for each day of such violation. 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. Examples of such violations are shown in Table 7 below. 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 7: Examples of Substantive Violations

Category	Example of Substantive Violations
Manufacturer Information Submission	• 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. • 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). • 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) 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 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 draft guidance). • Failure to process timely and complete reimbursement under a retrospective reimbursement structure as described in section 40.4 of this draft guidance.

One example of when CMS may impose a CMP is if a 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 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, if the Primary Manufacturer fails to timely submit the required information, CMS would engage in outreach, as well as a corrective action process (as described in section 40.2.3 of this draft guidance) to address the failure. If the issue is not mitigated following outreach and the corrective action process, CMS may choose to assess a CMP. In a case where a CMP is pursued, CMS will determine 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 Primary Manufacturer's good-faith engagement with CMS to rectify the noncompliance. The CMP will accrue for each day of the violation thereafter until the day the Primary Manufacturer 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).

CMS may require additional information to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. This may include recurring reporting (for example, providing evidence that MFP is being made available), or specific ad hoc requests for information related to targeted monitoring or auditing efforts. When applicable, CMS will provide a written request to the Primary Manufacturer with details for 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 extension 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 applicable, will be granted for each request. Manufacturers that fail to comply with requests for information required to administer or monitor compliance with the Negotiation Program on or before the due date may be subject to a CMP.

In the event the manufacturer does not meet the final established deadline to provide the requested information and CMS determines a CMP is warranted, the CMP will begin to accrue beginning on the day after the due date. For example, if CMS requests information for monitoring purposes by November 15, 2029, day one of the violation would be November 16, 2029. Each additional day of violation thereafter will be counted until the day the Primary Manufacturer 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 the information is submitted. Because the day of data submission is not included in CMP calculation, should a Primary Manufacturer submit the requested information on the day after the deadline, no CMP will be imposed.

To facilitate program operations and support manufacturer compliance, CMS will provide the Primary Manufacturer with: (1) written reminders of impending submission deadlines, including warning of potential liability for a CMP for submission violations; and (2) a Notification of Potential Noncompliance, if applicable, and the applicable next steps (see, for example, sections

40.2.3 and 100.1 of this draft guidance). If CMS determines a violation warrants a CMP, CMS will follow the procedures outlined in section 100.4 of this draft guidance to notify the Primary Manufacturer and initiate the CMP process.

A Primary Manufacturer that submits false information that is required under the Agreement and interferes with the administration of the Negotiation Program will be out of compliance with the requirement to submit information and may be subject to this 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.

100.3 Provision of False Information Related to the Small Biotech Exception and the Biosimilar Delay Rule

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) for the Small Biotech Exception, such manufacturer may be subject to a CMP equal to $100,000,000 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 Biosimilar Delay, such manufacturer may be subject to a CMP equal to $100,000,000 for each item of such false information.

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) 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 impose 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 Primary Manufacturer's right to a hearing (see below); and

- Information about where to file the request for a hearing.

In applicable cases (e.g., failure to provide required information), CMS will note the commencement date for a CMP accrual and alert the manufacturer that the daily CMP will continue to accrue until the period of noncompliance ends. CMS will send monthly noncompliance notices to the manufacturer during the noncompliance period to include the total amount of CMP accrued to date, the amount that will continue to accrue should the violation continue and required actions on the part of the Primary Manufacturer to mitigate the noncompliance period (e.g., submission of required information), if applicable.

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.

The CMP amount will cease to accrue once the manufacturer has demonstrated compliance with the requirement(s) at issue in the relevant CMP Notification. For accruing CMPs, following the end of the noncompliance period, and for all CMPs at the conclusion of any appeals process initiated by the Primary Manufacturer within 60 days of the CMP Notification, CMS will issue the final CMP Notification. As required by section 1128A of the Act, the final notification will add the following to the information included in the initial CMP Notification and monthly noncompliance notices:

- The final amount of the penalty;
- The date the penalty is due; and
- Instructions for submitting the CMP payment.

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.[87] For contract year 2027, CMS intends to continue the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 (described in this section of the draft guidance). 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

[87] 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).

provisions take effect in 2025 that may affect Part D plan sponsors' benefit and formulary design choices, but CMS does not yet have information on plan formularies for contract year 2025. 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 intends to continue monitoring Medicare Part D plans' compliance with all applicable formulary requirements and treatment of selected 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 intends to 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 might not warrant the same formulary placement 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.[88]

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 draft 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 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,

[88] 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.

2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

The 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 Part B and Part D Drug Inflation Rebate Program, 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.[89] MFP is excluded from AMP and thus does not affect the rebate calculation.[90]

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 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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[89] 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.

[90] Section 1927(k)(1)(B)(i)(VI), as amended by section 11001(b)(3) of the Inflation Reduction Act.

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 draft guidance, CMS applies the following definitions and standards. As described in section 50 of this draft guidance, CMS intends to publish the Negotiation Data Elements Information Collection Request (ICR) for initial price applicability year 2027, to be titled 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),[91] which 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).

CMS is soliciting comments from interested parties on potential revisions to definitions in this Appendix A that would further standardize and improve the consistency of submitted information across the selected drugs, facilitate CMS' interpretation of the submitted information, and reduce the reporting burden on Primary Manufacturers.

General

- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment.[92] 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 C.F.R. § 205.3).
- Labeler code: The first segment of the FDA-assigned NDC. Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to

[91] CMS intends to include 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 for purposes of initial price applicability year 2027 (see sections 50 and 60.4.2 of this draft guidance). CMS intends to publish the joint ICR titled 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 in the Federal Register for a 60-day public comment period during summer 2024, followed by a revised version of the ICR for a 30-day comment period.

[92] 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.

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 section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.[93] 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 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.[94] 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).

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[93] 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).

[94] See: https://www.va.gov/opal/docs/nac/fss/pl102585-2024-pbm-fcp-guidance-for-new-covered-drugs.pdf.

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 (IND) Application 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:

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.[95, 96] 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

[95] CMS acknowledges that the exact date of initial discovery might not be known, but Primary Manufacturers should use their best estimate.
[96] 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.

of the first IND application that went into effect as the end date for the 52-month period.[97]

- 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 (compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect basic pre-clinical research costs and relevant general and administrative 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.[98, 99] 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-Investigational New Drug (IND) Application 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, post-marketing trials that are conducted after the FDA has approved a product. Post-IND costs exclude FDA-required, post-marketing 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, 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

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[97] 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.

[98] 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.

[99] 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.

data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, post-marketing trial.
- 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 post-marketing 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.
- 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 (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, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

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 post-marketing trials that were not completed, Phase IV post-marketing studies for FDA-approved indications that were not required by FDA, post-IND costs for indications that did not receive FDA approval, and acquisition costs for failed or abandoned products.

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).[100] 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.

[100] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

- 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;
    - 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 October 31, 2024 (for selected drugs for initial price applicability year);
    - 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 parties (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 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 draft 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.

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;[101] utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug.

[101] 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);[102]
    - New Chemical Entity Exclusivity (NCE);[103]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[104]
    - New Clinical Investigation Exclusivity (NCI);[105]
    - Pediatric Exclusivity (PED);[106] and
    - Reference Product Exclusivity for Biological Products.[107]
- Active and pending FDA applications and approvals include all applications for approval under section 505(c) of the FD&C Act or sections 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[108] 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.[109] 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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[102] Section 527 of the FD&C Act.
[103] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[104] Section 505E(a) of the FD&C Act.
[105] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[106] Section 505A(b) & (c) of the FD&C Act.
[107] Section 351(k)(7) of the PHS Act.
[108] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.
[109] 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 price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the net Medicare Part D price as calculated by the Primary Manufacturer. This net Medicare Part D price would include specific data to which the manufacturer has access including coverage gap discounts and other supply chain concessions (e.g., wholesale discounts) not reflected in the sum of the plan-specific enrollment weighted amounts calculation, and utilization that may differ from the PDE data. The net Medicare Part D price 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 different medicine 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 pharmacological class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action as well as considering therapeutic alternatives in other drug 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: A selected drug may be considered a therapeutic advance when evidence indicates that the selected drug represents a substantial improvement in outcomes compared to the selected drug's therapeutic alternative(s) for an indication(s). In cases where there is no therapeutic alternative, a selected drug may be considered a therapeutic advance when there is a substantial improvement in outcomes for the condition or disease state treated by the selected drug. CMS will consider the extent to which a selected drug represents a therapeutic advance.
- 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 will 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, including patient-centered outcomes when available, to the extent that these outcomes correspond with a direct impact on individuals taking the drug. The caregiver perspective will be considered when there is a direct impact on the individuals taking the selected drug or therapeutic alternative.
- 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.[110]
- 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,

[110] 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).

ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[111]

- 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.[112] 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.

[111] See: https://www.cms.gov/pillar/health-equity.

[112] 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.