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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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DATE: May 12, 2025

TO: Interested Parties

FROM: Chris Klomp, 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SUBJECT: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Draft Guidance on the Medicare Drug Price Negotiation Program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 to consider opportunities to bring greater transparency to the Negotiation Program. Through this draft guidance, CMS seeks to gather input from a broad range of interested parties regarding the implementation of the Negotiation Program for initial price applicability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 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. Public feedback on all aspects of the negotiation process and manufacturer effectuation of the MFP is critical to achieving the goals of greater value for beneficiaries and taxpayers and continuing to foster innovation. CMS is committed to learning from, collaborating with, and engaging the public, including patients, consumer advocates, health and data experts, and pharmaceutical supply chain entities in the policy-making process.

[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.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the Department of Health and Human Services (hereinafter "the Secretary") to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this draft guidance for implementation of the Negotiation Program for initial price applicability year 2028, including for renegotiation, and for manufacturer effectuation of the MFP in 2026, 2027, and 2028. To improve program transparency, CMS is also voluntarily soliciting comments on the topics in this draft guidance, except section 90.3.[2] Across the document, CMS is soliciting comments on areas of policy where additional feedback is requested to inform future policy.

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 June 26, 2025 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 2028 and for manufacturer effectuation of the MFP in 2026, 2027, and 2028.

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 provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. The statutory directive in sections 11001(c) and 11002(c) thus specifies that CMS shall follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute. Congress underscored this directive by placing the Negotiation Program in the newly enacted Part E of Title XI of the Act.

This draft guidance describes how CMS will implement the Negotiation Program for initial price applicability year 2028 (January 1, 2028 to December 31, 2028), including the renegotiation process for MFPs[3] (whether negotiated or renegotiated) to take effect January 1, 2028. This draft guidance also sets forth additional policies regarding manufacturer effectuation of the MFP in 2026, 2027, and 2028, and specifies the requirements that will be applicable to manufacturers of drugs that are selected for negotiation or renegotiation. Additionally, this draft guidance includes information on the successor regulation exception to the IRA's formulary inclusion requirement for 2027 and 2028. Finally, this draft guidance describes the procedures that may be applicable to drug manufacturers, Medicare Part D plan sponsors (both Prescription Drug Plans (PDPs) and

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[2] CMS is not soliciting comments on section 90.3 of this draft guidance because the Department of the Treasury and the Internal Revenue Service (IRS) issued regulations that govern the administration of the excise tax (see Excise Tax on Designated Drugs; Procedural Requirements, 88 Fed. Reg. 67690, available at https://www.federalregister.gov/documents/2023/10/02/2023-21586/excise-tax-on-designated-drugs-procedural-requirements and Notice 2023-53; see also, 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).

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

Medicare Advantage Prescription Drug (MA-PD) Plans), pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D, in addition to hospitals, physicians, and other providers of services and suppliers that furnish or administer drugs to individuals enrolled under Medicare Part B (including individuals enrolled in Medicare Advantage plans under Part C). 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. Additionally, in final guidance, CMS may make changes to any policies if necessary to incorporate any enacted legislation impacting administration and operations of the Negotiation Program.

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

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

20. Overview

This draft guidance describes how CMS will implement the Negotiation Program for initial price applicability year 2028, building on policies established in final guidance for initial price applicability year 2027 and applying the experience of CMS from the first two cycles of negotiations. As required by law, this draft guidance includes policy to incorporate drugs payable under Part B into the Negotiation Program and implements requirements for renegotiation. This draft guidance also describes refinements to MFP effectuation policies for 2026 and 2027, including adjustments to Medicare Transaction Facilitator (MTF) operations, and the extension of such policies to 2028. Furthermore, this draft guidance establishes the successor regulation exception to the IRA's formulary inclusion requirement for 2027 and 2028. Given the ongoing implementation of this new program throughout 2025, CMS may make additional adjustments in the final guidance to reflect the agency's experience, including experiences through the second cycle of negotiation and preparation for the effectuation of MFPs agreed upon as part of initial price applicability year 2026 negotiations.

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

In accordance with sections 11001 and 11002 of the IRA, which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary is required to establish the Negotiation Program to negotiate MFPs for certain high expenditure, single source drugs covered by Medicare and to renegotiate the MFP for certain selected drugs. With respect to each initial price applicability year, CMS shall: (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) impose civil monetary penalties (CMPs) in accordance with section 1197 of the Act. With respect to initial price applicability year 2028 and subsequent years, CMS shall also: (1) determine renegotiation-eligible drugs; (2) select drugs for renegotiation; and (3)

renegotiate the MFP for any drug selected for renegotiation. To the extent applicable, any references in this draft guidance to the "MFP" includes a renegotiated MFP. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

To allow for public input, CMS is voluntarily soliciting comments on all sections of this draft guidance, except for section 90.3 (which refers to the Department of the Treasury regulations that govern the administration of the excise tax[4]). 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 2028 or for MFP effectuation in 2026, 2027, and 2028 will not be addressed in this guidance. The IRA requires implementation of the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. CMS intends to engage in rulemaking to address program policies related to implementation for initial price applicability year 2029 and subsequent years.

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

Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs for an initial price applicability year. First, CMS will identify qualifying single source drugs in accordance with section 1192(e) of the Act, as described in section 30.1 of this draft guidance. CMS will exclude certain drugs in accordance with section 1192(e)(3) of the Act. Next, in accordance with section 1192(d)(1)(A) of the Act, CMS will use Total Expenditures[5] under Part D of Title XVIII of the Act for these qualifying single source drugs calculated using Part D prescription drug event (PDE) data for dates of service between November 1, 2024 and October 31, 2025, and other information described below, to identify Part D high spend drugs. In accordance with section 1192(d)(1)(B) of the Act, CMS will use Total Expenditures[6] under Part B of Title XVIII of the Act for these qualifying single source drugs calculated using Part B claims data for dates of service between November 1, 2024 and October 31, 2025, and other information described below, to identify Part B high spend drugs. (In these steps, CMS will also exclude certain drugs in accordance with sections 1192(d)(2) and (3) of the Act.) These Part D

[4] See: Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507, available at https://www.federalregister.gov/documents/2024/07/05/2024-14706/excise-tax-on-designated-drugs-procedural-requirements#h-18. 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.

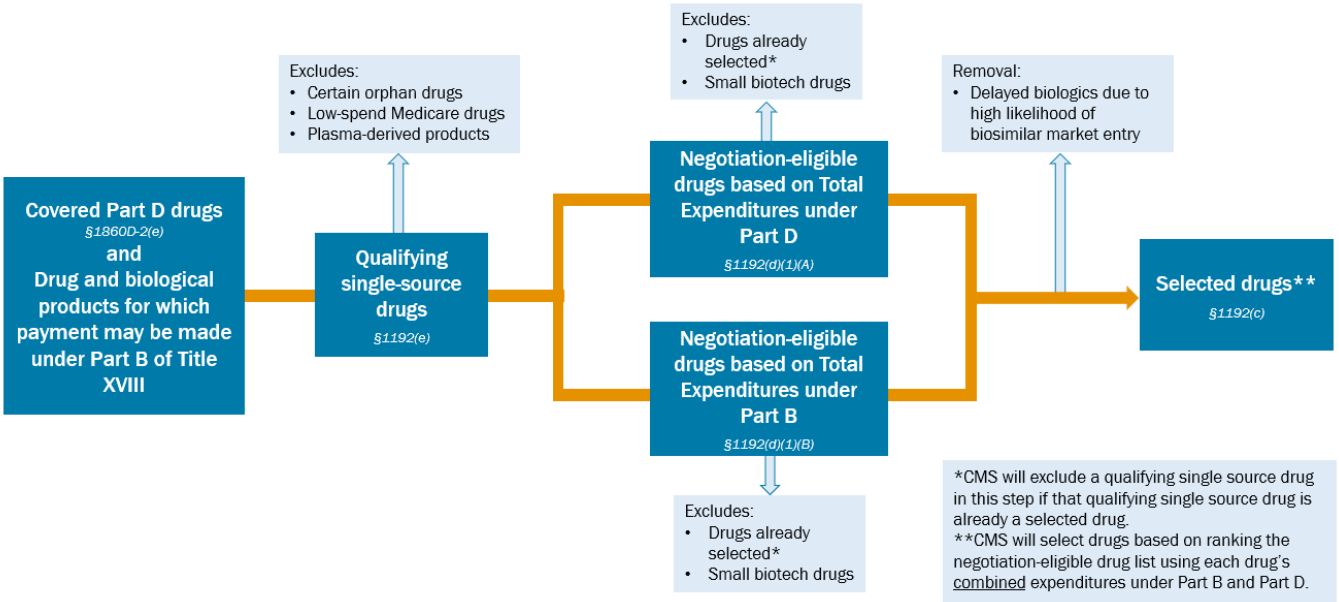
[5] For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) of the Act as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)) of the Act. The term "gross covered prescription drug costs" is also defined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

[6] For the purpose of the Negotiation Program, section 1191(c)(5) of the Act specifies that Total Expenditures under Part B of title XVIII excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service. For the purposes of this draft guidance, CMS will determine Total Expenditures by using Part B claims data to calculate total allowed charges (meaning the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service).

high spend drugs and Part B high spend drugs will be the negotiation-eligible drugs for initial price applicability year 2028 as described in section 30.2 of this draft guidance.

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

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



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

For initial price applicability year 2028, in accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) (hereinafter "a drug covered under Part D") or a drug or biological

product for which payment may be made under Part B of Title XVIII of the Act (hereinafter "a drug payable under Part B") that meets the following criteria:

- For drug products, a qualifying single source drug is a drug: (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the date of such approval; 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.

For biological products whose applications were previously submitted as NDAs and approved under section 505 of the FD&C Act but subsequently deemed to be approved biologics license applications (BLAs) under section 351 of the PHS Act, effective March 23, 2020, pursuant to section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed and marketed as biologics under section 351 of the PHS Act (hereinafter, "deemed biologics"), CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B)(ii) of the Act. This interpretation was adopted for initial price applicability year 2027. For initial price applicability year 2026, no interested party suggested interpreting the statute to make the March 23, 2020 deemed date for biologics the licensure date for this purpose, and CMS treated the earliest NDA approval date as the approval date for purposes of determining the time since approval under 1192(e)(1). Any biologic selected under that approach, including deemed biologics, would have been on market for at least 11 years before selection.

Section 1192(d)(3)(B) of the Act states that CMS shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or package type of the drug 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[7] 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),[8] inclusive of products that are marketed pursuant to different NDAs. If there are multiple NDAs with the same active moiety that include non-identical names reported for the NDA holder, including situations where it appears the NDA holder name has not yet been updated, CMS may further investigate whether such NDA(s) are held by the same entity for the purposes of identifying a potential qualifying single source drug using U.S. Food and Drug Administration (FDA) sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug will also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentences that are: (1) repackaged and relabeled products[9] that are marketed pursuant to such NDA(s); (2) authorized generic drugs (defined in section 1192(e)(2)(B)(i) of the Act and described further below) that are marketed pursuant to such NDA(s); or (3) multi-market approval (MMA)[10] products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);[11]
- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a BLA,[12] inclusive of products that are marketed pursuant to different BLAs. If there are multiple BLAs with the same active ingredient that include non-identical names reported for the BLA holder, including situations where it appears the BLA holder name has not yet been updated, CMS may further investigate whether such BLA(s) are held by the same entity for the purposes of identifying a potential qualifying single source drug using FDA sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug will also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentences that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s); (2) unbranded biological products (see section 1192(e)(2)(B)(ii) of the Act and the description further below) that are marketed

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[7] 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.
[8] As described in section 505(c) of the FD&C Act.
[9] For purposes of the Negotiation Program, the terms "repackage" and "relabel" have the meaning specified in 21 C.F.R. § 207.1.
[10] See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-and.
[11] Any dosage forms and strengths of the drug with the same active moiety that are distributed by a private label distributor and marketed pursuant to such NDAs will also be aggregated in the potential qualifying single source drug of that holder of the NDA.
[12] As described in section 351(a) of the PHS Act.

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).[13]

CMS will identify the active moiety or active ingredient of the drug using public sources such as RxNorm, OpenFDA, FDALabel, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file. CMS may also consult with FDA as appropriate to, for example, clarify whether a suffix or prefix in an ingredient name represents a genuine difference in active ingredient.

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

Table 1: Example Application of NDAs Containing the Same Active Moiety to Identification of a Potential Qualifying Single Source Drug

NDAs containing the same active moiety	**NDCs marketed by Entity A (holder of NDA-1, NDA-2, and NDA-3)**	**NDCs repackaged and marketed by Entity B**
NDA-1	NDC #1, NDC #2, NDC #3	NDC #10, NDC #11, NDC #12
NDA-2	NDC #4, NDC #5, NDC #6	
NDA-3	NDC #7, NDC #8, NDC #9	
12 Total NDCs included in this single potential qualifying single source drug		

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

[13] Any dosage forms and strengths of the biological product with the same active ingredient that are distributed by a private label distributor and marketed pursuant to such BLAs will also be aggregated in the potential qualifying single source drug of that holder of the BLA.

(as such term is defined in section 505(t)(3) of the FD&C Act); and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act[14] and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

If a drug is a fixed combination drug[15] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs. Therefore, all formulations of this distinct combination offered by the same NDA / BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not all) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. For example, a corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA / BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

CMS believes that treating distinct combinations of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs is generally appropriate. However, CMS acknowledges that there may exist fixed combination drugs for which one of the active ingredients or active moieties contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference. An example might include the addition of active moiety / active ingredient X to a different active moiety / active ingredient Y, where active moiety / active ingredient X affects the bioavailability of active moiety / active ingredient Y but is not therapeutically active against the disease state that active moiety / active ingredient Y is indicated for. In this example, the addition of active moiety / active ingredient X does not result in a clinically meaningful difference. CMS is soliciting comments on whether the addition of drugs payable under Part B may impact the fixed combination drug policy described in this draft guidance. In particular, CMS is soliciting comments on how CMS might consider grouping such fixed combination drug products with products containing at least one but not all of the active moiety(ies) / active ingredient(s) into the same potential qualifying single source drug for both drugs payable under Part B and/or covered under Part D, including input on terminology that could facilitate the effectuation of such a policy.

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

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

between the FDA date of approval or licensure of the potential qualifying single source drug, as applicable, and the selected drug publication date. To determine the date of approval for a potential qualifying single source drug that is a drug product with more than one FDA application number, CMS will use the earliest date of approval of the initial FDA application number assigned to the NDA holder for the active moiety (or in the case of fixed combination drugs, for the distinct combination of active moieties). To determine the date of licensure for a potential qualifying single source drug that is a biological product with more than one FDA application number, CMS will use the earliest date of licensure of the initial FDA application number assigned to the BLA holder for the active ingredient (or in the case of fixed combination drugs, for the distinct combination of active ingredients). The selected drug publication date for initial price applicability year 2028 is February 1, 2026, as specified in section 1191(b)(3) of the Act. As such, for initial price applicability year 2028, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before February 1, 2019, and the date of initial licensure for a biological product to be considered a qualifying single source drug must have been on or before February 1, 2015.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and February 1, 2026, then the potential qualifying single source drug defined above would meet this statutory criterion for qualifying single source drugs (even if less than seven years had elapsed between the approval dates for NDA-2 or NDA-3 and February 1, 2026), consistent with the statutory directive in section 1192(d)(3)(B) of the Act to aggregate data across dosage forms and strengths of the drug, including new formulations of the drug.

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 (i.e., a generic drug[16]), and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act (i.e., a biosimilar biological product[17]). CMS will use FDA reference sources, including the Orange Book[18] and Purple Book,[19] to determine whether a generic drug or biosimilar biological product has been approved or licensed for any of the strengths or dosage forms of the potential qualifying single source drugs for initial price applicability year 2028.

CMS will consider a generic drug or biosimilar to be marketed when the totality of the circumstances, including the data specified below, reveals that the manufacturer of that approved generic drug or licensed biosimilar is engaging in bona fide marketing of that drug or biosimilar. In accordance with sections 1192(c) and (e) of the Act, for the purpose of identifying qualifying single source drugs for initial price applicability year 2028, CMS will review PDE data for the

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[16] As used in this draft guidance, the term "generic drug" refers to a drug approved under an ANDA under section 505(j) of the FD&C Act.

[17] 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.

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

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

12-month period beginning January 16, 2025 and ending January 15, 2026, using PDE data available on January 16, 2026, as well as Average Manufacturer Price (AMP)[20] data for the 12-month period beginning December 1, 2024 and ending November 30, 2025, using the AMP data reported to CMS by December 31, 2025, for a given generic drug or biosimilar for which a potential qualifying single source drug is the listed drug or reference product. CMS has chosen these time periods to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time for such data to inform the selected drug list published no later than February 1, 2026, in accordance with section 1192(a) of the Act. For purposes of reviewing additional data that may be applicable to utilization of drugs payable under Part B and/or covered under Part D, CMS is considering reviewing, when available, average sales price (ASP) data, Medicaid State Drug Utilization Data (SDUD), and/or data from a nationally representative and commercially available database. CMS requests comments regarding, which, if any, additional data sources may include timely utilization data for drugs payable under Part B and/or covered under Part D.

The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry based on the totality of the circumstances. The sources of data described in the preceding paragraph, over the specified intervals, will be informative for that inquiry, but CMS' determination will not necessarily turn on any one source of data. Additional relevant factors may include whether the generic drug or biosimilar is regularly and consistently available for 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 generic drug or biosimilar, as articulated further in sections 70 and 90.4 of this draft guidance.

As an example, if a potential qualifying single source drug has at least one approved generic drug or licensed biosimilar that has high and consistent PDE utilization, AMP sales, and/or ASP sales, CMS will consider the generic(s) or biosimilar(s) of the potential qualifying single source drug bona fide marketed. As another example, a potential qualifying single source drug might have a newly or recently approved generic or licensed biosimilar and the product has relatively low PDE utilization, AMP sales, and/or ASP sales. In this example, if CMS finds in additional review of public information that the generic or biosimilar manufacturer has successfully launched their product, and there is no evidence of agreements limiting distribution of the generic or biosimilar product, then CMS will consider the generic or biosimilar product of the potential qualifying single source drug as bona fide marketed. As a third example, a potential qualifying single source drug might have an approved generic or licensed biosimilar product with no PDE utilization, AMP sales, and/or ASP sales. In this example, if CMS finds in additional review of public information that there are ongoing patent disputes and no generic or biosimilar manufacturer has successfully launched their product, then CMS will consider the generic or biosimilar product of the potential qualifying single source drug as not bona fide marketed. While the circumstances illustrated in these examples weigh in favor of, or against, a determination regarding bona fide marketing, CMS' ultimate determination on any particular

[20] "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.

drug will be based on the totality of the circumstances and not on the presence, or absence, of any single factor.

If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar products that CMS determines are approved or licensed, as applicable, and bona fide marketed based on the process described in this draft guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028. If CMS determines that the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028 because a manufacturer of such generic drug or biosimilar product has engaged in bona fide marketing of the generic drug or biosimilar, CMS will monitor to ensure continued bona fide marketing of the generic drug or biosimilar based on the approach described in section 90.4 of this draft guidance.

In identifying qualifying single source drugs, with respect to initial price applicability year 2028, CMS will limit exclusions from qualifying single source drugs to those described throughout section 30.1 above and identified under section 1192(e)(3) of the Act as described below in sections 30.1.1 through 30.1.3.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(A) of the Act, CMS will exclude certain orphan drugs when identifying qualifying single source drugs as described in section 30.1 of this draft guidance ("the Orphan Drug Exclusion"). Specifically, CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication (or indications)[21] 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 determine whether a potential qualifying single source drug qualifies for the Orphan Drug Exclusion, CMS will consider all dosage forms and strengths of the potential qualifying single source drug, as described in section 30.1 of this draft guidance. CMS will use the FDA Orphan Drug Product designation database[22] and information on FDA-approved indications from other publicly available databases and documents (such as FDALabel, FDA Online Label Repository,

[21] 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).

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

Drugs@FDA, and NLM DailyMed[23]) to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the Orphan Drug Exclusion. CMS will also consult with FDA, as appropriate, including to determine whether a drug is designated for only one rare disease or condition, or whether the approved indication(s) is for such disease or condition. In the event that a drug or biological product loses Orphan Drug Exclusion status, pursuant to sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act, CMS will use the date of the earliest approval of the drug or licensure of the biological product (as described above in section 30.1) to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act.

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(B) of the Act, CMS will exclude low-spend Medicare drugs or biological products with combined expenditures under Medicare Part B and Part D less than the inflation-adjusted threshold for the previous initial price applicability year,[24] increased by the annual percentage increase in the consumer price index for all urban consumers (CPI-U)[25] for the 12-month period ending on September 30, 2025, when identifying qualifying single source drugs ("the Low-Spend Medicare Drug Exclusion"). For initial price applicability year 2028, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify PDE data 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, 2024 and ending October 31, 2025. To allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that are available by December 1, 2025. CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug and any Part B claims billed as a compounded drug.[26] To allow a reasonable amount of

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[23] 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/.

[24] The inflation-adjusted threshold for initial price applicability year 2027 was $206,680,981.

[25] The "CPI-U" means the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (https://www.bls.gov/cpi/data.htm).

[26] As described in section 40.4.2.1 of this draft guidance, CMS provides that, for operational reasons at this time for 2026, 2027, and 2028, MFP refunds will not be required for PDE records for selected drugs that were billed as compounds. For alignment, CMS provides in sections 30.1.2, 30.2, 30.2.1, 60.2.1, 60.3.2, and 60.5 of this draft guidance that, for initial price applicability year 2028, PDE records with a compound code indicating the PDE record is for a compounded drug will be excluded from the PDE data used to calculate the low-spend Medicare drug exclusion (section 30.1.2), the ranking of negotiation-eligible drugs (section 30.2), the Small Biotech Exception Total Expenditure calculations (section 30.2.1), the ceiling for the MFP (section 60.2.1), the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative(s) (section 60.3.2), and the application of the MFP across dosage forms and strengths (section 60.5). A PDE record for a selected drug billed as a compound refers to a PDE record with a compound code field equal to "2=Compound." CMS will only use PDE records with a compound code field equal to "1=Not a Compound." A Part B claim billed as a compounded drug refers to Part B claims billed with HCPCS code J7999. For consistency with the treatment of compounded drugs covered under Part D, CMS will also exclude Part B claims billed as compounded drugs when calculating the low-spend Medicare drug exclusion (section 30.1.2), the ranking of negotiation-eligible drugs (section 30.2), the Small Biotech Exception Total Expenditure calculations (section 30.2.1), the ceiling for the MFP (section 60.2.1), and the application of the MFP

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 are available by December 1, 2025.

- 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 (meaning the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service) for purposes of determining Total Expenditures under Part B. Payment for drugs and biological products payable under Part B is made on the basis of claims for units of a drug or biological product's Healthcare Common Procedure Code System (HCPCS) code. Typically, "single source drugs and biologicals" as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes; however, there may be cases where a potential qualifying single source drug is assigned to a HCPCS code with other products. In such cases, CMS will use ASP sales volume data to apportion Part B expenditures based on the ratio of reported sales volume of the potential qualifying single source drug compared to reported sales volume 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.[27] Expenditures for a drug or biological product that are bundled or packaged into the payment for another service will be excluded from the calculation of total allowed charges under Part B.
- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2028 any drugs for which the sum of Total Expenditures under Part B and Part D is less than the inflation-adjusted threshold for the previous initial price applicability year, increased by the annual percentage increase in the CPI-U for the 12-month period ending on September 30, 2025.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(C) of the Act, CMS will exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1 of this 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,[28] and will refer to databases such as FDALabel and the FDA Online Label Repository[29] to verify if the product is derived from human whole blood or plasma. CMS also will consult with FDA, as appropriate.

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across dosage forms and strengths (section 60.5). As stated in section 40.4 of this draft guidance, CMS is not providing detailed policy on providing access to the MFP for selected drugs for which payment may be made under Part B at this time.

[27] As described in sections 30.2 and 30.2.1, CMS similarly will use ASP sales volume data to apportion Part B expenditures for the purpose of identifying whether a qualifying single source drug is a negotiation-eligible drug based on Total Expenditures under Part B and whether a qualifying single source drug qualifies for the Small Biotech Exception in Part B, in cases where a qualifying single source drug is assigned to a HCPCS code with other products.

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

[29] FDALabel: https://nctr-crs.fda.gov/fdalabel/ui/search; FDA Online Label Repository: https://labels.fda.gov/.

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

In accordance with sections 1192(a) and 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2028 is a qualifying single source drug that is among the 50 qualifying single source drugs with the highest Total Expenditures under Part D, or among the 50 qualifying single source drugs with the highest Total Expenditures under Part B. CMS will identify the negotiation-eligible drugs for initial price applicability year 2028 as follows:

- CMS will identify all qualifying single source drugs for initial price applicability year 2028 using the process described in section 30.1 of this 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 Part D high spend drugs described in section 1192(d)(1)(A) of the Act using the following steps:
    - CMS will identify PDE data for each 11-digit National Drug Code (NDC-11)[30] of a qualifying single source drug for dates of service during the 12-month period beginning November 1, 2024 and ending October 31, 2025. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that are available in CMS' data repository by December 1, 2025. CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug.
    - CMS will use this PDE data to calculate the Total Expenditures under Part D for each qualifying single source drug during the 12-month applicable period. CMS will: (1) remove qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act; (2) remove qualifying single source drugs CMS determines qualify for the exception for small biotech drugs, in accordance with section 1192(d)(3)(A)(ii) and as 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 12-month period; and (4) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part D during the applicable 12-month period.
    - When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part D, and such Total Expenditures are the 50th highest among qualifying single source drugs under Part D, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients, until CMS has identified 50 Part D high spend drugs.
- CMS will identify Part B high spend drugs described in section 1192(d)(1)(B) of the Act using the following steps:
    - CMS will identify Part B claims data for each qualifying single source drug for dates of service during the 12-month period beginning November 1, 2024 and ending October 31, 2025. To allow a reasonable time for providers and suppliers

[30] 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.

to submit Part B claims, CMS will use Part B claims data for the dates of service described above that are available in CMS' data repository by December 1, 2025.

- CMS will use these Part B claims data to calculate the Total Expenditures under Part B for each qualifying single source drug during the 12-month applicable period. Typically, "single source drugs and biologicals" as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes; however, there may be cases where a qualifying single source drug is assigned to a HCPCS code with other products. In such cases, CMS will use ASP sales volume data to apportion Part B expenditures based on the ratio of reported sales volume of the qualifying single source drug compared to reported sales volume of all products assigned to the HCPCS code to calculate the Total Expenditures under Part B. As required by section 1191(c)(5) of the Act, when calculating Total Expenditures under Part B, CMS will exclude expenditures for a drug or biological product that are bundled or packaged into the payment for another service. CMS will exclude any Part B claim billed as a compounded drug.
- CMS will: (1) remove qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act (in accordance with section 1192(d)(3)(B) of the Act, this removal will encompass qualifying single source drugs that have been selected for initial price applicability years 2026 and 2027 based on Part D expenditures, as discussed in more detail below in this section 30.2 of draft guidance); (2) remove qualifying single source drugs CMS determines qualify for the exception for small biotech drugs, in accordance with section 1192(d)(3)(A)(ii) of the Act and as described in section 30.2.1 of this draft guidance; (3) rank the remaining qualifying single source drugs by Total Expenditures under Part B during the applicable 12-month period; and (4) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part B during the applicable 12-month period.
- When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part B, and such Total Expenditures are the 50th highest among qualifying single source drugs under Part B, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients, until CMS has identified 50 Part B high spend drugs.

- CMS will consider these 50 Part D high spend drugs and 50 Part B high spend drugs to be the negotiation-eligible drugs for initial price applicability year 2028.

In accordance with section 1192(d)(1) of the Act, beginning with initial price applicability year 2028, the assessment of negotiation-eligibility for each qualifying single source drug is determined based on Total Expenditures for that qualifying single source drug under both Part D and Part B. In keeping with this inclusive assessment of the negotiation-eligibility of a qualifying single source drug, and in accordance with sections 1192(d)(3)(A)(i) and 1192(d)(3)(B) of the Act, CMS will not include a qualifying single source drug on the list of negotiation-eligible Part D high spend drugs or Part B high spend drugs if that qualifying single source drug is already a selected drug.

30.2.1 Exception for Small Biotech Drugs

In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception" or "SBE"). The statute requires that CMS evaluate whether a qualifying single source drug qualifies for the SBE based on Total Expenditures under Part B or Part D. CMS intends to make separate determinations with respect to the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"), and the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track"). For initial price applicability year 2028, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE. A manufacturer that would like an SBE determination on multiple qualifying single source drugs must submit a unique application for each qualifying single source drug.

To apply the criteria that comprise the Part B Track and Part D Track of the SBE, CMS needs to identify qualifying single source drugs. CMS will define a qualifying single source drug based on the aggregation policies outlined in section 30.1 of this draft guidance for initial price applicability year 2028. This ensures the qualifying single source drug reflects initial price applicability year 2028 concepts and avoids potential inconsistencies in the calculations that comprise the Part B Track.

For the purposes of the SBE, CMS needs to collect information to accurately identify: the "Part D 2021 Manufacturer," which is the entity that had the Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A of the Act in effect for the qualifying single source drug on December 31, 2021; and the "Part B 2021 Manufacturer," which is the entity that held the New Drug Application(s) or Biologics License Application(s) (NDA(s) / BLA(s)) for the qualifying single source drug on December 31, 2021. This information is used in the Part B Track and Part D Track considerations outlined in 1192(d)(2)(A)(ii)(II) and 1192(d)(2)(A)(i)(II), respectively. In addition, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all corporations or partnerships, sole proprietorships, and other entities that, on December 31, 2021, were treated as a single employer (i.e., part of the same controlled group) under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 (IRC) with the Part B 2021 Manufacturer or Part D 2021 Manufacturer. The controlled group of the Part D 2021 Manufacturer comprises all entities that, as of December 31, 2021, were treated as a single employer with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021. The controlled group of the Part B 2021 Manufacturer comprises all entities that, as of December 31, 2021, were treated as a single employer with Part B 2021 Manufacturer.

However, CMS does not have information about which entities were treated as a single employer with the Part B 2021 Manufacturer or the Part D 2021 Manufacturer under the applicable IRC provisions and the Treasury regulations thereunder. Therefore, a manufacturer that seeks the SBE for its qualifying single source drug(s) ("Submitting Manufacturer") must submit information to CMS about the Part B 2021 Manufacturer and/or the Part D 2021 Manufacturer, its controlled group (e.g., P number, labeler code(s)), and its products (e.g., NDA(s) and/or BLA(s)) in order

for the drug to be considered for the exception. To the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s) / BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. CMS is setting forth this policy to ensure that only the entity with which CMS would negotiate in the event that the qualifying single source drug is selected for negotiation, as described in section 40 of this draft guidance, is able to seek the SBE.

In applying the Part D Track of the SBE, the statute requires that CMS consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the qualifying single source drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021.[31] To identify and exclude drugs eligible for the SBE, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures during 2021 under Part D for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021.

Likewise, in applying the Part B Track of the SBE, the statute requires that CMS consider Total Expenditures under Part B during 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the qualifying single source drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group. To identify and exclude drugs eligible for the SBE, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures under Part B during 2021 for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group for which payment may be made under Part B.

Additionally, the limitation at section 1192(d)(2)(B)(ii) of the Act states that a qualifying single source drug is not eligible for an SBE if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025, or January 1, 2026, for acquisitions occurring during 2025.[32] For initial price applicability year 2028, in order for the Submitting Manufacturer to have its qualifying single source drug(s)

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[31] As stated in section 50.1.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available at https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf (hereinafter, the "Manufacturer Discount Program Final Guidance"): "A manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP Agreement would be considered to have had an agreement in effect during 2021."

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

considered for an SBE, CMS must consider whether the Submitting Manufacturer was acquired after 2021, and if so, whether the acquiring entity is a manufacturer that will not meet the definition of specified manufacturer effective January 1, 2025 or January 1, 2026, for acquisitions occurring during 2025. For purposes of implementing this limitation, CMS will use the determinations of the Medicare Part D Manufacturer Discount Program ("Manufacturer Discount Program") as to whether the acquiring entity met the definition of specified manufacturer in the applicable period. CMS will consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount Program as either a specified manufacturer under section 1860D-14C(g)(4)(B)(ii) of the Act or a specified small manufacturer under section 1860D-14C(g)(4)(C)(ii) of the Act.[33] For an acquisition of a manufacturer to be relevant to the limitation, and therefore to potentially preclude a drug from being considered a qualifying single source drug that could be eligible for an SBE, the transaction must occur after 2021 and must involve the acquisition of the Submitting Manufacturer after the Submitting Manufacturer held the NDA(s) / BLA(s) for the qualifying single source drug.

CMS is publishing a revision of the currently approved Small Biotech Exception Information Collection Request (ICR), entitled "Negotiation Program Drug Selection Information Collection Request for Initial Price Applicability Year 2028" (CMS-10844, OMB 0938-1443) (hereinafter the "Drug Selection ICR"), on May 13, 2025, for a 60-day public comment period that will close on July 14, 2025.[34]

The Drug Selection ICR Forms address the collection of information for initial price applicability year 2028 only. A manufacturer seeking to have the SBE apply to its drug(s) for initial price applicability year 2028 must submit a request for an SBE for initial price applicability year 2028 regardless of whether the manufacturer submitted a request for a prior initial price applicability year and irrespective of CMS' determination in a prior initial price applicability year. For initial price applicability year 2028, section 1192(d) of the Act requires CMS to evaluate whether a qualifying single source drug qualifies for the SBE based on Total Expenditures under Part B or Part D; the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE.

As specified in the Drug Selection ICR Forms, CMS anticipates that the Submitting Manufacturer will submit a request for a Small Biotech Exception using the CMS Health Plan

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[33] 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).

[34] To view the Drug Selection ICR Forms for initial price applicability year 2028 (CMS-10844, OMB 0938-1443) available for a 60-day public comment period, which starts on May 13 and will close on July 14, 2025, 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 2028 includes the information collection forms for the SBE and the Biosimilar Delay in the same Federal Register notice (see section 30.3.1 of this draft guidance).

Management System ("the CMS HPMS") by the date specified by CMS.[35] CMS intends to provide a deadline that CMS believes is necessary to allow sufficient time for manufacturers to complete the activities required to apply for the SBE, as well as provide CMS with time to make a determination prior to the initial price applicability year 2028 selected drug publication date. CMS intends to provide the submission deadline once the Drug Selection ICR for initial price applicability year 2028 is finalized. After reviewing a submitted SBE request, CMS may request additional information from the Submitting Manufacturer as necessary to make a determination with respect to an SBE request. CMS plans to make any such follow-up request in writing to the Submitting Manufacturer via email. Information submitted in a request for an SBE that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).

CMS will not consider incomplete submissions. Upon receipt of a complete request for an SBE, CMS will take the following steps to identify whether a qualifying single source drug qualifies for the Small Biotech Exception:

1. CMS will first analyze whether the qualifying single source drug for which the Submitting Manufacturer requests an SBE is excluded from SBE consideration under the limitation set forth in section 1192(d)(2)(B)(ii) of the Act. If the Submitting Manufacturer was acquired after 2021 by another manufacturer, CMS will rely on the determination by CMS under the Manufacturer Discount Program as to whether the acquiring entity will meet the definition of a "specified manufacturer" effective January 1, 2025 or January 1, 2026, for acquisitions occurring during 2025. If the acquiring entity is a manufacturer that does not meet the definition of a "specified manufacturer," the limitation applies, and the Submitting Manufacturer's qualifying single source drug cannot qualify for the SBE for initial price applicability year 2028.
2. Provided the limitation does not apply, CMS will identify the Part B 2021 Manufacturer and/or the Part D 2021 Manufacturer of the qualifying single source drug on December 31, 2021 based on information submitted in the request for an SBE.

If the limitation set forth in section 1192(d)(2)(B)(ii) of the Act does not apply, and the manufacturer submits a complete request for an SBE pertaining to a qualifying single source drug covered under Part D, CMS will take the following steps to identify whether a qualifying single source drug qualifies for the Small Biotech Exception Part D Track:

1. CMS will identify the complete set of NDC-11s for which the Part D 2021 Manufacturer and its controlled group as of December 31, 2021 had a CGDP Agreement in effect as of December 31, 2021.

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[35] As specified in the Drug Selection ICR Forms available for a 60-day public comment, CMS will provide the deadline for submissions upon approval of the Drug Selection ICR from the Office of Management and Budget. CMS anticipates providing a 30-day submission period. Access to the SBE functionality to request an SBE will be granted automatically to active manufacturer users in HPMS. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program" PDF, available at: https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

2. Using the complete set of NDC-11s for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021, CMS will identify PDE data for dates of service during the 12-month period beginning January 1, 2021, and ending December 31, 2021.
3. Using the PDE data for: (1) the qualifying single source drug; (2) the complete set of drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect as of December 31, 2021; and (3) all drugs covered under Part D, CMS will determine whether:
    - The Total Expenditures under Part D for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part D for all drugs covered under Part D; and
    - The Total Expenditures under Part D for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part D for all drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect as of December 31, 2021.

The Total Expenditures under Part D for the qualifying single source drug will be determined using calendar year 2021 PDE data for the qualifying single source drug for initial price applicability year 2028, as defined by the aggregation policies outlined in section 30.1 of this draft guidance. The Total Expenditures under Part D for all drugs covered under Part D will be determined using calendar year 2021 PDE data for all drugs covered under Part D. The Total Expenditures under Part D for all drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect as of December 31, 2021 will only include PDE data for NDC-11s with labeler codes associated with the Part D 2021 Manufacturer or any member of the Part D 2021 Manufacturer's controlled group. For each of these Total Expenditures calculations, CMS will exclude any PDE data with a compound code indicating the PDE record is for a compounded drug, as described in section 30.1.2 of this draft guidance.

If the limitation set forth in section 1192(d)(2)(B)(ii) of the Act does not apply, and the manufacturer submits a complete request for an SBE pertaining to a qualifying single source drug paid under Part B, CMS intends to take the following steps to identify whether a qualifying single source drug qualifies for the Small Biotech Exception Part B Track:

1. CMS will identify the complete set of NDC-11s for all qualifying single source drug(s) for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021.
2. Using the HCPCS codes associated with the complete set of NDC-11s for qualifying single source drugs for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021, CMS will identify Part B claims data for dates of service during the 12-month period beginning January 1, 2021, and ending December 31, 2021.
    - Typically, "single source drugs and biologicals" as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes; however, there may be cases where a qualifying single source drug is assigned to a HCPCS code with other products. In such cases, CMS will use ASP sales volume data to apportion Part B expenditures based on the ratio of reported sales volume of the

qualifying single source drug compared to reported sales volume of all products assigned to the HCPCS code to calculate the Total Expenditures under Part B for the qualifying single source drug. Expenditures for a drug or biological product that are bundled or packaged into the payment for another service will be excluded from the calculation of total expenditures under Part B.

3. Using the Part B claims data for: (1) the qualifying single source drug; (2) the complete set of qualifying single source drugs for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021; and (3) all qualifying single source drugs paid under Part B, CMS will determine whether:
    - The Total Expenditures under Part B for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B; and
    - The Total Expenditures under Part B for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021.

The Total Expenditures under Part B for the qualifying single source drug and Total Expenditures under Part B for all qualifying single source drugs payable under Part B will be determined using calendar year 2021 Part B claims data for the qualifying single source drugs in initial price applicability year 2028, as defined by the aggregation policies outlined in section 30.1 of this draft guidance. The Total Expenditures under Part B for all qualifying single source drugs payable under Part B for which the Part B 2021 Manufacturer or any member of its controlled group held the NDA(s) / BLA(s) as of December 31, 2021 will include Part B claims for NDC-11(s) associated with qualifying single source drug(s) that correspond to the NDA(s) / BLA(s) held by the Part B 2021 Manufacturer or any member of its controlled group. For each of these Total Expenditures calculations, CMS will exclude any Part B claim billed as a compounded drug, as described in section 30.1.2 of this draft guidance.

If a manufacturer submits a complete request for an SBE for both the Part B Track and the Part D Track pertaining to a qualifying single source drug payable under Part B and covered under Part D, respectively, CMS intends to make separate determinations under the Part B Track and Part D Track of the SBE. For initial price applicability year 2028, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE.

A determination by CMS that a given qualifying single source drug qualifies for the SBE for initial price applicability year 2028 does not determine if the drug will qualify for the temporary floor for a small biotech drug that is selected for initial price applicability years 2029 or 2030 as described in section 1194(d) of the Act. CMS will provide information about section 1194(d) of the Act in future guidance or rulemaking.

CMS anticipates notifying the Submitting Manufacturer by February 2026 of its SBE determination for initial price applicability year 2028. This information will only be shared after the selected drug list for initial price applicability year 2028 has been published. CMS will

publish the number of drugs that receive the SBE for initial price applicability year 2028 as part of publishing the selected drug list no later than February 1, 2026. For initial price applicability year 2027, CMS received SBE requests which resulted in CMS determining four qualifying single source drugs qualified for the SBE. The determination that these drugs qualified for the SBE applied only to initial price applicability year 2027.[36]

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

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2028

In accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 15 (or all, if such number is less than 15) negotiation-eligible drugs for negotiation for initial price applicability year 2028 as follows:

1. CMS will rank the list of negotiation-eligible drugs identified, as described in section 30.2 of this draft guidance, by combined Total Expenditures under both Part B and Part D in descending order: the negotiation-eligible drug with the highest Total Expenditures under Part B and Part D will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part B and Part D will be listed last. If a negotiation-eligible drug appears on both high-spend lists, it will receive only one ranking for purposes of selection, according to its combined Total Expenditures under both Part D and Part B.
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 2028.
    - In the event that two or more negotiation-eligible drugs have the same combined Total Expenditures under Part B and Part D to the dollar, and such combined Total Expenditures are the 15th highest among negotiation-eligible drugs, CMS will rank those negotiation-eligible drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the initial FDA application number for its active moiety / active ingredient, and select based on that ranking until there are 15 selected drugs (or until all drugs are selected, if the number of negotiation-eligible drugs is less than 15).

30.3.1 Delay in the Selection and Negotiation of Certain Biological Products with High Likelihood of Biosimilar Market Entry

In accordance with section 1192(b)(1)(C) of the Act, CMS will remove from the ranked list of negotiation-eligible drugs described in section 30.3 of this 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

[36] Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027 Fact Sheet, available at https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf.

("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is hereinafter a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by FDA. If neither the Biosimilar has been licensed nor the BLA has been submitted to FDA, the Biosimilar Manufacturer eligible to submit the request is the organization planning to be the sponsor of the BLA submitted for review by FDA. CMS believes that this approach is appropriate because: (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year; and (2) the status of the application for licensure for the Biosimilar is material to CMS' consideration of a request for a Biosimilar Delay, as described in this section 30.3.1 of this draft guidance.

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request") as stated in section 1192(f)(1)(B)(i)(II) of the Act. Together, CMS refers to an Initial Delay Request and an Additional Delay Request as "Biosimilar Delay Requests." CMS did not grant any Initial Delay Requests for initial price applicability year 2027; therefore, Additional Delay Requests are not relevant for initial price applicability year 2028. CMS is providing more information about the Additional Delay Request process within this draft guidance to respond to previous comments and to receive feedback for CMS consideration in rulemaking applicable to future initial price applicability years.[37]

CMS will publish the Drug Selection ICR on May 13, 2025 for a 60-day comment period that will close on July 14, 2025. As specified in the Drug Selection 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 the date specified by CMS.[38] CMS anticipates providing a 30-

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[37] Within the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS solicited comments regarding the types of documentation and information that may constitute "clear and convincing evidence [that] the manufacturer of [the] biosimilar biological product has made a significant amount of progress towards both such licensure and the marketing of such biosimilar biological product" under section 1192(f)(2)(B)(i)(II) of the Act to inform CMS' policy development for this issue. CMS received responses to this comment solicitation and summaries of the comments received are included in the Comment Summary and Response section of the final guidance for initial price applicability year 2027, available at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. This draft guidance incorporates these public comments as appropriate.

[38] As specified in the Drug Selection ICR Supporting Statement – Part A, available for a 60-day public comment, CMS intends to provide the opening date for submissions after approval of the Drug Selection ICR by the Office of Management and Budget (refer to the Drug Selection ICR Supporting Statement – Part A for additional information). Access to Initial Delay Request functionality will be granted automatically to active manufacturer users in the CMS HPMS. Instructions for manufacturers to gain access to the CMS HPMS can be found in the

day submission window. Information regarding the submission of an Initial Delay Request is addressed in detail within the Drug Selection ICR Forms. Because CMS did not grant any Initial Delay Requests for initial price applicability year 2027, CMS is not including a specific data collection request within the Drug Selection ICR Forms for an Additional Delay Request. CMS anticipates including specific questions necessary for CMS to gather the information for an Additional Delay Request in a future revision to the Drug Selection ICR Forms and will provide opportunity for public comment on those proposed revisions at that time. This section 30.3.1 and the following subsections of this section 30.3.1 include details on the policies for implementation of Initial Delay Requests for initial price applicability year 2028. As discussed above in this section, while Additional Delay Requests are not relevant for initial price applicability year 2028, CMS is providing information about the Additional Delay Request process within this draft guidance to respond to previous comments and to receive feedback for CMS consideration in rulemaking applicable to future initial price applicability years.

Information submitted in a Biosimilar Delay Request that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).

30.3.1.1 Procedures for Submission of Initial Delay Requests and Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2028

Procedures for Submission

CMS will not consider late or incomplete submissions. Upon receipt of a complete Initial Delay Request, CMS will take the following approach to identify whether an Initial Delay Request may be granted for a negotiation-eligible drug:

- 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 (which refers collectively to the requirements described in section 30.3.1.3 of this draft guidance).
- Second, if the Initial Delay Request meets all statutory requirements other than the high likelihood requirement, CMS will review the Initial Delay Request to determine whether it demonstrates that there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the statutorily-defined selected drug publication date for the initial price applicability year (hereinafter the "High Likelihood Deadline"), which is February 1, 2028 for Initial Delay Requests for initial price applicability year 2028. For purposes of its review of marketing in the context of the Biosimilar Delay, CMS intends to consider whether the totality of the circumstances, including the data specified below, demonstrates a high likelihood that the Biosimilar Manufacturer will engage in bona fide marketing of that Biosimilar.

"Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program" PDF, available at: https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

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, 2028.

In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Initial Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request. For Initial Delay Requests for initial price applicability year 2028, CMS plans to make any such follow-up request in writing to the Biosimilar Manufacturer via email. Any such written request will specify the additional information required, the format and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information.

The one exception to the ICR submission deadline and the follow-up information that may be requested by CMS for an Initial Delay Request for initial price applicability year 2028 is as follows: per section 30.3.1.3 of this draft guidance, for CMS to determine that there is a high likelihood of the Biosimilar being licensed and marketed prior to February 1, 2028, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than January 15, 2026. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 PM PT on January 15, 2026, in order to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list to be published no later than February 1, 2026, in accordance with section 1192(a) of the Act.

The list of selected drugs published for initial price applicability year 2028 will reflect the results of CMS' determinations with respect to any Initial Delay Requests that are submitted, i.e., a Reference Drug that, absent a successful Initial Delay Request, would have been selected, will not appear on the selected drug list published no later than February 1, 2026, if it is named in a successful Initial Delay Request.

After completing its review, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2028 in writing of CMS' determination regarding such request. This notification will occur on or after the date that the selected drug list for initial price applicability year 2028 is published, but no later than February 28, 2026, and will include a brief summary of CMS' determination, including:

- Whether the Initial Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined 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 2028 absent the Initial Delay Request; or
- failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028.

CMS will also notify each Primary Manufacturer (as defined in section 40 of this 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 2028, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests will not be notified. CMS will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2028, absent successful Initial Delay Requests, as part of publishing the selected drug list no later than February 1, 2026.

Requirements for Granting an Initial Delay Request

The statute specifies that the following requirements must be met in order for CMS to grant an Initial Delay Request:

1. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be, absent the Biosimilar Delay, a selected drug for the initial price applicability year.
    - Biosimilar Manufacturers that believe that a Reference Drug for their Biosimilar may be a selected drug for initial price applicability year 2028 may submit an Initial Delay Request, and CMS will disregard that application if the Reference Drug would not, in fact, be a selected drug for initial price applicability year 2028. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for drugs payable under Part B and/or covered under Part D, including data published by CMS, including but not limited to data on the Medicare Part B Drug Spending Dashboard[39] and the Medicare Part D Drug Spending Dashboard[40], which may allow them to determine the likelihood that a given drug may be a selected drug.
2. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests submitted with respect to initial price applicability year 2028, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2012, and January 1, 2016.
    - Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs. Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date

[39] Available at: https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard.
[40] Available at: https://data.cms.gov/tools/medicare-part-d-drug-spending-dashboard.

for an initial price applicability year and before the Reference Manufacturer would have entered into an agreement under the Negotiation Program. Therefore, CMS believes the exception to the definition of "extended-monopoly drug" in section 1194(c)(4)(B)(ii) of the Act will not apply at the time that a delay would be requested for initial price applicability years 2026 through 2029. Accordingly, CMS believes that the Biosimilar Delay under section 1192(f) of the Act is applicable for initial price applicability year 2028. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2028, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years[41] prior to the start of the initial price applicability year on January 1, 2028.

3. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by FDA or accepted for review.
    - Note that in order for CMS to grant an Initial Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval.
4. In accordance with section 1192(f)(2)(D)(iii) of the Act, an Initial Delay Request cannot be granted if more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, "partnership" is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.
6. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that:
    - requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
    - directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. For Initial Delay Requests submitted with respect to initial price applicability year 2028, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after February 1, 2026, as violating this requirement.
7. In accordance with section 1192(f)(1)(A) of the Act and as described in section 30.3.1.3 of this draft guidance, CMS must determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.

[41] Section 1194(c)(4)(A) of the Act defines "extended-monopoly drug."

30.3.1.2 Procedures for Submission of Additional Delay Requests and Requirements for Granting an Additional Delay Request After the Initial Delay Period

Procedures for Submission
Upon receipt of a complete Additional Delay Request, CMS will take the following approach to identify whether an Additional Delay Request may be granted for a negotiation-eligible drug.

- First, if an Additional Delay Request includes all required elements and was timely submitted, CMS will review the Additional Delay Request to determine if it meets all statutory requirements described in this section 30.3.1.2 of this draft guidance, with the exception of the high likelihood and the significant amount of progress towards licensure and marketing requirements;
- Second, if the Additional Delay Request meets all statutory requirements other than the high likelihood requirement and significant amount of progress requirement, CMS will review the Additional Delay Request to determine whether:
    1. it demonstrates a high likelihood that the Biosimilar will be licensed and marketed prior to the date that is two years after the selected drug publication date for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request, as described in section 30.3.1.3 of this draft guidance. For purposes of its review of marketing in the context of the Biosimilar Delay, CMS will consider whether the totality of the circumstances, including the data specified below, demonstrates a high likelihood that the Biosimilar Manufacturer will engage in bona fide marketing of that Biosimilar; and
    2. it demonstrates that a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar as described in section 30.3.1.4 of this draft guidance.

In considering an Additional Delay Request, CMS will cease consideration upon finding that the Additional Delay Request has failed to meet any of these requirements. For example, if CMS determines an Additional Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements. If CMS determines an Additional Delay Request fails to meet one or more of the statutory requirements described in this section 30.3.1.2 of this draft guidance, with the exception of the high likelihood requirement or significant amount of progress requirement, CMS will not consider whether that Additional Delay Request demonstrates (1) a high likelihood that the Biosimilar will be licensed and marketed prior to the date that is two years after the selected drug publication date for which the Reference Drug would have been included as a selected drug on the selected drug list but for the successful Initial Delay Request, as described in section 30.3.1.3 of this draft guidance; or (2) a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar, as described in section 30.3.1.4 of this draft guidance.

In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Additional Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Additional Delay Request.

With respect to any Additional Delay Requests submitted for future initial price applicability years, CMS will provide information in future rulemaking about the specific dates, similar to the dates included above for a determination of an Initial Delay Request, such as notification of CMS' determination of an Additional Delay Request. At this time, after completing its review for Additional Delay Requests, CMS will notify each Biosimilar Manufacturer that submits an Additional Delay Request for an applicable initial price applicability year in writing of CMS' determination regarding such request. This notification will occur on or after the date that the selected drug list for an applicable initial price applicability year is published and will include a brief summary of CMS' determination, including:

- Whether the Additional Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined that the Additional Delay Request was unsuccessful, including but not limited to:
    - failure to submit all elements of the Additional Delay Request by the applicable deadline;
    - failure to meet another statutory requirement for granting a request (other than the high likelihood and significant progress requirements);
    - failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed prior to the date that is two years after the selected drug publication date for which the Reference Drug would have been included as a selected drug on the selected drug list but for the successful Initial Delay Request, as described in section 30.3.1.3 of this draft guidance; or
    - failure to show clear and convincing evidence that a significant amount of progress towards both licensure and marketing of the Biosimilar has occurred since the Biosimilar Manufacturer's submission of the successful Initial Delay Request for the Biosimilar.

Requirements for Granting an Additional Delay Request

The statute specifies that the following requirements must be met in order for CMS to grant an Additional Delay Request for the Biosimilar:

1. In accordance with section 1192(f)(2)(B)(i) of the Act, the Secretary must have determined that, for the biological product identified in a successfully granted Initial Delay Request, licensure and marketing under section 351(k) of the PHS Act has not commenced during the time between the publication date of the selected drug list for the initial price applicability year for which the Initial Delay Request was granted and the date that is 1 year following that publication date.
2. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by FDA or accepted for review.
3. In accordance with section 1192(f)(2)(D)(iii) of the Act, no more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
4. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that:

- requires or incentivizes the Biosimilar Manufacturer to submit an Additional Delay Request; or
- directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.[42]

6. In accordance with section 1192(f)(2)(B)(i)(I) of the Act and as described in section 30.3.1.3 of this draft guidance, CMS must reevaluate to determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.
7. In accordance with section 1192(f)(2)(B)(i)(II) of the Act and as described in section 30.3.1.4 of this draft guidance, CMS must determine, on the basis of clear and convincing evidence, that the Biosimilar Manufacturer has made a significant amount of progress towards both licensure and marketing of the Biosimilar.
8. In accordance with section 1192(f)(2)(D)(ii) of the Act, a Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is not eligible for an Additional Delay Request if there would have been a change in status to a long-monopoly drug, as defined in section 1194(c)(5) of the Act, with respect to the initial price applicability year for which the Biosimilar Manufacturer is submitting an Additional Delay Request.

30.3.1.3 High Likelihood

In accordance with section 1192(f)(1)(A) and section 1192(f)(2)(B)(i)(I) of the Act, CMS will review Biosimilar Delay Requests to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. For purposes of application of this section to an Additional Delay Request, CMS is providing information about the Additional Delay Request process within this draft guidance to respond to previous comments and to receive feedback for CMS consideration in rulemaking applicable to future initial price applicability years.

Accordingly, for Initial Delay Requests submitted with respect to initial price applicability year 2028, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028, in order to grant the request. If CMS does not find that there is a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2028, based on the criteria described below, CMS will deny the Initial Delay Request. For an Additional Delay Request, CMS must reevaluate to determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline for the successful Initial Delay Request submission for such Biosimilar. If CMS reevaluates and does not find that there is a high likelihood that the Biosimilar will be marketed before the High Likelihood Deadline for the successful Initial Delay Request submission for the Biosimilar, CMS will deny the Additional Delay Request.

In accordance with section 1192(f)(3) of the Act, Biosimilar Delay Requests must demonstrate both of the following in order to meet the high likelihood threshold:

[42] CMS will provide information in future rulemaking about the specific dates, similar to the dates included for a determination of an Initial Delay Request, such as notification of CMS' determination of an Additional Delay Request.

1. An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by FDA.[43]
    - For Initial Delay Requests submitted with respect to initial price applicability year 2028, the Biosimilar's application for licensure must be approved or accepted for review by FDA no later than January 15, 2026 in order to permit CMS time to review the information and finalize the selected drug list prior to publishing the selected drug list for initial price applicability year 2028.
        i. Note that if the Biosimilar's application for licensure has not been accepted for review by January 15, 2026, including in the case where the Biosimilar Manufacturer submitted an application for licensure that has not been accepted for review by FDA or for which a filing determination is pending, CMS will deny the Initial Delay Request for initial price applicability year 2028.
    - CMS will provide information about the specific timing for an Additional Delay Request for specific initial price applicability years in future rulemaking.
2. Clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, based on the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act that has been submitted to CMS.

To demonstrate clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, CMS will require that the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS by the Biosimilar Manufacturer as part of its request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date, and so CMS believes that evidence showing that a Biosimilar meets these two requirements is sufficient to establish clear and convincing evidence that the Biosimilar will be marketed.

First, the Biosimilar Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline for the successful Initial Delay Request submission for the Biosimilar. CMS will only consider patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. For example, if a Biosimilar Manufacturer has obtained licensure with biosimilar labeling that omits a patent-protected indication or other patent-protected information, then such patents that cover the omitted indication or the omitted information would not be considered to be "applicable to the Biosimilar." Specifically, CMS will consider this requirement met if (1) there are no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar; (2) one or more court decisions or decisions by the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the

[43] 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.

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 the High Likelihood Deadline, without imposing improper constraints on the Biosimilar Manufacturer.[44]

CMS is soliciting comments regarding whether there is additional or alternative evidence that may demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline. For example, CMS is soliciting comments regarding whether there are industry-recognized milestones that occur during ongoing patent litigation, including cases that are eligible for appeal, that, if successfully achieved by a Biosimilar Manufacturer, would demonstrate a high likelihood that the patent dispute will not be a barrier to marketing the Biosimilar. Additionally, CMS is soliciting comments on whether CMS should consider public-facing statements in which the Biosimilar Manufacturer asserts that ongoing patent disputes will be resolved within the relevant time period for the High Likelihood Deadline. Finally, CMS is soliciting comments on whether investments in operationalization efforts, or other Biosimilar Manufacturer activity, may be evidence that demonstrates a patent dispute will be resolved or not prevent marketing of the Biosimilar by the High Likelihood Deadline.

Second, the Biosimilar Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline for the successful Initial Delay Request submission for the Biosimilar (which is February 1, 2028 for Initial Delay Requests for initial price applicability year 2028). To assess this requirement, CMS will consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before February 1, 2028; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. CMS chose these criteria because they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In determining whether a Biosimilar Delay Request satisfies the high likelihood threshold, CMS may use all the information described in section 30.3.1.1 and section 30.3.1.2 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 the High Likelihood Deadline:

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[44] 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, 2026. CMS will provide information about the specific timing requirements related to Additional Delay Request for specific initial price applicability years in future rulemaking.

- All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- The Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (e.g., in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product.

30.3.1.4 Significant Amount of Progress

As discussed above, CMS is providing information about the Additional Delay Request process, including information in this section, within this draft guidance to respond to previous comments and to receive feedback for CMS consideration in rulemaking applicable to future initial price applicability years.

In accordance with section 1192(f)(2)(B)(i)(II) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar Manufacturer has made a significant amount of progress towards licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request for the Biosimilar:

- All agreements related to the Biosimilar filed with the 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 (as described in section 1192(f)(1)(B)(ii)(I)(bb) of the Act); and
- Additional information and documents that CMS may request after CMS has reviewed the information required for submission of the Additional Delay Request necessary to make a determination about an Additional Delay Request (as described in section 1192(f)(1)(B)(ii)(II) of the Act).

Recognizing that approximately one year has passed since submission of the successful Initial Delay Request, CMS will consider whether the Biosimilar Manufacturer demonstrates that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. Specifically, the determination of whether a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar since the successful Initial Delay Request submission for such Biosimilar will be based on a holistic review of the documentation submitted with the Additional Delay Request, which includes the documentation in any follow-up requests.

CMS will consider if the Biosimilar Manufacturer can demonstrate affirmative progress towards being operationally ready to market the Biosimilar.

CMS will consider the Biosimilar Manufacturer's progress on the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug since the successful Initial Delay Request submission for the Biosimilar evidenced in both any updates or supplements to the documents specified in section 1192(f)(1)(B)(ii)(III) of the Act.

30.3.1.5 Failure of the Biosimilar to Be Licensed and Marketed

In accordance with section 1192(f)(2)(B) of the Act, CMS must determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. For successful Initial Delay Requests submitted with respect to initial price applicability year 2028, CMS will notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is licensed and marketed during the initial delay period by November 5, 2026. If CMS determines that the Biosimilar is not licensed and marketed during the initial delay period, the Biosimilar Manufacturer will have the opportunity to submit an Additional Delay Request.

For purposes of application of this section to an Additional Delay Request, CMS is providing information about the Additional Delay Request process within this draft guidance to respond to previous comments and to receive feedback for CMS consideration in rulemaking applicable to future initial price applicability years.

If the Biosimilar Manufacturer chooses not to submit an Additional Delay Request, or submits an Additional Delay Request that CMS determines does not meet all requirements, CMS will (subject to the circumstances discussed below) include the Reference Drug on the selected drug list for the initial price applicability year that is one year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request (e.g., the selected drug list for initial price applicability year 2029 for successful Initial Delay Requests for initial price applicability year 2028). If a different biosimilar product is marketed before the publication of the selected drug list for the applicable initial price applicability year, CMS could also determine, in accordance with section 1192(c) of the Act and sections 30.1, 60.7, 70, and 90.4 of this draft guidance, that the Reference Drug no longer meets the criteria to be a selected drug and will be excluded from such applicable list of drugs selected for an initial price applicability year.

Further, in accordance with section 1192(f)(2)(C) of the Act, CMS must determine whether each Biosimilar named in a successful Additional Delay Request is licensed and marketed during the second delay period. CMS will specify the date by which CMS will notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Additional Delay Request is licensed and marketed during the second delay period in future rulemaking. If CMS determines that the Biosimilar is not licensed and marketed during the second delay period, CMS will (subject to the circumstances below) include the Reference Drug on the selected drug list for the initial price applicability year that is two years after the initial price applicability year of the successful Initial Delay Request. CMS could also determine, in accordance with section 1192(c) of the Act and sections 30.1, 60.7, 70, and 90.4 for this draft guidance, that the Reference Drug no longer meets the criteria to be a selected drug and will be excluded from such applicable list of drugs selected for an initial price applicability year.

In accordance with sections 1192(f)(2)(B)(ii), 1192(f)(2)(C), and 1192(f)(4)(A) of the Act, if CMS delayed the selection and negotiation of a Reference Drug for one or two years in accordance with sections 30.3.1.1 or 30.3.1.2 of this draft guidance, respectively, the Biosimilar was not licensed and marketed, and the manufacturer of the Reference Drug agrees to an MFP for the Reference Drug, the Reference Manufacturer is required to pay a rebate for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the delay.

Section 1192(f)(4)(B) of the Act specifies that the rebate owed by the Reference Manufacturer, for the price applicability year for which an Initial Delay Request was granted will be calculated as follows:

- In the case of a Reference Drug that is a drug covered under Part D, 75 percent of the difference between the AMP, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug multiplied by the number of units dispensed under Part D for the Reference Drug in each calendar quarter of the price applicability period that would have applied but for the delay; and
- In the case of a Reference Drug payable under Part B, 80 percent of the difference between the payment amount under section 1847A(b) of the Act, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug, multiplied by the number of units of the billing and payment code of the Reference Drug administered or furnished under Part B (excluding units that are packaged into the payment amount for an item or service and are not separately payable under Part B) for each calendar quarter of the price applicability period that would have applied but for the delay.

For the price applicability year for which an Additional Delay Request was granted, CMS will adjust the MFP as described in section 1195(b)(1)(A) of the Act to account for changes in the CPI-U.

Before applying a rebate, CMS will determine if the Reference Drug transitioned to a long monopoly drug, at the time of its inclusion on the selected drug list for the initial price applicability year that is the year after the successful Initial Delay Request or successful Additional Delay Request, as applicable, and CMS has determined that the Biosimilar was not licensed or marketed. In the case of a Reference Drug that CMS determines transitioned to a long-monopoly drug during the delay, in accordance with section 1192(f)(4)(C) of the Act, the rebate calculation will substitute the MFP negotiated for the Reference Drug with the following amount. The amount will be equal to 65 percent of the average non-FAMP for 2021 (or the first full year following market entry if there is no non-FAMP for 2021) increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry) to September of the year prior to the selected drug publication date for the initial price applicability year that would have applied but for the Initial Delay Request or the Additional Delay Request. For example, if inclusion of the Reference Drug on the selected drug list is delayed until initial price applicability year 2029 due to a successful Initial Delay Request, and the Reference Drug transitions to a long-monopoly drug, the rebate calculation will use September of the year prior to the selected drug publication date for initial price applicability

year 2028 (September 2025) for the purposes of adjusting for inflation the average non-FAMP for 2021.

In accordance with section 1192(f)(4)(B) of the Act, CMS intends to apply the MFP to the rebate calculation for all the previous initial applicability years where the Reference Drug would have been on the selected drug list if not for the delay. For example, if the Reference Drug would have been on the list for initial price applicability years 2028 and 2029 but for the approval of an Initial Delay Request and an Additional Delay Request and the Biosimilar was not licensed and marketed, CMS will use the MFP agreed to for initial price applicability year 2030 to calculate the rebate amount for initial price applicability years 2028 and 2029.

In accordance with section 1192(f)(4)(D) of the Act, the rebates paid for drugs payable under Part B will be deposited in the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act. The rebates paid for drugs covered under Part D will be deposited in the Medicare Prescription Drug Account established under section 1860D–16 of the Act, which is within the Federal Supplementary Medical Insurance Trust Fund. CMS will provide additional information about the administration of rebates, including the timing and mechanism for notifying manufacturers when a rebate is owed and the process for payment, in future rulemaking. CMS is soliciting comments on the timing and delivery mechanism for notification and process for payment.

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

30.4 Publication of the Selected Drug List

In accordance with sections 1191(b)(3) and 1192(a) of the Act, CMS will publish the selected drug list for initial price applicability year 2028 no later than February 1, 2026. This list will include the 15 (or all, if such number is less than 15) drugs payable under Part B and/or covered under Part D selected for negotiation for initial price applicability year 2028, including the active moiety / active ingredient (or in the case of fixed combination drugs, the distinct combination of active moieties / active ingredients) for each selected drug and the NDC-9s, NDC-11s, and HCPCS codes for the selected drug, as applicable. CMS will also publish a list of the up to 50 top negotiation-eligible drugs (including the up to 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D, as described in section 30.3 of this draft guidance, and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable. Because section 1192(d)(2)(A) of the Act excludes a qualifying single source drug that receives the SBE from the definition of a negotiation-eligible drug, a qualifying single source drug that receives the SBE will not be included in this list of the up to 50 top negotiation-eligible drugs. To promote greater transparency into the process for identifying selected drugs, this list of top drugs based on combined Total Expenditures will not include those negotiation-eligible drugs that qualify for the Biosimilar Delay; however, because section 1192(f)(1)(A) of the Act specifies that a biological product may only qualify for the Biosimilar Delay if the biological product would be included on the selected drug list but for the Biosimilar Delay, the list of the up to 50 top negotiation-eligible drugs will reflect the removal of any biological product that qualified for the Biosimilar Delay solely as it relates to the 15 top negotiation-

eligible drugs. Additionally, CMS will publish the list of drugs selected for renegotiation, if any, no later than February 1, 2026, as described in section 130.2.2 of this draft guidance.

The NDC-9s and NDC-11s for each selected drug will be identified by compiling all NDC-11s belonging to the selected drug associated with HCPCS codes on Part B claims with utilization in the 12-month period beginning November 1, 2024 and ending October 31, 2025, and all NDC-11s belonging to the selected drug that had Part D PDE utilization in this same 12-month period. CMS will also identify any additional NDC-11s associated with the NDA(s) / BLA(s) of the selected drugs as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file or the NDC Directory (including its NDC Excluded Drugs Database file) and remove any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B (e.g., NDC-11s for which there are no PDE records with a coverage status code of "C" and which are not associated with any HCPCS codes). CMS will post the selected drug list, including the NDC-9s, NDC-11s, and HCPCS codes (as applicable) for each selected drug, on the CMS website and update this information in accordance with section 40.2 of this draft guidance. CMS may revise the selected drug list published pursuant to this section prior to or after the publication of any agreed-upon MFP as described in section 60.6 of this 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, and renegotiate, as applicable, an MFP with "the manufacturer" of the selected drug (section 130 of this draft guidance discusses renegotiation with "the manufacturer" in accordance with section 1193(a)(2) of the Act). To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2028, CMS intends to designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer").[45]

Likewise, for initial price applicability year 2028, CMS intends to refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on the NDA or BLA as a "Secondary Manufacturer." A Secondary Manufacturer will include any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meet these criteria. A manufacturer that is not listed as a manufacturer on the NDA / BLA and without an agreement in place with the Primary Manufacturer would not be considered a Secondary Manufacturer. Examples of agreements that could result in a Secondary Manufacturer relationship may include, but are not limited to, royalty agreements, licensing

[45] In sections 40.2-40.5, 40.7, 50, 60-60.6, 60.8, 90, 100-100.2, 100.5, and 130 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.

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 (the "Medicare Drug Price Negotiation Program Agreement," hereinafter also referred to as an "Agreement") with the willing Primary Manufacturer of each selected drug and believes this approach aligns with the statute's requirement to negotiate to determine an MFP with "the manufacturer" of a selected drug in accordance with section 1193(a) of the Act. This Agreement, as described in this section 40, 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) of the Act, a Primary Manufacturer that enters into an Agreement must collect and report necessary information applicable to any Secondary Manufacturer(s) as described in section 40.2 of this 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 dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug. The scope of a Primary Manufacturer's responsibility to provide access to the MFP for the selected drug is limited to units of such drug sold by the Primary Manufacturer or a Secondary Manufacturer. CMS emphasizes that the requirement for Primary Manufacturers to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug, as described in section 80 of this 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 will require that for initial price applicability year 2028, the Primary Manufacturer of a selected drug is the entity that does each of the following:

1. Signs the Agreement with CMS, as described in section 40.1 of this draft guidance;
2. Collects and reports all data required for negotiation, and if applicable, renegotiation under section 1193(a)(4) of the Act, including the negotiation data elements, as described in section 40.2, section 50.1, and Appendix A of this draft guidance;
3. Negotiates an MFP with CMS, as described in section 40.3 of this draft guidance, and if applicable, renegotiates an MFP with CMS, as described in section 130 of this draft guidance;
4. Ensures the MFP, or renegotiated MFP, is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities, with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug, as described in section 40.4 of this 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 to CMS for use in applying the aggregation rule for the Small Biotech Exception or the Biosimilar Delay; failing to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but which has since undergone negotiation as described in section 1192(f)(4) of the Act; or not providing access to the MFP to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug, as described in sections 40.5, 90, and 100 of this 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 2028 is February 28, 2026. The Primary Manufacturer must use the CMS HPMS to identify the relevant authorized representative(s) and effectuate the Agreement.[46]

To be eligible to sign the Agreement, and obtain electronic signature access within the CMS HPMS Negotiation Program module, which is necessary to sign the Agreement, an authorized representative must be the Primary Manufacturer's Chief Executive Officer, Chief Financial Officer, an individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer, or an individual that has been granted delegated authority to perform electronic

[46] See: https://hpms.cms.gov/app/ng/home/.

signatures on behalf of one of the individuals previously noted by a senior official of the Primary Manufacturer. To make a request to obtain electronic signature access, an authorized representative must prepare an official letter that states the user's name(s), role(s) (e.g., Chief Executive Officer), CMS user ID, the P number that will be used for CMS and the Primary Manufacturer to interact for the purposes of the Negotiation Program related to the relevant selected drug, and that electronic signature access is required. CMS anticipates providing additional instructions related to requesting electronic signature authorization prior to the publication of the selected drug list for initial price applicability year 2028. Once additional instructions are provided, CMS recommends taking action as soon as possible to facilitate timely communication and effectuation of the Agreement. The authorized representative(s) must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Agreement, including any Addenda. CMS notes that it is a requirement of the CMS HPMS that the person accessing the CMS HPMS have a Social Security Number (SSN). An authorized representative of the Primary Manufacturer must access the CMS HPMS and sign the Agreement by February 28, 2026.

The negotiation period for initial price applicability year 2028 will begin on the earlier of two dates: the date on which the Agreement is executed (i.e., signed by both CMS and the Primary Manufacturer) or February 28, 2026. If an Agreement is fully executed before February 28, 2026, the negotiation period (as defined in section 1191(b)(4) of the Act) will begin on the date on which the Agreement is signed by the last party to sign it. If the Agreement is not fully executed by February 28, 2026, then pursuant to 26 U.S.C. § 5000D(b)(1), a period will begin on March 1, 2026, during which the Primary Manufacturer could be exposed to potential excise tax liability. Instructions for the Agreement and a template of the Agreement are available on the CMS website.[47]

Section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program, the CGDP,[48] and the Manufacturer Discount Program. If a Primary Manufacturer decides it is unwilling to enter into an Agreement for the Negotiation Program, it may expedite its exit from the Manufacturer Discount Program by submitting to CMS a notice that incorporates both: (1) a notice of decision not to participate in the Negotiation Program; and (2) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program.[49] If CMS determines the Primary Manufacturer's notice complies with these requirements, the Primary Manufacturer's request will constitute good cause to terminate the Primary Manufacturer's agreement(s) under the Manufacturer Discount Program, pursuant to section 1860D-14C(b)(4)(B)(i) of the Act, to expedite the date on which none of the drugs of the Primary

[47] See "Instructions for this Agreement" and the "Medicare Drug Price Negotiation Program Agreement" on the CMS website at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.
[48] The CGDP, established under section 1860D-14A of the Act, remained in place through December 31, 2024. Because the CGDP is no longer in place, CMS has removed references to the CGDP in discussion of Primary Manufacturer termination. CGDP requirements are codified in Subpart W of 42 C.F.R. Part 423 and remained in place until December 31, 2024.
[49] 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.

Manufacturer are covered by an agreement under section 1860D-14C of the Act. CMS has determined (and hereby provides notice) that it will automatically grant such termination requests upon receipt, and that it will expedite the effective date of the Primary Manufacturer's termination of its Manufacturer Discount Program agreements consistent with the statutory limitation that termination shall not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination.

If a Primary Manufacturer decides it is unwilling to enter into an Agreement for the Negotiation Program 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. CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program. Therefore, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its 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 38 U.S.C. § 8126(h)(5)), as described in section 50.1.1 and Appendix A of this draft guidance, and any information that CMS requires to carry out the Negotiation Program, including but not limited to, information related to the factors listed in section 1194(e)(1) of the Act, as described in section 50.1 and Appendix A of this draft guidance. This information must be submitted by the Primary Manufacturer to CMS no later than March 1, 2026 for initial price applicability year 2028.

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

Certain data, as described in section 50.1, section 130.4, and Appendix A of this draft guidance, must reflect any NDCs included in the selected drug marketed by any Secondary Manufacturer(s). The Primary Manufacturer is responsible for collecting such data from such Secondary Manufacturer(s) and including this information in its submission to CMS.

For each selected drug for initial price applicability year 2028, CMS will populate the CMS HPMS with the NDC-11s published in accordance with section 30.4 of this draft guidance,

including those NDC-11s of the selected drug with Part D PDE utilization or NDC-11s of the selected drug that are associated with HCPCS codes in Part B claims data in the 12-month period beginning November 1, 2024 and ending October 31, 2025, as well as any additional NDC-11s associated with the NDA(s) / BLA(s) of the selected drug as found in recent updates of the NSDE file, the NDC Directory (including its NDC Excluded Drugs Database file), and removing any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B (e.g., NDC-11s for which there are no PDE records with a coverage status code of "C" and which are not associated with any HCPCS codes). This list will include any NDC-11s of the selected drug marketed by the Primary Manufacturer or any Secondary Manufacturer. CMS will transmit this list to the Primary Manufacturer of the selected drug. In connection with the data submission described in section 50.1 of this 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 for products distributed by or under the name of a private label distributor;
- whether any of the listed NDC-11s are neither marketed nor controlled by the Primary Manufacturer or a Secondary Manufacturer;
- whether any of the listed NDC-11s represent a sample package;
- whether any of the listed NDC-11s represent an inner package or an outer package; and
- whether any of the listed NDC-11s have been discontinued.

CMS will collect this information in the CMS HPMS as part of the collection of the other data elements described in section 50.1 of this 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-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[50] 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 2028. The NDC-11s on this list will be included in ceiling calculations for initial price applicability year 2028 as described in section 60.2 of this draft guidance, to the extent data is available to support such calculations. CMS will also use the NDC-11s on this list for the calculations used to apply the MFP across dosage forms and strengths of the selected drug

[50] This list will include NDCs of the selected drug that are associated with HCPCS codes. CMS will organize data at the NDC-11 level because CMS groups NDC-11s for aggregation purposes via identification of the holder of the associated NDA/BLA and identification of the active moiety/active ingredient. The data Primary Manufacturers are required to report under section 1194(e)(1) is also generally maintained at the NDC-11 level. CMS will identify the HCPCS codes with which selected drugs are associated and for which payment may be made under Part B of Title XVIII via published NDC-HCPCS crosswalks.

for initial price applicability year 2028 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 for a drug distributed by or under the name of a private label distributor may explain why a Primary Manufacturer did not report Wholesale Acquisition Cost (WAC) for a particular NDC-11 of a selected drug).

The Primary Manufacturer has an ongoing obligation to timely report any changes in this information to ensure the list of NDC-11s of the selected drug in the CMS HPMS remains complete and accurate consistent with this 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 by or on behalf of the Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug. If CMS believes these new NDC-11s are not likely to have Part B or Part D utilization in the future, these NDC-11s will not be added to the list of NDC-11s of the selected drug. As another example, a Primary Manufacturer must report to CMS any NDC-11s of the selected drug that the Primary Manufacturer previously indicated as being marketed and controlled solely by a manufacturer that is not the Primary Manufacturer or Secondary Manufacturer, but that are newly marketed or controlled by the Primary Manufacturer or a Secondary Manufacturer. Failure of the Primary Manufacturer to provide timely information material to the accuracy of the list of NDC-11s of the selected drug as described in this section 40.2 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.

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)).[51]

CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information of Primary Manufacturers, including Exemptions 3 and/or 4 of the FOIA, and that strikes an appropriate balance between: (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program; and (2) avoiding treating information that does not qualify for such protection as proprietary. Thus, for initial price applicability year 2028, CMS will treat information on non-FAMP as proprietary.

For initial price applicability year 2028, CMS will also treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section

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

1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat prior Federal financial support, approved patent information, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as non-proprietary. Within a Primary Manufacturer's response to a particular data element required in the Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS-10844, OMB 0938-1452) [52] (hereinafter the "Drug Price Negotiation ICR"), the response may include information that is non-proprietary because it is publicly available or otherwise does not represent trade secrets and confidential commercial or financial information, such as the introductory language within an explanation field of a data element. Additionally, if a Primary Manufacturer provides a Common Technical File or Drug Master File, that is what is commonly titled "a drug dossier," within the manufacturer's submission of data submitted to CMS in accordance with section 1194(e)(2) of the Act, CMS will treat the submission of a drug dossier as proprietary because CMS understands that this type of document is typically not publicly available. In the Primary Manufacturer's submission of information in response to the Drug Price Negotiation ICR, the Primary Manufacturer may identify for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included in this section as proprietary by CMS. For example, the Primary Manufacturer would have an opportunity to specify any information included in a drug dossier that the Primary Manufacturer believes is proprietary and should be protected from disclosure.

Pursuant to section 1195(a)(2) of the Act and as discussed in section 60.6.1 of this draft guidance, CMS is required to publish the explanation of the MFP by March 1, 2027, for initial price applicability year 2028. In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer for their selected drug (and submitted by the public as discussed in more detail in section 50.2.1 of this draft guidance) that are determined to be non-proprietary and will not disclose any protected health information (PHI), personally identifiable information (PII), or information that is protected from disclosure under other applicable law. Public submissions of section 1194(e)(2) data may also include submissions from a Primary Manufacturer that do not pertain to the selected drug of the Primary Manufacturer (see section 50.2.1 of this draft guidance for more information about use and disclosure of public submissions).

[52] This ICR was formerly 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 (IRA) Information Collection Request". As discussed in section 50 of this draft guidance, CMS intends to publish the Drug Price Negotiation ICR in the Federal Register for a 60-day public comment period in Summer 2025 and intends to publish a revised version of the ICR for a 30-day comment period in Fall 2025.

Within the explanation of the MFP, CMS may also make public high-level comments about the section 1194(e)(1) and section 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any PHI / PII or any proprietary information reported to CMS under section 1193(a)(4) of the Act for purposes of the negotiation. For example, CMS will not make public the research and development costs reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say "the manufacturer has recouped its research and development costs." Any proprietary information obtained during an audit will also remain confidential, except as necessary to use that information in the course of a judicial enforcement proceeding.

Similar to the approach taken for publication of the public MFP explanations for initial price applicability year 2026, for each drug, CMS will make available on the CMS website redacted versions of section 1194(e)(1) and section 1194(e)(2) submitted data.

40.2.2 Data and Information Use Provisions and Limitations

CMS will not publicly discuss ongoing negotiations with a Primary Manufacturer, except as outlined below. As described in section 60.6.1 of this 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. In advance of this public narrative, CMS may share certain aggregate or non-selected drug specific information, for example regarding status of the negotiation process or conclusion of negotiations.

A Primary Manufacturer may choose to publicly disclose information regarding its ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this 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 the negotiation process.

40.2.3 Opportunity for Corrective Action Following Information Submission
Recognizing the substantial role that manufacturer-submitted information will play in the Negotiation Program and in administering and monitoring the Negotiation Program, CMS intends to provide Primary Manufacturers with an opportunity for corrective action in the event a submission is incomplete or inaccurate. Upon receipt of Primary Manufacturer-submitted information – for example, information on the section 1194(e)(1) factors – CMS intends to review the submission for completeness and accuracy. Should CMS determine a submission is incomplete or contains inaccurate information, CMS intends to provide a written request to the Primary Manufacturer to clarify the submission, correct the inaccuracy, or provide the necessary information, with a deadline by which the Primary Manufacturer must respond. Following resubmission, CMS may follow up with the Primary Manufacturer to clarify any information included in the resubmission and confirm full accuracy and completeness of the required information.

If the Primary Manufacturer has failed to clarify its submission or if CMS determines the submission remains incomplete or inaccurate, CMS may issue a Request for a Corrective Action Plan (CAP) outlining the needed action and establishing a five business-day deadline for the Primary Manufacturer to correct the submission and/or provide additional information to validate the accuracy/completeness of the original submission. CMS intends to make efforts to be available to engage with the Primary Manufacturer about the specifics of a request for corrected information and to answer questions and provide clarification. Note that the information required under section 1193(a)(4) of the Act, including the section 1194(e)(1) factors, is information required by CMS to administer and monitor the Negotiation Program in accordance with section 1193(a)(5) of the Act; as such, failure to provide complete and accurate section 1194(e)(1) data, initially or in response to CMS' initial questions or Request for a CAP, may result in the Primary Manufacturer being subject to a CMP as authorized under section 1197(c) of the Act and as described in section 100.2 of this draft guidance. If CMS decides to assess a CMP, the process established in section 100.5 of this draft guidance will be followed.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years
CMS will use the CMS HPMS to share the initial offer and concise justification, to share any subsequent written offer(s), and to receive any written counteroffer(s) from the Primary Manufacturer of a selected drug. A Primary Manufacturer that signs the Agreement will be required to adhere to the process and deadlines described in section 60 of this 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 statutory written counteroffer, the Primary Manufacturer will populate an Addendum in the CMS HPMS containing the MFP identified in the statutory written counteroffer and sign the Addendum; if CMS wishes to accept the statutory written counteroffer,

it will countersign the Addendum in the CMS HPMS. CMS will determine that negotiations have concluded upon execution by both parties of the Addendum setting forth the agreed-upon MFP.

Pursuant to section 1194(f) of the Act, for initial price applicability year 2028, CMS may select for renegotiation selected drugs for initial price applicability years 2026 and 2027 if such drugs meet certain eligibility and selection criteria (described further in section 130 of this draft guidance). If a drug is selected for renegotiation for initial price applicability year 2028, and if agreement is reached with respect to a renegotiated MFP, the Primary Manufacturer will be obligated to make the renegotiated MFP available as described in sections 40.4 and 130 of this draft guidance.

40.4 Providing Access to the MFP in 2026, 2027, and 2028

After entering into an Agreement with CMS and in accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must, for 2026, 2027, and 2028, as applicable, provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act and section 80 of this 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. Beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028 per section 130 of this draft guidance, such Primary Manufacturers must also provide access to the MFP, or renegotiated MFP, as applicable, to hospitals, physicians, and other providers of services and suppliers with respect to MFP-eligible individuals (described in section 1191(c)(2)(B) of the Act and section 80 of this draft guidance) who are furnished or administered that selected drug during a price applicability period. That is, the Primary Manufacturer is required to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug included on the list maintained on the CMS HPMS and published in accordance with sections 30.4 and 60.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this 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) or, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, if payment may be made for such dosage forms, strengths, and package sizes under Medicare Part B.

Although the Primary Manufacturer is obligated to provide access to the MFP for these dosage forms, strengths, and package sizes of the selected drug that are dispensed, furnished, or administered to MFP-eligible individuals, the Primary Manufacturer is not obligated to make any sales of the selected drug. As described in section 40.2 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable, the Primary Manufacturer has an ongoing obligation to timely report any changes to the NDC-11s for the selected drug to ensure the list of NDC-11s of the selected drug in the CMS HPMS remains

complete and accurate. As described in section 60.6 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 and this draft guidance, CMS will update the MFP file as needed. The MFP file will contain the single MFP for a 30-day equivalent supply of the selected drug, the NDC-9 per unit price, the NDC-11 per package price, and the HCPCS code dosage price, and will be updated annually to show the inflation-adjusted MFP for the selected drug. Section 60.6 of this draft guidance contains more details related to the MFP file.

Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for such drug.[53] In Part D, the negotiated price of a drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point-of-sale. That is, in the case of a selected drug for which an MFP is in effect, the MFP-eligible individual's Part D cost-sharing is based on a negotiated price that cannot exceed the MFP plus any dispensing fees for such drug. Therefore, the requirement that the price used for MFP-eligible individual cost-sharing and benefit administration cannot exceed the applicable MFP (plus dispensing fees) helps to ensure that MFP-eligible individuals will have access to the MFP at the point-of-sale for selected drugs covered under Part D. While section 1193(a) of the Act requires the Primary Manufacturer to provide access to the MFP to MFP-eligible individuals, meeting this obligation to make the MFP available to MFP-eligible individuals will be facilitated by Part D plan sponsors in the normal course of operations.

However, section 1193(a) of the Act also requires that the Primary Manufacturer provide access to the MFP for the selected drug to pharmacies, mail order services, and other dispensing entities (hereinafter "dispensing entities") with respect to MFP-eligible individuals who are dispensed such drugs and, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, to hospitals, physicians, and other providers of services and suppliers (hereinafter "Part B providers") with respect to MFP-eligible individuals who are furnished or administered such drugs. CMS requires that Primary Manufacturers establish processes to ensure that dispensing entities that dispense drugs and Part B providers that furnish or administer drugs to MFP-eligible individuals have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in this section and section 90.2 of this draft guidance. CMS defines "providing access to the MFP" as ensuring that the acquisition cost of the dispensing entity or Part B provider for the selected drug (as discussed in more detail in section 40.4.1) is no greater than the MFP.

A Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity or Part B provider when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity or Part B provider's acquisition cost and the MFP. For selected drugs dispensed to MFP-eligible individuals, this means that, unless the dispensing entity's

[53] 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.

acquisition cost for the selected drug is equal to or less than the MFP, or, as detailed in section 40.4.5 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 transmit payment of an amount that provides access to the MFP within 14 calendar days of when the MTF sends data to the Primary Manufacturer that verify the selected drug was dispensed to an MFP-eligible individual (hereinafter the "14-day prompt MFP payment window").

A Primary Manufacturer must effectuate any agreed-upon MFPs for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028 when dispensed, furnished, or administered to MFP-eligible individuals on or after January 1, 2028. CMS is not at this time including detailed policy on providing access to the MFP for selected drugs payable under Part B. To the extent appropriate and feasible, CMS intends to align the policies and operations for providing access to the MFP for selected drugs payable under Part B with those for selected drugs covered under Part D. Unless otherwise specified, the MFP effectuation policies described hereinafter apply only to selected drugs covered under Part D and dispensed to MFP-eligible individuals as defined by section 1191(c)(2)(A) and described in section 80 of this draft guidance.

While Primary Manufacturers and dispensing entities participating in Part D plan networks will be required to enroll in the MTF DM, and we expect that Primary Manufacturers and dispensing entities will use the MTF platform (including the voluntary MTF PM) to support access to the MFP for selected drugs starting January 1, 2026, it is possible that the private sector could develop alternative solutions for sharing verified data or for routing refund payments from manufacturers to dispensing entities. Therefore, CMS is soliciting comments on potential private market solutions that could offer an alternative to the MTF and the extent to which interested parties perceive a need for ongoing MTF support over time.

The MTF could be expanded to support MFP effectuation for drugs payable under Part B beginning with initial price applicability year 2028. CMS is soliciting comments on how the effectuation of MFP refund payments for drugs payable under Part B might differ from what is outlined for drugs covered under Part D, such as recommendations on the most effective means for the MTF Payment Module (hereinafter the "MTF PM") to facilitate MFP refund payments for drugs payable under Part B to Part B providers with respect to MFP-eligible individuals who are furnished or administered the selected drug, recommendations about whether the MTF Data Module (hereinafter the "MTF DM") should include a standard default refund amount among the claim-level data elements and how such refund amount could be calculated, considerations for claim-level data elements for selected drugs payable under Part B that Primary Manufacturers should receive from the MTF DM, considerations for the claim-level payment elements for selected drugs payable under Part B when payment is and is not facilitated by the MTF PM, and comments on workflows, data flows and payment flows for the MTF DM and MTF PM with respect to drugs payable under Part B. CMS intends to provide detailed policy on providing access to the MFP for selected drugs payable under Part B in the future.

If a retrospective refund is necessary to effectuate the MFP, CMS notes that the Primary Manufacturer must *transmit* (as described in section 40.4.2.1 of this draft guidance) an MFP refund amount within 14 days, as opposed to ensuring the dispensing entity has *received* the

MFP reimbursement within 14 days, in order to comply with the 14-day prompt MFP payment window. As noted in the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS intends for the 14-day prompt MFP payment window to align with the timing requirement in the longstanding prompt pay rules in Part D for plan sponsors.[54] Clarifying that the 14-day prompt MFP payment window requires the MFP refund payment to be transmitted within 14 days provides for greater consistency with the Part D prompt pay rules, which establish a required timeframe for plan sponsors to issue, mail, or otherwise transmit payment, as opposed to a deadline by which plan sponsors must ensure pharmacies have received payment. Additionally, this definition should provide interested parties and CMS with a clear standard by which to monitor whether Primary Manufacturers have made the MFP available on a timely basis, especially with respect to payment methods (e.g., paper checks) where it might be difficult for parties to ensure that the payment amount has been received by the dispensing entity before the end of the 14-day prompt MFP payment window. While the 14-day prompt MFP payment window is intended to align with the timing requirements in the Part D prompt pay rules, dispensing entities should be aware that they may not receive payment from a Part D plan sponsor for the Part D claim on the same date that the Primary Manufacturer provides a retrospective MFP refund to the dispensing entity. Due to operational differences between the Part D program and the Negotiation Program, the respective prompt payment windows for a particular dispense may start on different dates for the Part D plan sponsor and the Primary Manufacturer.

CMS reiterates that section 1193(a)(3)(A) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to dispensing entities that dispense the selected drug to MFP-eligible individuals. Similarly, section 1193(a)(3)(B) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to Part B providers that furnish or administer the selected drug to MFP-eligible individuals. The Primary Manufacturer is also obligated to ensure that the MFP is available for units of the selected drug that are marketed and sold by any Secondary Manufacturer(s) and dispensed, furnished, or administered to MFP-eligible individuals. Commercial and other payers continue to have discretion to consider Medicare payment rates, including the MFP, in establishing their own payment policies.

CMS received extensive feedback from interested parties and, based upon that feedback, has completed an MTF data exchange acquisition process to engage an MTF Contractor[55] for the Negotiation Program to facilitate the exchange of data between Primary Manufacturers and dispensing entities. The MTF DM will support the verification that the selected drug was dispensed to an MFP-eligible individual, as described in section 40.4.2 of this draft guidance. As described in section 40.4.2 of this draft guidance, CMS believes mandatory participation for Primary Manufacturers and dispensing entities in the MTF's data exchange functionality is necessary to administer the Negotiation Program and Part D program, as well as to promote

[54] See 42 C.F.R. § 423.520, Prompt Payment by Part D Sponsors, which requires the Part D sponsor to transmit payment to pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.
[55] For the purposes of this guidance, CMS uses the term "MTF Contractor" or "MTF Contractors" to refer generally to the contractors that CMS has engaged to provide services in connection with the MTF, including the MTF DM and MTF PM.

compliance and oversight. CMS intends for the MTF DM to serve a similar purpose for drugs payable under Part B.

CMS conducted listening sessions and reviewed comments regarding payment options outlined in draft guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027. Interested parties were generally supportive of payment facilitation in addition to data exchange. Therefore, CMS also completed an acquisition process to engage a separate MTF Contractor to support the MTF PM. The MTF PM will facilitate passing through payments from Primary Manufacturers that elect to use the MTF PM that will complement the data-related activities of the MTF DM. CMS intends that the MTF PM will also be available to Primary Manufacturers for drugs payable under Part B.

CMS hosts frequent MTF systems and technical calls to engage with manufacturers and dispensing entities on implementation details and operational topics such as system integration, secure data exchange protocols, system user experience, and other components to inform the design and functionality of the MTF DM and MTF PM and to share information and hear feedback on technical and operational aspects of the Negotiation Program.

While CMS is committed to helping to facilitate exchange of data and passing through payment, the Primary Manufacturer is ultimately responsible for calculating the appropriate amount to effectuate the MFP and ensuring that timely payment is made to the dispensing entity or Part B provider, as applicable. Stakeholders using the MTF systems should also remain mindful of their obligations to comply with all applicable laws, regulations and guidance including, but not limited to, fraud and abuse laws such as the Anti-Kickback Statute. CMS may refer potential fraud and abuse concerns to law enforcement, including the Department of Justice and Office of the Inspector General, as applicable.

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

CMS understands that changes to the MFP effectuation process described in section 40.4 of the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 may impact the development of interested parties' MFP effectuation implementation solutions. CMS highlights that the following key changes are made in sections 40.4.1 through 40.4.5 of this draft guidance: (1) articulation of the factors manufacturers should consider when determining whether an MFP refund is required and the amount of any such refund in order to meet their statutory obligation to make MFP available (section 40.4.1); (2) the inclusion of new claim-level data elements and clarification on how the MTF DM will handle and process specific claim edits in CMS' Drug Data Processing System (DDPS) (section 40.4.2);

(3) additional and updated information about the Medicare Transaction Facilitator Data Module User Agreement (hereinafter the "MTF DM User Agreement"), including the impact of transfer of ownership of a selected drug or termination of participation in the Negotiation Program on the MTF DM User Agreement and surviving responsibilities (section 40.4.2.1); (4) clarification that the MTF DM will produce remittances for all MFP refund payments facilitated by the MTF PM or for claims for which the Primary Manufacturer indicates to the MTF DM that the MFP was provided prospectively (section 40.4.2); (5) further clarification on the issuance and timing of payment to dispensing entities that elect to receive MFP refund payments from the MTF PM in the form of paper checks and details related to situations in which a paper check is not deposited by the dispensing entity (section 40.4.3); and (6) clarification on Primary Manufacturers' responsibilities when terminating participation in the MTF PM (section 40.4.3). Additionally, CMS provides clarification that the claim-level data elements and claim-level payment elements shall be returned in a single response file to the MTF DM. As noted above, CMS is also soliciting comments on how the introduction of selected drugs payable under Part B may affect the MFP effectuation process as compared to selected drugs covered under Part D, including how those changes would likely correspond with the MTF data and payment workflows outlined in sections 40.4.2, 40.4.3, and 40.4.4 of this draft guidance.

40.4.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount

As described above, a Primary Manufacturer may meet its statutory obligation under section 1193(a)(3) of the Act to make the MFP available to dispensing entities by retrospectively transmitting payment for the difference between the dispensing entity's acquisition cost and the MFP (i.e., the MFP refund amount), within the 14-day prompt MFP payment window. CMS recognizes that dispensing entities and manufacturers may face significant challenges establishing a reliable actual acquisition cost for a selected drug that could be used to determine the MFP refund amount. For example, using each individual dispensing entity's actual acquisition cost for each particular dispensed unit of a selected drug could be challenging due to differences in purchasing agreements with suppliers that contribute to variable drug costs among dispensing entities, the number of dispensing entities for which to account, pricing variability among individual units of a selected drug within each dispensing entity's inventory, difficulties in reconciling the misalignment in the cost of a drug product when it is acquired for purchase and the changes in cost through the point at which that product is dispensed, and restrictions and sensitivities around sharing proprietary pricing information with third-party vendors. However, a Primary Manufacturer and dispensing entity may choose to calculate the MFP refund using a dispensing entity's actual acquisition cost rather than a standardized pricing metric that serves as a reasonable proxy for the dispensing entity's acquisition cost.

CMS recognizes the significant operational challenges that Primary Manufacturers and dispensing entities may face in calculating a retrospective refund amount based on real-time actual acquisition cost. CMS believes that allowing a Primary Manufacturer flexibility to determine its preferred methodology for calculating its MFP refund payments aligns with the Primary Manufacturer's statutory obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP, as required under section 1193(a)(3) of the Act. CMS outlines in section 90.2 of this draft guidance what factors it will consider when evaluating whether an MFP refund amount appears consistent with availability of the MFP.

Primary Manufacturers should consider such factors when determining whether an MFP refund is necessary to effectuate the MFP and when calculating the amount of such a refund; please see section 90.2 of this draft guidance for more information on these factors. CMS encourages interested parties to use the complaints process within the complaint and dispute system, as outlined in section 90.2.2 of this draft guidance, to address issues regarding access to the MFP. CMS intends to review complaints regarding access to the MFP on a case-by-case basis and monitor overall trends and emerging compliance issues reported via the complaints and disputes system, including issues related to determining acquisition costs.

CMS believes using WAC to calculate an SDRA generally best approximates the acquisition costs of dispensing entities and offers a reliable refund amount for both manufacturers and dispensing entities that agree to use such a standardized pricing metric. WAC, as defined by section 1847A(c)(6)(B) of the Act, is the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Additionally, the use of WAC as a standardized pricing metric in the calculation of the SDRA addresses concerns raised by interested parties that use of acquisition cost would create significant administrative burdens and avoids dispensing entities having to share proprietary or confidential pricing information with Primary Manufacturers. WAC is a widely available pricing metric, published and regularly updated in common pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process and would not require the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates, between parties.

The MTF DM will use WAC, as published in pharmaceutical pricing database compendia on the date of service of the Part D claim, as the standardized pricing metric to calculate the SDRA. As described in section 40.4.2 of this draft guidance, the MTF DM will provide the Primary Manufacturer with the SDRA (i.e., WAC per unit on the date of service of the Part D claim minus MFP per unit on the date of service of the Part D claim, then multiplied by the quantity dispensed) as part of the transmitted claim-level data elements. The Primary Manufacturer may elect to use the SDRA, as appropriate, to calculate and make the retrospective MFP refund payment to dispensing entities. CMS maintains that WAC is the best option to calculate the SDRA for the MTF DM for the reasons stated above and due to the support expressed by interested parties.[56]

The obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP rests with the Primary Manufacturer. A Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines some other amount is appropriate and sufficient to make the MFP available. A dispensing entity can work

[56] In response to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS received comments from interested parties, including manufacturers and dispensing entities, overwhelmingly supporting the use of a standardized proxy for acquisition cost, such as WAC, to calculate the MFP refund amount. See https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

with Primary Manufacturers to establish an MFP refund amount using the dispensing entity's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available, and the Primary Manufacturer would indicate such agreed amount when reporting the claim-level payment elements, described in sections 40.4.3 and 40.4.4 of this draft guidance, provided by the Primary Manufacturer to the MTF DM. In the exceedingly rare case that the NDC for a Part D claim does not have a published WAC available to CMS for the date of service of the claim, the MTF DM will not provide the Primary Manufacturer with the calculated SDRA and will leave the field null in the transmitted claim-level data elements for the claim. Unless access to the MFP was provided prospectively or, as detailed in section 40.4.5 of this draft guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, the Primary Manufacturer remains obligated to pay an appropriate refund amount to ensure the dispensing entity has access to the MFP and is responsible for calculating that refund amount. As for the rare cases where the MTF DM does not provide the Primary Manufacturer with a calculated SDRA, Primary Manufacturers are encouraged to include information on their approach to calculating an MFP refund amount when an SDRA is not provided in the Primary Manufacturer's MFP Effectuation Plan for initial price applicability year 2026 and are required to include this information beginning with initial price applicability year 2027 as outlined in section 90.2.1 of this draft guidance.

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 dispensing entity's actual acquisition cost or a reasonable proxy for such a cost, such as WAC (i.e., the SDRA). If the Primary Manufacturer and a dispensing entity agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost (e.g., WAC as used in the SDRA), as opposed to the dispensing entity's actual acquisition cost for that particular unit of the selected drug, then CMS intends to consider a retrospective refund paid pursuant to that calculation to be sufficient for the Primary Manufacturer to meet its obligation to make the MFP available to the dispensing entity. Additionally, as described in more detail in sections 40.4.3.1 and 40.4.4.2 of this draft guidance, the Primary Manufacturer is required to transmit claim-level payment elements to the MTF DM and, should the Primary Manufacturer pay an amount other than the SDRA, the Primary Manufacturer is required to indicate that an amount other than the SDRA was made available and provide the amount of payment determined to be the MFP refund when reporting claim-level payment elements to the MTF DM. If a dispensing entity believes that they have not received a retrospective refund that effectuates the MFP, CMS recommends the dispensing entity remediate with the Primary Manufacturer directly. If remediation between the parties cannot be reached, interested parties are encouraged to use the complaints process, within the complaint and dispute system outlined in section 90.2.2 of this draft guidance in addressing issues regarding access to the MFP.

40.4.2 Medicare Transaction Facilitator Data Facilitation

As discussed in section 40.4 of this draft guidance, CMS has engaged an MTF Contractor for the MTF DM to facilitate the exchange of certain claim-level data elements and claim-level payment elements for selected drugs. As discussed in further detail below, CMS requires Primary Manufacturers to participate in the MTF DM for purposes of data exchange to exchange key data files necessary for MFP effectuation. In recent rulemaking, CMS finalized a requirement for Part

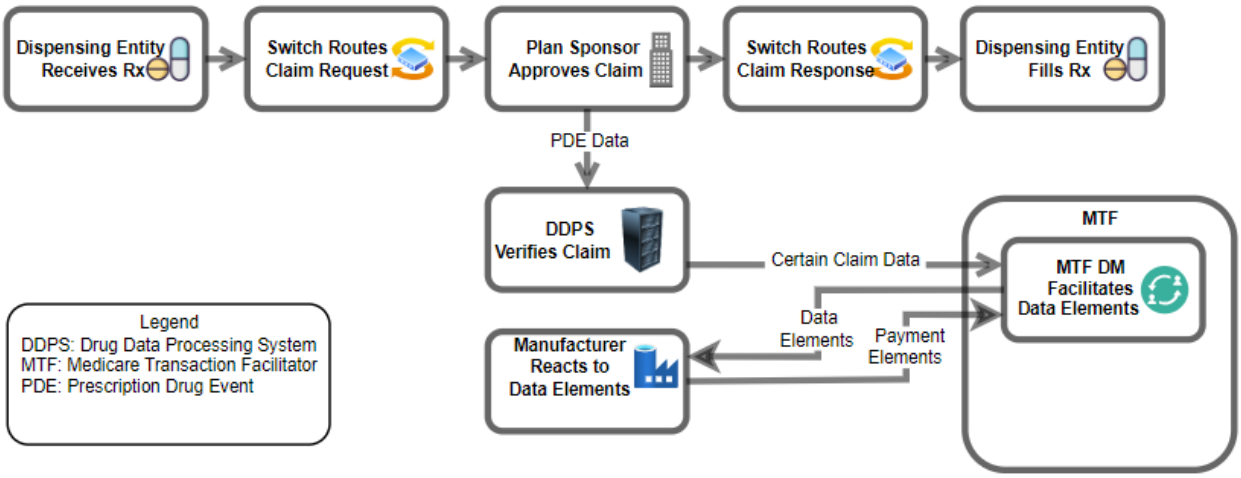
D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM.[57] Dispensing entity participation in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and making available remittances (e.g., paper checks) or an Electronic Remittance Advice (ERAs) that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act (HIPAA), providing access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are drugs covered under Part D, and ensuring accurate Part D claims information and payment. Neither Primary Manufacturers nor dispensing entities shall be required to pay any fees to participate in the MTF DM, including but not limited to user fees or transaction fees, as CMS intends to bear the cost of operationalizing the MTF. In addition, regardless of whether the MFP refund is passed through the MTF PM or payment is made outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

The MTF DM is intended to accomplish the following tasks in the administration of the Negotiation Program: (1) support verification that the selected drug was dispensed to an MFP-eligible individual and furnish the manufacturer with certain claim-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual and identifying the dispensing entity that dispensed the selected drug to the MFP-eligible individual; (2) initiate the 14-day prompt MFP payment window for the Primary Manufacturer to transmit certain claim-level payment elements and, if applicable, the MFP refund for each claim for a selected drug; (3) collect such payment elements for each claim for a selected drug from Primary Manufacturers indicating whether a refund is being paid and the amount of the refund being paid to make the MFP available, if applicable; and (4) make available an ERA for electronic payments or a remittance for payment made by paper check to dispensing entities for payments the Primary Manufacturer passes through the MTF PM.

For illustrative purposes, Figure 2 depicts a basic conceptual overview of the currently anticipated mandatory MTF DM data flow for drugs covered under Part D. CMS will leverage Part D claims data (PDE data) in this data exchange. CMS may revisit the data flow in the future and anticipates technical specifications to evolve as development of the MTF DM's data functionality and information systems progress. Although Figure 2 illustrates data flow for Part D drug claims, as discussed in section 40.4 of this draft guidance, CMS intends to also use the MTF to facilitate data exchange for drugs payable under Part B that are furnished or administered to MFP-eligible individuals and is soliciting comments for how the data flow for Part B drug claims may differ from what is outlined below.

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

Figure 2: Diagram of MTF Data Flow



40.4.2.1 Primary Manufacturer Participation in the MTF DM

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering and monitoring compliance with the Negotiation Program, participation in the MTF DM is mandatory for Primary Manufacturers. CMS intends to require all Primary Manufacturers that reach an agreed upon MFP for initial price applicability years 2027 and 2028 to register with the MTF DM by April 1 of the calendar year before the MFP would go into effect, beginning April 1, 2026; for example, Primary Manufacturers with MFPs that will take effect on January 1, 2027 will need to enroll by April 1, 2026. For Primary Manufacturers that reached an agreed upon MFP that takes effect on January 1, 2026, CMS will contact each Primary Manufacturer regarding the deadline for MTF DM enrollment as the MTF system becomes available for enrollment in 2025. CMS also will require all Primary Manufacturers to maintain the functionality necessary to receive certain claim-level data elements from the MTF DM and return certain claim-level payment elements to the MTF DM. During registration, Primary Manufacturers will be required to furnish information necessary for the MTF DM to complete remittances and ERAs for refunds paid through the MTF PM by the Primary Manufacturer, including but not limited to bank account information if participating in the MTF PM, and to furnish information necessary for the MTF DM to support resolution of complaints and disputes, including circumstances where the Primary Manufacturer chooses not to pass payment through the MTF PM.

Each Primary Manufacturer will be required to sign user agreements to participate in the MTF; all Primary Manufacturers will be required to sign an MTF DM User Agreement[58] with CMS during the MTF DM enrollment process. Primary Manufacturers who elect to participate in the MTF PM will also be required to sign the Medicare Transaction Facilitator Payment Module Contractor Agreement (hereinafter the "MTF PM User Agreement") with the MTF PM Contractor. These MTF agreements establish the rights and responsibilities of all parties involved in the MTF. The MTF agreements contain data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF. The Primary

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

Manufacturer will have one MTF DM User Agreement; if the Primary Manufacturer is the Primary Manufacturer of multiple selected drug(s) for which it agrees to MFPs, including, for example, selected drugs chosen for different initial price applicability years, the Primary Manufacturer will add all such selected drugs to the same signed MTF DM User Agreement. In the event the Primary Manufacturer transfers ownership of all NDAs or BLAs of a selected drug following the process established in section 40.7 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable, the transferring Primary Manufacturer's MTF agreement(s) will terminate as to that transferred selected drug in accordance with the terms of the MTF DM User Agreement and, if applicable, the MTF PM User Agreement. In accordance with the terms of the MTF DM User Agreement, the new acquiring Primary Manufacturer will assume responsibility as the Primary Manufacturer of such selected drug and will be required to sign an MTF DM User Agreement if the Primary Manufacturer does not currently hold an MTF DM User Agreement, or will be required to add the acquired selected drug to an existing MTF DM User Agreement. The transferring Manufacturer must provide CMS at least 30 days written notice before the effective date of any transfer of ownership covered by the MTF DM User Agreement.

If the Medicare Drug Price Negotiation Program Agreement with respect to a selected drug is terminated in accordance with section 40.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable, the MTF DM User Agreement will automatically terminate with respect to such selected drug effective as of the effective date of termination of the Medicare Drug Price Negotiation Program Agreement with respect to such selected drug. Termination of the MTF DM User Agreement as to a particular selected drug will not affect other selected drug(s) covered by the agreement. Termination of the MTF DM User Agreement as to a selected drug will not affect the Primary Manufacturer's responsibility for effectuating the MFP for dispenses of such selected drug to MFP-eligible individuals with a date of service before the effective date of the termination of the MTF DM User Agreement with respect to such selected drug, except in cases where the Primary Manufacturer has transferred ownership of the selected drug(s) as discussed above (in which case the acquiring Primary Manufacturer is responsible for effectuating MFP for such dispenses).

Notwithstanding the termination of the MTF DM User Agreement with respect to a selected drug, certain requirements and obligations shall survive termination as specified in the MTF DM User Agreement. Because there is a runout of claims for selected drugs dispensed prior to the effective date of termination for which the Primary Manufacturer remains responsible under the statute for providing access to the MFP (except in cases where the Primary Manufacturer has transferred ownership of the selected drug(s) to an acquiring Primary Manufacturer as discussed above), the Primary Manufacturer will still have access to the MTF to address any claims with dates of service prior to termination until such claims are resolved.

As described in sections 40.4.3 and 40.4.4 of this draft guidance, all Primary Manufacturers will be required to utilize MTF DM data functionality to report to the MTF DM information (claim-level payment elements) about how the Primary Manufacturer has made the MFP available for each claim for which the Primary Manufacturer received data from the MTF DM, or why no

MFP refund payment has been made on a claim. These data exchange requirements apply to each Primary Manufacturer irrespective of how the Primary Manufacturer effectuates the MFP (i.e., through prospective sales of a selected drug to a dispensing entity, either directly or through the supply chain, or through a retrospective refund to a dispensing entity, which may be facilitated by the MTF PM as described in section 40.4.3 of this draft guidance or through another payment facilitation method of the Primary Manufacturer's choosing).

CMS acknowledges that a Primary Manufacturer may choose to contract with one or more third-party vendors to perform required operations on behalf of the Primary Manufacturer. Such required operations are discussed in this section 40.4.2.1 of this draft guidance on the MTF data exchange and in sections 40.4.3 and 40.4.4 of this draft guidance on retrospective refund payment. The Primary Manufacturer remains responsible for compliance with all Negotiation Program requirements notwithstanding any actions that third-party vendors may perform on the Primary Manufacturer's behalf.

Requiring Primary Manufacturers to exchange specified data with the MTF DM is necessary for several reasons. First, exchange of data with the MTF DM ensures a uniform approach to the start of the 14-day prompt MFP payment window for each claim for a selected drug. Second, requiring Primary Manufacturers to exchange claim-level data with the MTF supports the MTF DM in producing ERAs or remittances, as applicable, when the Primary Manufacturer transmits payments through the MTF PM (or to document that dispensed drugs were prospectively purchased at MFP). Third, the Primary Manufacturer exchange of claim-level payment information supports CMS in monitoring the extent to which the Primary Manufacturer has made MFP available, pursuant to CMS' obligation under section 1196(b) of the Act to monitor Primary Manufacturers' compliance with the terms of the Agreements. Failure by the Primary Manufacturer to register with the MTF DM or to meet the MTF data exchange requirements, including maintaining functionality to receive certain claim-level data elements from the MTF DM and transmission of claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, would be a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act (see section 100.2 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable).

The claim-level data elements for Part D claims for NDCs of a selected drug that the MTF DM will send to the Primary Manufacturer are listed in Table 2. These data will be exclusively transmitted through the MTF DM to the Primary Manufacturer or its designated third-party vendor. In selecting the claim-level data elements that will be sent to Primary Manufacturers, CMS considered numerous data elements recommended by interested parties, such as an encrypted beneficiary identification number and claim reimbursement amounts. CMS believes that the selected data elements provide the minimum necessary information to verify the selected drug was dispensed to an MFP-eligible individual.

Table 2: MTF DM Claim-Level Data Elements

MTF DM Data Elements List	Purpose	Data Source
Record ID	Identifies the type of record, such as claim detail, file header, and file trailer	MTF
MTF Internal Claim Number (ICN)	Identifies the internal unique identifier assigned by the MTF to support claim adjustments	MTF
MTF XRef ICN	Links an adjustment to previous MTF ICN	MTF
Process Date	Identifies MTF processed date	MTF
Transaction Code	Indicates original claim, adjustment, reversal, etc.	MTF
Medicare Source of Coverage	Identifies coverage under Medicare Part B or Part D	MTF
Date of Service	Verifies MFP eligibility	PDE Record
Service Provider Identifier Qualifier	Verifies MFP eligibility	PDE Record
Service Provider Identifier	Verifies MFP eligibility	PDE Record
Prescription/Service Reference Number	Verifies MFP eligibility	PDE Record
Prescriber ID	Identifies prescriber	PDE Record
Prescriber ID Qualifier	Identifies prescriber	PDE Record
Fill Number	Verifies MFP eligibility	PDE Record
Product/Service Identifier	Verifies MFP eligibility	PDE Record
Quantity Dispensed	Assists the manufacturer in calculating a refund	PDE Record
Days' Supply	Assists the manufacturer in calculating a refund	PDE Record

MTF DM Data Elements List	Purpose	Data Source
340B Claim Indicator (as voluntarily reported by dispensing entity)	Assists the manufacturer in assessing applicability of section 1193(d)(1) of the Act	PDE Record
Contract Number	Verifies MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) Per Unit on Date of Service of Claim	Provides list price on claim date of service	MTF
Maximum Fair Price (MFP) Per Unit on Date of Service of Claim	Assists the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (SDRA) ((WAC-MFP) x Quantity Dispensed)	Assists the manufacturer in calculating a refund	MTF
Service Provider Payment Method Preference	Indicates dispensing entity's specified preference for payment via electronic transfer of funds or paper check	MTF
Previous MFP Refund Paid Product/Service Identifier	Indicates product associated with the Previous MFP Refund Paid Amount, if applicable	MTF
Previous MFP Refund Paid Amount	Indicates refund amount previously paid by manufacturer for the claim, if applicable	MTF
Previous MFP Refund Paid Date	Indicates date associated with the Previous MFP Refund Paid Amount, if applicable	MTF
Previous MFP Refund Paid Quantity	Indicates quantity associated with the Previous MFP Refund Paid Amount, if applicable	MTF

MTF DM Data Elements List	Purpose	Data Source
Previous MFP Refund Paid Method for Determining MFP Refund Amount	Indicates basis for determining refund amount associated with the Previous MFP Refund Paid Amount, if applicable	MTF

The combination of "Date of Service," "Service Provider Identifier Qualifier," "Service Provider Identifier," "Prescription/Service Reference Number," and "Fill Number" identify unique Part D claims. Other data elements listed in Table 2 will provide additional information about each claim to the Primary Manufacturer that may be useful in calculating the retrospective refund, if applicable, including "Product/Service Identifier," "Quantity Dispensed," "Days' Supply," "Contract Number," "WAC Per Unit on Date of Service of Claim," and "MFP per unit on Date of Service of Claim."

Beginning January 1, 2025, the "Submission Clarification Code" value of "20" and the "Submission Type Code" value of "AA" was added to the PDE record to indicate a 340B claim.[59] A dispensing entity may voluntarily apply these indicators to a Part D claim to indicate the claim is being billed for a 340B drug.[60] The MTF's provision of the "340B Claim Indicator" data element does not represent or imply that CMS verified the 340B status of the claim nor that dispensing entities are required to include this code on claim submissions. The MTF will also include the field "Service Provider Payment Method Preference" to indicate to Primary Manufacturers if the dispensing entity responsible for the claim has indicated their preference to receive payment via electronic funds transfer or paper check (see section 40.4.3 of this draft guidance for services that the MTF PM will provide to facilitate the transfer of funds between participating Primary Manufacturers and dispensing entities). "Prescriber ID" and "Prescriber ID Qualifier" reflect the National Provider Identifier (NPI) of the prescriber as listed on the claim, which may be useful (although not sufficient, as noted in section 40.4.5 of this draft guidance) for 340B nonduplication efforts. "Transaction Code" will be populated by the MTF when sending claim-level data elements to Primary Manufacturers and by Primary Manufacturers when sending claim-level payment elements to the MTF. Further detail on use of the Transaction Code field will be provided in future guidance or technical instructions. The MTF will have additional data elements (i.e., "MTF internal claim number (ICN)," "Record ID," "MTF XRef ICN," "Process Date," and "Medicare Source of Coverage") that will assist in the facilitation of information on claim adjustments and reversals; further detail on claim adjustments and reversals is provided in sections 40.4.3.2 and 40.4.4.4 of this draft guidance and will be provided in future guidance or technical instructions.

The claim-level data elements that the Primary Manufacturer will receive from the MTF DM will include the SDRA that will reflect the difference between the WAC per unit and the MFP per unit of the selected drug on the date of service, then multiplied by the quantity dispensed, as

[59] See: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.
[60] 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.

described in section 40.4.1 of this draft guidance. Regardless of whether the Primary Manufacturer chooses to pass payment through the MTF PM, the Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP. The MTF DM's provision of the SDRA claim-level data element does not supersede that responsibility or indicate that payment of such an amount will be sufficient for the Primary Manufacturer to meet its statutory obligation to make the MFP available. Rather, this claim-level data element is intended to provide an additional data point to assist the Primary Manufacturer in determining and paying an amount sufficient to make the MFP available consistent with the statute.

Lastly, the claim-level data elements that the Primary Manufacturer will receive from the MTF DM will include information about the previously paid MFP refund, if any, if an adjustment to a previously addressed claim is made. These data elements will show the Primary Manufacturer the MTF record for the immediate prior MFP refund payment made for the specific claim, if any.

See section 40.4.1 of this draft guidance for additional detail regarding retrospective refunds and section 40.4.3 of this draft guidance for additional detail on the voluntary MTF PM payment pass through services. As the approach for effectuating retrospective MFP refunds is further developed, additional data elements may be added to improve efficiency in processing these data.

The MTF DM will provide Primary Manufacturers with data that has been verified by both the Part D plan sponsor and DDPS, a CMS system used to process all Medicare PDE records and related data, resulting in dual verification of both an individual's eligibility for Part D and Part D coverage of the selected drug for each claim being transmitted. When a Part D plan sponsor receives a claim for a selected drug from a dispensing entity, before making any payment, the Part D plan sponsor verifies that the beneficiary listed on the claim is enrolled in Medicare Part D and coverage is provided under Part D for the dispensed drug. After the Part D plan sponsor verifies Medicare eligibility and coverage of the selected drug, the plan pays the dispensing entity no more than the MFP plus any dispensing fees for the selected drug. Then, the Part D plan sponsor sends the data on the Part D claim as a PDE record to DDPS.[61]

CMS, using DDPS, also performs verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim. After CMS verifies MFP eligibility for the individual related to the claim, DDPS will transmit the PDE record for the Part D claim for the selected drug to the MTF DM, which will prepare the file of claim-level data elements listed in Table 2 for MFP-eligible claims for transmittal to the applicable Primary Manufacturer.[62] The MTF DM also will confirm that NDCs on PDE records received from DDPS appear on the list of NDCs for

[61] Currently, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. CMS finalized in rulemaking a change effective in contract year 2026 to shorten the current 30-day window for plans to submit initial PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities. See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

[62] At this time for 2026 and 2027, this file transmittal will exclude claim-level data elements from any PDE data with a compound code indicating the PDE record is for a compounded drug. CMS is exploring operational changes to the PDE record layout that would provide CMS with visibility into data on the quantity dispensed for a selected drug when that selected drug is billed as a compound, at which point such PDE record may be used to allow for inclusion in the claim-level data elements that are included in the file transmittal.

the selected drug maintained in the CMS HPMS prior to sending to the Primary Manufacturer. Therefore, because MFP eligibility status of the individual has been twice validated, by the plan sponsor and DDPS, and the selected drug NDC has been validated by the MTF DM before the data elements are sent from the MTF DM to the Primary Manufacturer, the data elements will have been verified as involving a selected drug that was dispensed to an individual who is MFP-eligible.

Data validation edits are applied against PDE data submitted to DDPS to ensure the information accepted by the system is in accordance with statute, regulation, and program guidance and instruction. PDE records are deemed final action once all DDPS edits are resolved. CMS recognizes that certain DDPS edits do not directly relate to verification of the MFP eligibility of a claim for the purposes of the Negotiation Program, such as edits related to the Manufacturer Discount Program. For administrative efficiency and to minimize new reporting obligations on manufacturers and dispensing entities, CMS decided to leverage the existing PDE data flow to support verification of MFP eligibility through the MTF DM data exchange.

While PDEs include a wide range of data that is necessary for Part D plan sponsor payment purposes, only a subset of the PDE data is directly relevant to and necessary for verifying that a selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual. Requiring all DDPS edits to be resolved before the PDE data is used by the MTF DM to generate and transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window would delay transmission to the Primary Manufacturer of claims that have been verified as a dispense of the selected drug to an MFP-eligible individual, which in turn could cause financial hardship for dispensing entities by delaying payment of an MFP refund on such claim as Part D plans have up to 90 days to resolve DDPS edits.[63]

Therefore, CMS intends to maintain a list of DDPS edits that directly relate to the determination and verification of MFP eligibility for the purposes of the Negotiation Program, such as missing service provider ID or missing or invalid date of service, which will be posted on the CMS website. DDPS edits were identified as related to the determination and verification of MFP eligibility if they directly relate to the data elements listed in Table 2 in this draft guidance, impact the verification of an individual as MFP-eligible in accordance with section 1191(c)(2) of the Act, or identify duplicate PDE records. The current list of DDPS edits CMS has identified as related to the determination and verification of MFP eligibility is in Appendix B of this draft guidance. CMS is soliciting comments on this compilation of DDPS edits for its stated purpose and suggestions for DDPS edits to include or exclude.

CMS intends to process claims in the following manner:

1. If a claim does not have any DDPS edits, the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window.

[63] In accordance with the timeliness standards established in 90 Fed. Reg. 15827 which appeared in the April 15, 2025 Federal Register, Part D sponsors must resolve rejected PDE records within 90 calendar days following the receipt of rejected record status from CMS. See: https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

2. If a claim, through DDPS processing, cleared all of the DDPS edits that are on CMS' list of edits directly related to MFP eligibility and only has DDPS edits that are not on such CMS list, the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window because it has been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual.
3. If a claim has DDPS edits that are on CMS' list of edits directly related to MFP-eligibility or has not yet cleared all of the DDPS edits that are on such CMS list of edits, the MTF DM will not transmit the claim-level data elements to the Primary Manufacturer because it has not been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual. The MTF DM will monitor for resolution of these edits. If all such edits directly related to MFP-eligibility are resolved within 90 days of the rejection, then the MTF DM will transmit the claim-level data elements to the Primary Manufacturer to initiate the 14-day prompt MFP payment window. If the edits are not resolved within this timeframe, the MTF DM will notify the dispensing entity that no refund payment has been paid for the claim through a remittance. If a subsequent PDE record for the claim indicates these edits are resolved, the MTF DM will transmit the claim's data elements to the Primary Manufacturer and initiate the 14-day prompt MFP payment window. CMS is considering what role, if any, the MTF and/or Primary Manufacturers could play in notifying dispensing entities of claims that are not resolved within the time frame discussed above and requests interested parties submit comments on this issue.

Primary Manufacturers may not impose additional reporting requirements on dispensing entities to support MFP eligibility verification, regardless of whether the Primary Manufacturer utilizes the MTF PM. The provision of additional patient information (such as an encrypted "Medicare Beneficiary Identifier") by the MTF DM will not help the Primary Manufacturer to verify the selected drug was dispensed to an MFP-eligible individual because the Primary Manufacturer would also need access to the individual's Medicare eligibility status to verify eligibility. That information is stored with the Medicare plans and DDPS. As stated above, the claim-level data elements will be derived from claims that have been verified for Medicare eligibility by both the Part D plan and DDPS, obviating the need for additional verification by the Primary Manufacturer. In addition, providing additional specific information on individual beneficiaries that constitutes PII or PHI could increase privacy and security risks, even with the use of an encrypted identifier. As a point of reference, the Manufacturer Discount Program, which also sends data elements to manufacturers for the purposes of determining manufacturers' payment obligations, does not provide specific information that identifies individual enrollees.

Once the data has been verified by the Part D plan sponsor and DDPS, and the MTF DM has verified that a claim has no DDPS edits directly related to MFP-eligibility, the MTF DM will make the claim-level data elements listed in Table 2 available to the Primary Manufacturer to notify them that the selected drug was dispensed to an MFP-eligible individual. Claim-level data will be batched across all claims available to the MTF DM as received for all NDCs for the selected drug.

The MTF DM's transmission of the claim-level data elements to the Primary Manufacturer starts the 14-day prompt MFP payment window, within which the Primary Manufacturer must transmit the claim-level payment elements (described further in sections 40.4.3 and 40.4.4 of this draft guidance) for each claim identified in the claim-level data elements that the MTF DM transmits to the Primary Manufacturer and, if applicable, must transmit payment of an amount that provides access to the MFP when an MFP refund is appropriate. The date of transmission of the claim-level data elements from the MTF DM to the Primary Manufacturer is considered day 0 of the 14-day prompt MFP payment window. If a retrospective refund is required to effectuate the MFP, the Primary Manufacturer must transmit payment no later than 11:59 PM PT on day 14. The Primary Manufacturer will be considered to have transmitted payment within the 14-day prompt MFP payment window if either (1) when payment is passed through the MTF PM, the Primary Manufacturer sends the claim-level payment elements to the MTF DM on or before day 14 authorizing payment to the dispensing entity; or (2) when payment is made outside of the MTF PM, the Primary Manufacturer sends the claim-level payment elements to the MTF DM and sends the MFP refund amount to the dispensing entity on or before day 14. Regardless of whether the Primary Manufacturer uses the MTF PM or not to make the MFP refund payment, under this definition, the transmission of payment is considered to have occurred when the Primary Manufacturer takes the last step on its part to make payment to the dispensing entity. In cases where the MTF PM is used, this final step for payment is the authorization via the payment elements for the MTF PM to send along payment to the dispensing entity in the amount directed by the Primary Manufacturer. In cases where payment is made outside of the MTF PM, the final step is the Primary Manufacturer sending the MFP refund amount to the dispensing entity (e.g., electronically or by mailing a paper check) because the submission of payment elements alone will not result in the dispensing entity being paid without further action by the Primary Manufacturer. Failure to meet these obligations may cause the Primary Manufacturer to be subject to CMPs (see section 100 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable). If a Primary Manufacturer believes that there is an error with the claim-level data received, it can submit a dispute by following the process outlined in section 90.2.2 of this draft guidance.

The Primary Manufacturer will be the sole manufacturer authorized to receive this claim-level data directly from the MTF DM about its selected drug and will be responsible for receiving such data for all NDCs of the selected drug subject to an MFP, including those marketed and sold by a Secondary Manufacturer. The Primary Manufacturer must ensure that any data sharing with and any activity by Secondary Manufacturer(s) or third-party vendors contracted by the Primary Manufacturer comply with applicable privacy and security laws, regulations, and CMS requirements to protect the claim-level data elements received from the MTF DM. The Primary Manufacturer also must ensure any activity by Secondary Manufacturer(s) complies with the requirements for the Primary Manufacturer to provide access to the MFP by ensuring an MFP refund reaches the dispensing entity when an MFP refund is appropriate, and the Primary Manufacturer must transmit reports with claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window.

Table 3 describes the timing and required actions of Primary Manufacturers to comply with the 14-day prompt MFP payment window based on the Primary Manufacturer's elected MFP

effectuation method when making the MFP available through retrospective refunds. If the Primary Manufacturer has made the MFP available prospectively, then no subsequent payment is needed; however, the Primary Manufacturer is still required to submit its claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window.

Table 3: Primary Manufacturer Payment Approaches to MFP Effectuation

	Payment Passed Through MTF Payment Module (PM)	**Payment Made Outside the MTF Payment Module (PM)**	
Pathway Description	Passing MFP refund payments through the MTF PM	Typically passing MFP refund payments through the MTF PM, but has a mutually agreed upon separate payment arrangement with a dispensing entity	Not passing MFP refund payments through the MTF PM
Action to meet the 14-day prompt MFP payment window	Transmit claim-level payment elements to the MTF DM authorizing electronic fund transfer to and transmission of MFP refund payment by the MTF PM	Transmit the MFP refund payment to the dispensing entity, and transmit payment elements to the MTF DM once payment has been transmitted	
Deadline For Action	No later than 11:59 PM PT on Day 14 after the MTF DM transmits the claim-level data elements to the Primary Manufacturer, with the clock beginning (Day 0) on the day the MTF DM transmits the claims-level data to the Primary Manufacturer.		
Payment Transmission Date Recorded as:	The system-generated date and time the payment elements sent by the Primary Manufacturer are received by the MTF DM, authorizing electronic funds transfer to and transmission of MFP refund payment by the MTF PM	The date and time the MFP refund payment is transmitted from the Primary Manufacturer to the dispensing entity, as reported by the Primary Manufacturer in the claim-level payment elements*	
Result Following Action	MTF PM transmits MFP refund payment to the dispensing entity (electronically or via paper check)	MFP refund payment is required to be transmitted by the Primary Manufacturer prior to submission of claim-level payment elements. No required action by the MTF.	

* For MFP refunds via paper check, the payment transmission date should be recorded as the date on which the paper check was mailed.

40.4.2.2 Dispensing Entity Enrollment in the MTF DM

CMS finalized in rulemaking a requirement that Part D plan sponsors, starting in contract year 2026, include in their pharmacy agreements provisions requiring the pharmacy to be enrolled in the MTF DM.[64] Dispensing entity enrollment in the MTF DM is needed for necessary operations

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

related to administration of the Negotiation Program and the Part D program, including creating and making available remittances or ERAs, maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are drugs covered under Part D, and ensuring accurate Part D claims information and payment. The MTF DM will provide dispensing entities with remittances or ERAs to reconcile MFP refund payments when a Primary Manufacturer chooses to pass payment through the MTF PM. For payments made outside of the MTF PM, CMS also plans to provide Primary Manufacturers with access to view information through the MTF portal, such as a dispensing entity's banking information, in order to support the Primary Manufacturer in making available to the dispensing entity an ERA or remittance, as applicable. Interested parties strongly requested that MFP refunds be accompanied by an ERA or remittance. The ERA or remittance connects claims payment determination and amount with how the payment was made, including the electronic funds transfer information, if applicable. Dispensing entities need an ERA or remittance to close out open accounts receivable for each claim for which a Primary Manufacturer owes an MFP refund.

CMS will develop a flexible, efficient enrollment process that accommodates various structures to (1) provide the MTF DM with bank account information and a secure location for creating and making available the ERA or remittance, as applicable; (2) maintain the accuracy of that information over time; and (3) maintain the functionality necessary to receive ERAs or remittances, as applicable. Information collected from the dispensing entity will support payment pass through both for the MTF PM and Primary Manufacturers choosing to operate their own payment arrangements. Information that dispensing entities will provide will include but not be limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or NPI; (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) deposit or account number with financial institution; (6) type of registered financial account; and (7) secure location for making available the ERA or remittance, as applicable.[65] Dispensing entities will also indicate their election of whether they prefer receiving payments through electronic funds transfers, which will be the default election for dispensing entities at the time of enrollment, or paper checks. This preference will be included on the claim-level data elements transmitted to all Primary Manufacturers, regardless of whether they participate in the MTF PM or not. If the MFP refund payment is passed through the MTF PM, then the MTF PM will transmit the Primary Manufacturer's payment to the dispensing entity in accordance with the dispensing entity's indicated preference. If the Primary Manufacturer declines to participate in the MTF PM and elects to establish its own payment facilitation methods, then the Primary Manufacturer is required to provide an electronic reimbursement mechanism for dispensing entities that have indicated their preference to receive electronic transfer of funds. For dispensing entities that have indicated their preference to receive payment via paper check, the Primary Manufacturer would need to, at a minimum, ensure that paper checks are provided as a reimbursement mechanism. CMS published the Medicare

https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

[65] CMS issued an information collection request titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request" on October 28, 2024 for a 60-day comment period. In this ICR, CMS solicited feedback on all data fields necessary to provide accurate, timely ERAs or remittances for all MFP refund transactions and conduct general program administration and oversight. See: http://federalregister.gov/documents/2024/10/28/2024-25009/agency-information-collection-activities-proposed-collection-comment-request.

Transaction Facilitator for Initial Price Applicability Year 2026 and 2027 ICR for a 60-day public comment period that closed on December 27, 2024. The ICR included details on information that dispensing entities will be required to provide. CMS published this revised ICR for 30-day public comment period on April 1, 2025.[66]

In response to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS received several comments from dispensing entities and their representatives expressing concern that the operations of the MTF and the timeline for the 14-day prompt MFP payment window would create delays in cashflow compared to the existing requirements for Part D prompt payment by plan sponsors. Commenters particularly noted that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund. Based on comments received, CMS is concerned that this challenge will be most acute in the transition period when MFPs for selected drugs first become effective in January 2026 and at the start of each subsequent initial price applicability year when MFPs for new selected drugs first become effective (i.e., at the start of a price applicability period with respect to a selected drug). CMS does not anticipate this challenge to continue with respect to a selected drug once MFP refunds for that selected drug are flowing and dispensing entities become accustomed to the 14-day prompt MFP payment window.

CMS recognizes that the success of the Negotiation Program is, in part, dependent on Medicare beneficiaries' access to selected drugs through dispensing entities, which in turn necessitates that dispensing entities—particularly those that rely primarily on prescription revenue to maintain business operations—are able to timely access the MFP. Therefore, during the MTF DM enrollment, CMS will ask dispensing entities to self-identify whether they are a dispensing entity that anticipates having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. This information will be provided to Primary Manufacturers to assist in the development of their MFP Effectuation Plans, as described in section 90.2.1 of this draft guidance. Consistent with section 1193(a)(5) of the Act and as described in section 90.2.1 of this draft guidance, CMS will require Primary Manufacturers to include their approach to mitigating material cashflow concerns in their MFP Effectuation Plans.

Prior to the deadlines for the submission of MFP Effectuation Plans, CMS will provide Primary Manufacturers with a list of dispensing entities that have self-identified as anticipating material cashflow challenges. Primary Manufacturers may use this list to inform development and implementation of their mitigation processes for addressing material cashflow concerns. For example, CMS expects dispensing entities of the types that have raised material concerns about cashflow related to the effectuation of MFP—such as sole proprietor rural and urban pharmacies with high volume of Medicare Part D prescriptions dispensed, pharmacies who predominantly rely on prescription revenue to maintain business operations, long-term care pharmacies, 340B covered entities with in-house pharmacies, and Indian Health Service, Tribal, and Urban Indian

[66] See: https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912

(I/T/U) pharmacies—may self-identify through this process. CMS expects that the requirement that Primary Manufacturers establish mitigation processes for addressing these material cashflow challenges will better enable them to work with dispensing entities to ensure continued beneficiary access to their selected drugs. CMS will evaluate the degree to which this pharmacy self-identification process provides useful data for Primary Manufacturers in developing MFP Effectuation Plans and may reconsider this approach in the future.

Dispensing entities will need to certify that information provided to the MTF DM is accurate and up to date. CMS will require each dispensing entity enrolling in the MTF DM to sign an MTF DM User Agreement with CMS during the enrollment process. This agreement will include provisions such as data use, privacy, and security requirements for engaging with the MTF DM. This agreement also will include requirements for collecting, using, sharing, and safeguarding financial information. During enrollment, independent dispensing entities may elect to receive payment through a third-party vendor, such as a pharmacy services administrative organization (PSAO) or reconciliation vendor, and will be required to indicate that payment should be issued to such party as part of the enrollment process.

CMS expects that dispensing entities would maintain records accounting for any refunds owed to them by a Primary Manufacturer should there be a payment discrepancy for which they engage in the dispute or complaint resolution process set forth in section 90.2.2 of this draft guidance. As the approach for creating and making available ERAs or remittances, as applicable, to dispensing entities is further developed, additional requirements for dispensing entities may be necessary to support making this information available.

To assist dispensing entities in reconciling MFP refund payments, regardless of a Primary Manufacturer's election to use the MTF PM to pass through payment, CMS expects Part D plan sponsors to include SDRAs on all Part D claims for selected drugs with a negotiated MFP in effect. The National Council for Prescription Drug Programs (NCPDP) will provide instruction to Part D plans sponsors regarding this new message, which will furnish dispensing entities with an estimate of the manufacturer MFP refund amount equal to the SDRA as calculated by the plan sponsor. If the SDRA accurately reflects the dispensing entity's acquisition costs, a dispensing entity may use this estimated amount to create an accounts receivable. NCPDP will furnish additional direction to plan sponsors on implementing the SDRA on the claim response. The SDRA is an estimate and is not a guarantee of payment of an MFP refund by a Primary Manufacturer or an indication that payment of a refund amount equal to the SDRA will be sufficient to provide access to the MFP. The Primary Manufacturer is responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP, and there are situations where an MFP refund may not be applicable (e.g., the selected drug was purchased prospectively at or below the MFP) or the SDRA may be insufficient to provide access to the MFP.

Dispensing entities are encouraged to remediate with the manufacturer directly if they believe that they have not received a retrospective refund payment that effectuates the MFP. If remediation between the parties cannot be reached, Primary Manufacturers and dispensing entities may use the complaints process, within the complaint and dispute system, as described in

section 90.2.2 of this draft guidance, so that CMS is alerted to situations where MFP may not have been made available.

40.4.3 MTF Payment Facilitation

CMS has received many requests from a variety of interested parties, including dispensing entities, manufacturers, and other interested parties in the pharmaceutical supply chain, to support the facilitation of MFP refund payments between Primary Manufacturers and dispensing entities. These requests have included the establishment of MTF payment facilitation functionality (i.e., the MTF PM) to assist Primary Manufacturers and dispensing entities in effectuating payment between parties in a reliable, predictable, and consistent manner without incurring significant burden or cost.

Interested parties commented to CMS that drug manufacturers do not generally provide payments directly to dispensing entities and that a direct means to provide payments typically does not exist. Currently, most transactions are processed through third-party vendors, such as wholesalers and distributors. After publication of the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS received significant feedback from interested parties urging the establishment of a payment facilitation mechanism that would create standardization, predictability, and reduced burden for all parties. In response to comments, CMS considered whether a new framework could support manufacturers in furnishing MFP refund payments to dispensing entities on claims for selected drugs to MFP-eligible individuals.

CMS has engaged with an MTF Contractor to develop the MTF payment functionality through the MTF PM as a mechanism to facilitate the transfer of MFP refund payments from participating Primary Manufacturers to dispensing entities. Participation in the MTF PM will be voluntary for Primary Manufacturers, which will have the option of passing MFP refund payments to dispensing entities through the MTF PM or using their own processes outside of the MTF PM. If the Primary Manufacturer participates in the MTF PM, the Primary Manufacturer and dispensing entity remain free to reach an agreement to use a mutually agreed-upon process outside of the MTF PM to pay MFP refunds. As discussed in section 40.4.3.3 of this draft guidance, the MTF PM will not require an affirmative election of participation by dispensing entities for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer.

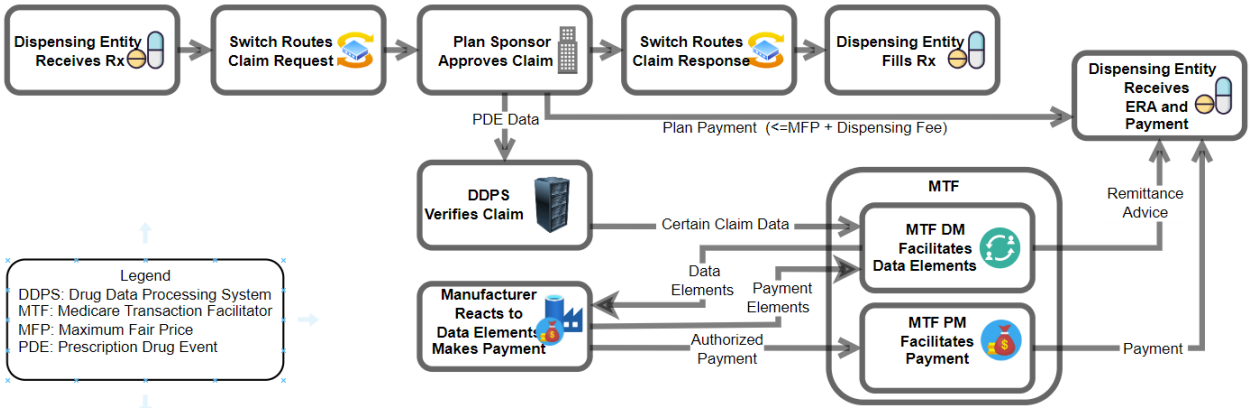
The provision of voluntary MTF payment facilitation services through the MTF PM does not supersede or alter the Primary Manufacturer's obligation under section 1193(a)(3)(A) of the Act to provide access to the MFP to dispensing entities for MFP-eligible individuals who are dispensed selected drugs. While the statute does not provide CMS with an express role in effectuating the MFP, CMS intends for the MTF PM to serve in a ministerial, facilitating role that would assist Primary Manufacturers in meeting their statutory obligations by passing through refund payments paid by participating Primary Manufacturers to dispensing entities.

The purpose of the voluntary MTF PM is to connect the Primary Manufacturer to the dispensing entity and to facilitate transmission of an MFP retrospective refund on MFP-eligible claims of

selected drugs from the Primary Manufacturer to the dispensing entity in accordance with section 1193(a)(3) of the Act. The MTF PM will (1) provide Primary Manufacturers with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments to dispensing entities; and (2) provide Primary Manufacturers with a credit/debit ledger system to track the flow of MFP refunds and to handle reversals, adjustments, and other claim revisions inevitable in a dynamic claim payment system.

CMS expects that most Primary Manufacturers will participate in the MTF PM, given prior feedback requesting a single platform for facilitating MFP refund payments. The combined data and payment facilitation functionality present in the MTF DM and the MTF PM discussed here, and depicted in Figure 3 below, attempts to address the interests expressed by dispensing entities and manufacturers in a single platform for transmitting MFP refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments. Figure 3 represents the flow of data and payment for a claim where the Primary Manufacturer participates in the MTF PM and chooses to pass the MFP refund payment to the dispensing entity through the MTF PM. Even if the Primary Manufacturer elects to participate in the MTF PM, the Primary Manufacturer and dispensing entity may establish a mutually agreed-upon process for effectuating the MFP outside of the MTF PM. The payment process will be different than the payment flow depicted in Figure 3 if the Primary Manufacturer elects not to participate in the MTF PM or if the Primary Manufacturer participates in the MTF PM, but the MFP refund payment for a particular claim is effectuated through a mutually agreed-upon process outside of the MTF PM. Although Figure 3 illustrates the MTF payment flow for Part D drug claims, as discussed in section 40.4 of this draft guidance, CMS intends to offer the MTF to facilitate payment exchange for drugs payable under Part B that are furnished or administered to MFP-eligible individuals and is soliciting comments for how the payment flow for Part B drug claims may differ from what is outlined below.

Figure 3: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM



As stated above, the MTF PM's ministerial role as a mechanism for facilitating the pass-through of MFP refund payments from a participating Primary Manufacturer to dispensing entities will not supersede or alter the Primary Manufacturer's statutory obligation to effectuate the MFP. As described in section 90.2 of this draft guidance, the Primary Manufacturer is required to establish a process to ensure the MFP is made available to MFP-eligible individuals and dispensing

entities, and neither CMS nor its MTF Contractors will determine the amount of payment the Primary Manufacturer chooses to transfer through the MTF PM. Moreover, the MTF PM's transfer of the Primary Manufacturer's authorized MFP refund payment to a dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity and shall not otherwise discharge the Primary Manufacturer's statutory obligation to make the MFP available. Neither CMS nor its MTF Contractors will assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, the MTF Contractors will perform a ministerial function at the behest and direction of the participating Primary Manufacturer with respect to the pass through of the Primary Manufacturer's funds in the amounts and to the dispensing entities identified by the Primary Manufacturer in its claim-level payment elements.

Because the MTF PM will only pass payments between Primary Manufacturers and dispensing entities, under no circumstances will federal funds be used for these transactions or to resolve or make payment related to disputes that may arise between parties when the MTF PM is utilized, including with respect to nonpayment or insufficient payment by a particular party. Additionally, CMS will not float or issue funds to a dispensing entity on the Primary Manufacturer's behalf in anticipation of a future MFP refund payment from the Primary Manufacturer to the dispensing entity. CMS expects and encourages interested parties to work together as necessary to develop mechanisms to assure timely effectuation of MFP refund payments consistent with statute, CMS' guidance, and all other applicable laws, regulations, and guidance, including without limitation the Anti-Kickback Statute. For example, the following approaches might be pursued by interested parties to provide timely payment, potentially focused on dispensing entities that self-identify as anticipating having material cash flow concerns at the start of the initial price applicability year, and all of which could be paired with retrospective reconciliation once the Primary Manufacturer receives claim-level data elements from the MTF DM: (1) Primary Manufacturers could make prospective sales of selected drugs to dispensing entities at the MFP while leveraging virtual inventory management systems and pharmaceutical wholesaler chargebacks where applicable; (2) Primary Manufacturers could establish pre-funded MFP refund payment accounts directly with dispensing entities; and/or (3) Primary Manufacturers could leverage established relationships between dispensing entities and PSAOs to establish accounts that are pre-funded by the Primary Manufacturer for the PSAOs to use to disburse MFP refund payments to dispensing entities, with the PSAOs facilitating any necessary financial, reconciliation, and administrative services for the dispensing entity, thus minimizing the number of point of contacts for the Primary Manufacturer. Neither CMS nor the MTF Contractors will be responsible for funding or paying the refund amounts owed by the Primary Manufacturer in instances where the Primary Manufacturer does not pay an MFP refund owed to a dispensing entity, including in cases where the Primary Manufacturer may be unable to pay (e.g., bankruptcy, insolvency, etc.). Neither CMS nor its MTF Contractors will accrue any interest on funds held by the MTF PM during the period before the funds are transferred to the dispensing entity (or returned to the Primary Manufacturer in the event of unclaimed funds, as discussed below). The MTF PM will serve only as a mechanism to transfer funds of the Primary Manufacturer to dispensing entities as directed by the Primary Manufacturer in the amounts authorized by the claim-level payment elements transmitted by the Primary Manufacturer and will not collect funds for any other use. Separately, neither Primary Manufacturers nor

dispensing entities shall be required to pay any fees to the MTF PM in connection with the pass through of MFP refund payments, including but not limited to user fees or transaction fees, as CMS intends to bear the cost of operationalizing the MTF PM.

Scenarios may arise where the MTF PM is responsible for temporarily holding unclaimed funds, for example, a dispensing entity ceases operations, yet the MTF PM still receives MFP refund payments designated for that dispensing entity. In the scenario described, unclaimed funds will be returned to the Primary Manufacturer. For Primary Manufacturers that elect to participate in the MTF PM, the return of unclaimed funds may also include scenarios where the MTF PM issues a check to a dispensing entity that has elected to receive MFP refund payments in the form of a paper check, but the dispensing entity has not deposited the issued paper check in the requisite time frame outlined by the MTF PM Contractor. In the described scenario the check shall be made void and funds returned to the Primary Manufacturer. Any disputes related to unclaimed funds will be reconciled directly between the Primary Manufacturer and the dispensing entity.

Primary Manufacturers that elect to use the MTF PM to pass through payments will be required to execute the MTF PM User Agreement with the MTF PM Contractor outlining each party's rights, responsibilities, and potential liabilities associated with the transfer and receipt of funds through the MTF PM. [67] Issues arising from the operational work of facilitating MFP refund payments via the MTF system will be resolved in accordance with MTF technical instructions and user guides, and aligned with the applicable MTF agreements. CMS does not assume responsibility for any liability arising from the performance of MTF PM activities.

To participate in the MTF PM, a Primary Manufacturer will indicate to CMS its intention to use the MTF PM as part of the Primary Manufacturer's written plan for effectuating the MFP, described in section 90.2.1 of this draft guidance. At the time of enrollment in the MTF DM,[68] the Primary Manufacturer will be provided with an opportunity to participate in the MTF PM. If the Primary Manufacturer elects to enroll in the MTF PM, it will participate in the MTF PM for all its selected drugs and typically with all dispensing entities. However, if a Primary Manufacturer elects to participate in the MTF PM, nothing about the MTF PM User Agreement precludes a Primary Manufacturer from establishing a mutually agreed-upon process for effectuating the MFP outside of the MTF PM with dispensing entities. The Primary Manufacturer will transmit MFP refund payments through the MTF PM Contractor and agree to the MTF PM terms and conditions as outlined in the MTF PM User Agreement. The Primary Manufacturer will also have the option to delegate to a third-party vendor the function of issuing MFP refund payments via the MTF PM and reporting claim-level payment elements, as described in section 40.4.3.1 of this draft guidance, if the manufacturer intends to contract out the management of those activities to a third-party vendor to interface with the MTF PM. However, the Primary Manufacturer will be the sole entity authorized to participate in the MTF PM for its selected drug, and it will be the sole entity permitted to authorize a contracted third-party vendor to support it in performing its required activities of reporting claim-level payment

[67] See: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation
[68] As outlined in section 40.4.2 of this draft guidance, enrollment in the MTF DM is required of Primary Manufacturers to receive claim-level data elements and to report claim-level payment elements back to the MTF.

elements and transmitting MFP refund payments through the MTF PM. Notwithstanding any delegation to a third-party vendor, the Primary Manufacturer remains ultimately responsible for calculating the appropriate amount to effectuate the MFP and ensuring that timely access to the MFP is made available to dispensing entities.

Section 40.4.3 of this draft guidance addresses what is required of a Primary Manufacturer that elects to pass payments through the MTF PM and section 40.4.4 of this draft guidance addresses what is required of a Primary Manufacturer when the MFP refund payment is not passed through the MTF PM either because the Primary Manufacturer chooses not to participate in the MTF PM or the Primary Manufacturer participates in the MTF PM, but has an agreement with the dispensing entity to make payments outside the MTF PM with respect to that dispensing entity. Sections 40.4.3 and 40.4.4 of this draft guidance discuss the Primary Manufacturer's reporting requirements under each scenario, respectively.

40.4.3.1 Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When Primary Manufacturer Passes Payment through the MTF PM
Reporting of claim-level payment elements is required regardless of whether the Primary Manufacturer elects to participate in the MTF PM. This section outlines the reporting of claim-level payment elements to the MTF DM that is required of a Primary Manufacturer when passing MFP refund payments through the MTF PM. The reporting of claim-level payment elements that is required of a Primary Manufacturer that does not elect to participate in the MTF PM and issues payments outside of the MTF PM is described in section 40.4.4 of this draft guidance. If a Primary Manufacturer and dispensing entity establish a mutually agreed-upon method for effectuating the MFP outside of the MTF PM, regardless of the Primary Manufacturer's participation status in the MTF PM, the Primary Manufacturer will be required to provide the claim-level payment elements described in section 40.4.4 of this draft guidance for transactions made outside of the MTF PM.

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering the Negotiation Program and monitoring compliance with the requirement to provide access to the MFP, the Primary Manufacturer will be required to transmit claim-level payment elements to the MTF DM within 14-days after the MTF DM sends the claims-level data elements in Table 2 to the Primary Manufacturer regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer, or whether access to the MFP is provided prospectively or retrospectively. Among other things, the claim-level payment elements will be used to create an ERA or remittance, as applicable, that the MTF DM will make available to the dispensing entity for Primary Manufacturers that pass payments through the MTF PM (unless the MFP is effectuated between parties outside of the MTF PM, in which case the MTF DM will not make an ERA or remittance available). Due to the anticipated high volume of claims for selected drugs, CMS anticipates that Primary Manufacturers may engage a third-party vendor and/or automate the transmission of claim-level payment elements to the MTF DM. Primary Manufacturers remain responsible for ensuring that reported claim-level payment element information is accurate and submitted on a timely basis.

For all claim-level data elements that are transmitted by the MTF DM to the Primary Manufacturer (regardless of whether a refund is paid, and regardless of whether the selected drug

was initially sold by the Primary Manufacturer or a Secondary Manufacturer), Primary Manufacturers will be required to report claim-level payment elements that include: (1) the corresponding claim-level data elements previously transmitted by the MTF DM, listed in Table 2 in section 40.4.2 of this draft guidance; and (2) the claim-level payment elements listed in Table 4 below associated with each claim within 14 days of receipt of the claim-level data elements in Table 2. The claim-level data elements and corresponding claim-level payment elements for each MFP eligible claim shall be returned in a single response file to the MTF DM. Claim-level payment elements will include the MTF PM facilitation indicator, the method for determining the MFP refund amount, the amount of payment sent as the MFP refund, and claim-level data elements for inclusion in the ERA or remittance made available to dispensing entities when Primary Manufacturers choose to pass payment through the MTF PM. CMS notes that two claim-level payment elements, NPI of the Entity Receiving the MFP Refund and Quantity of Selected Drug, established in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 were removed from this draft guidance to eliminate redundancy with the two corresponding claim-level data elements. As CMS further develops the approach for creating and making available ERAs and remittances to dispensing entities and operational technical specifications, CMS may add claim-level payment elements.

If the Primary Manufacturer is unable to transmit the claim-level payment elements, for example, if there is a technical breakdown in the transmission process, the Primary Manufacturer must continue to attempt to transmit the claim-level payment elements in good faith until successful transmission of the claim-level payment elements and must maintain documentation of the Primary Manufacturer's good faith effort in case there is a related complaint or dispute.

The Primary Manufacturer's transmission of claim-level payment elements to the MTF DM will indicate to the MTF PM the amount of MFP refund payment that the Primary Manufacturer authorizes for the MTF PM to pass through to the dispensing entity following receipt of the claim-level data elements received. The claim-level payment elements also act as the Primary Manufacturer's authorization for the MTF DM to send the payment instruction to the MTF PM to pass through payment for applicable claims. CMS expects MFP refund payments for MFP-eligible claims paid through the MTF PM to occur following Primary Manufacturer authorization of such payment by transmitting the claim-level payment elements. Additional information on timing of MTF PM payment processing will be available as CMS continues to evolve technical specifications. CMS intends to prioritize expeditious pass through of payment to the dispensing entity as it builds the MTF PM and engages the MTF PM Contractor. For payments made through the MTF PM, the MTF DM will timestamp the receipt of the claim-level payment elements when transmitted by the Primary Manufacturer to the MTF DM. Failure by the Primary Manufacturer to transmit all claim-level payment elements to the MTF DM consistent with the timing of the 14-day prompt MFP payment window will be considered a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act (see section 100 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable).

Table 4: Example Manufacturer Claim-Level Payment Elements List for Primary Manufacturers Passing Payment through the MTF PM[69]

Payment Elements	Purpose
MTF PM Facilitation Indicator	Indicates whether transmission of the MFP refund should be facilitated through the MTF PM
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5).
Amount of Payment to be Transmitted as the MFP Refund by the MTF PM	Indicates the amount the MTF PM should pay to the dispensing entity, prior to the application of any credits.
Transaction Code[70]	Indicates if the MFP refund payment is in response to an original claim, or if it is an adjustment or reversal to a previously submitted set of claim-level payment elements.

CMS understands there are several reasons why a given claim provided to the Primary Manufacturer may not receive a retrospective MFP refund or may receive an MFP refund equal to an amount other than the SDRA. For example, the Primary Manufacturer and the dispensing entity may have an arrangement in place where the selected drug is prospectively purchased by the dispensing entity at or below the MFP. To account for such scenarios, the Primary Manufacturer will be required to report a mandatory claim-level payment element, "Method for Determining MFP Refund Amount," to be populated with one of several pre-identified justification codes indicating whether the MFP refund payment was made using the SDRA, a different amount, or the reason an MFP refund payment was not provided.[71] Examples of these justification codes, listed in Table 5, include codes indicating the drug was prospectively purchased at or below the MFP; the Primary Manufacturer and dispensing entity have a separately negotiated refund amount distinct from the SDRA; or the claim is excluded from MFP refunds under section 1193(d)(1) of the Act. CMS believes that identifying standardized justifications for the claim-level payment elements will allow Primary Manufacturers to establish efficient processes to provide such information to the MTF. CMS intends to work with interested parties to add justification codes, if necessary, to meet reporting needs.

When a Primary Manufacturer reports a code other than "1" for the "Method for Determining MFP Refund Amount" claim-level payment element, it will be required to maintain supporting

[69] These elements are representative examples only, and CMS will provide the exact claim-level payment elements in forthcoming guidance or technical instructions as operations develop.

[70] Transaction Code is the same field received in the claim-level data elements from the MTF DM. Primary Manufacturers will update the Transaction Code field before submitting claim-level payment elements to the MTF DM.

[71] Nothing in this section precludes a Primary Manufacturer and a dispensing entity from reaching agreements outside of the MTF to establish an adjusted refund amount based on the dispensing entity's acquisition costs, which could be paid by the Primary Manufacturer through the MTF PM or through an alternative process outside of the MTF PM that is mutually agreed upon by the parties.

documentation as outlined in section 90.2.1 of this draft guidance, demonstrating why the MFP refund was provided at an amount other than the SDRA, or was not provided, for the applicable claim. This documentation is described in further detail in section 90.2 of this draft guidance.

Table 5: Examples of Justification Codes and Values for the "Method for Determining MFP Refund Amount" Claim-Level Payment Element for Primary Manufacturers[72]

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this draft guidance)
1	Standard Default Refund Amount Transmitted	Record of successful payment to the MTF PM.
2	Amount Other than Standard Default Refund Amount Transmitted	Documentation could include: invoices from the dispensing entity, a contractual outside agreement with the dispensing entity establishing an acquisition cost agreed to between the Primary Manufacturer and the dispensing entity, or other evidence of the dispensing entity's acquisition cost for the selected drug and proof of successful MFP refund payment.
3	No Refund Transmitted – Prospective MFP Access	Invoice documentation of the drug sold at or below MFP, or an outside agreement between the Primary Manufacturer and dispensing entity establishing prospective purchasing of the selected drug at or below MFP.
4	No Refund Transmitted – Section 1193(d)(1) Exception	• At a minimum, either records from the Primary Manufacturer's process for ensuring 340B nonduplication of claims and the conclusion reached for the claim, where the process has demonstrated a valid and reliable method to accurately identify 340B eligibility, or demonstrated confirmation from a 340B covered entity or from any vendor/third party administrator that the 340B covered entity employs to determine 340B eligibility status. • Documentation that the 340B ceiling price is less than MFP and the "Service Provider Identifier" matching the claim-level data elements the MTF DM transmitted to the Primary Manufacturer is for the covered entity or its contract pharmacy.

[72] CMS will issue and maintain the exact codes to be used in future guidance or technical instructions, including further guidance on what to submit if not populating a code in a specific field. Some codes will not be relevant for payments transmitted through the MTF PM and will only apply to payments transmitted outside the MTF PM, or situations where payment is not made, as discussed in section 40.4.4 of this draft guidance.

Code	Value	Examples of Documentation to Maintain (see section 90.2 of this draft guidance)
5	No Refund Transmitted – Payment Transmission Attempted but Unsuccessful	This code would be available in the event a Primary Manufacturer attempts to transmit an MFP refund to a dispensing entity outside of the MTF PM, using an alternative payment method, but is unable to complete the transmission. In these cases, the Primary Manufacturer must maintain documentation of all attempts to demonstrate that a good faith effort to provide an MFP refund was made.
6	No Refund Transmitted – Other	Documentation to justify the reason why no refund was transmitted that does not align with any other justification code.
7	Refund Transmitted Consistent with Alternative Reconciliation	Documentation of the Primary Manufacturer's GAAP-compliant method of accounting for claims reconciliation, and how that was used to calculate any transmitted refund.

By transmitting the claim-level payment elements to the MTF DM including the "MTF PM Facilitation Indicator" indicating that payment should be made through the MTF PM, the Primary Manufacturer will authorize the electronic funds transfer of payment equal to the total refunds to be paid through the MTF PM and the transmission of such MFP refund payments by the MTF PM to the dispensing entities identified in the claim-level payment elements (in the amounts directed by the claim-level payment elements). The MTF PM may require additional authorization for fund transfer from the Primary Manufacturer after this step as CMS continues to develop the MTF processes. Once the Primary Manufacturer transmits the claim-level payment elements which authorizes MFP refund payment, and once the MTF PM considers any credits at the dispensing entity NPI-level for each selected drug, for each Primary Manufacturer as part of the credit/debit ledger system described in section 40.4.3.2 of this draft guidance, the MTF PM will route the payment provided from the Primary Manufacturer to the corresponding dispensing entities included in the claim-level payment elements using the dispensing entities' documented banking information and preferred payment method (i.e., electronic funds transfer or paper check). The MTF DM and MTF PM will maintain a record documenting whether the claim-level payment elements were sent within the 14-day prompt MFP payment window for every payment passed through the MTF PM to further assist in the dispute and complaint resolution process between interested parties, described in section 90.2.2 of this draft guidance. Primary Manufacturers will be able to view the payment status for each claim routed to the MTF PM through their connection to the MTF DM.

The MTF PM will transmit electronic payment or will issue a paper check on behalf of the Primary Manufacturer to the dispensing entity based on whether the dispensing entity has indicated its preference to receive MFP refund payments in the form of electronic funds or a paper check. When a Primary Manufacturer elects to pass payment through the MTF PM and a dispensing entity has indicated a preference to receive payment in the form of a paper check, the MTF PM will issue a paper check using the Primary Manufacturer's funds and on the behalf of

the Primary Manufacturer, as described in 90.2.1 of this draft guidance. In such instance, participating Primary Manufacturers will send claim-level payment elements to the MTF DM authorizing electronic funds transfer to, and transmission of MFP refund payment by, the MTF PM. Whenever payment is passed through the MTF PM, the MTF DM will make an ERA (for electronic transfer of funds) or remittance (for payment made via paper check) available to dispensing entities. For informational purposes, the MTF DM will issue a receipt file to Primary Manufacturers that elect to participate in the MTF PM. This receipt file will provide a notice to the Primary Manufacturer that acknowledges receipt and processing of claim-level payment elements by the MTF DM and the MFP refund payment status including successful payment transmission and the application of credits as described in section 40.4.3.2 of this draft guidance for payments made through the MTF PM. CMS is soliciting comments on content for the receipt file that would be informative for Primary Manufacturers.

Primary Manufacturers participating in the MTF PM may still make payments through an MFP effectuation method outside of the MTF PM that is mutually agreed upon with the dispensing entity. When a mutually agreed-upon process is implemented, the Primary Manufacturer will need to abide by the requirements outlined in sections 40.4.4 and 90.2.1 of this draft guidance. These requirements include, but are not limited to, including detail on a distinct payment facilitation method in the Primary Manufacturer's plan for effectuating the MFP; following claim-level payment element reporting required when the MTF PM is not used to make payment (as described in section 40.4.4.2 of this draft guidance); maintaining generally accepted accounting principles (GAAP) compliant and auditable accounting of payments, credits and debits; maintaining appropriate documentation to support MFP refund amounts; and issuing an ERA for electronic payments or remittance for payments issued by check.

If a Primary Manufacturer decides to terminate participation in the MTF PM, the Primary Manufacturer must update its MFP Effectuation Plan, complying with the notice requirements in section 90.2.1 of this draft guidance. The Primary Manufacturer remains responsible for making the MFP available through the transmission of payment via the MTF PM for any claims for which the claim-level payment elements have been transmitted to the MTF DM prior to the effective date of termination, unless the Primary Manufacturer has in place an alternative arrangement for making the MFP available, as documented in the MFP Effectuation Plan.

40.4.3.2 Primary Manufacturer and MTF PM MFP Refund Payment Adjustments due to Claim Amendments Through the MTF PM

For Primary Manufacturers that pass payments through the MTF PM, regardless of whether MFP refund payments are issued to dispensing entities electronically or through paper check, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level, for each selected drug based on information reported by the Primary Manufacturer in the claim-level payment elements. CMS has received many requests to provide clarification on how MFP refunds will be reconciled when MFP refund payment occurs for a claim that is subsequently reversed or adjusted. To address changes in MFP refund payments due to claim reversals, adjustments, or determinations that a claim is not MFP-eligible after issuance of an MFP refund payment, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level for each selected drug for Primary Manufacturers that participate in the MTF PM and where payment is

facilitated through the MTF PM. The credit/debit ledger system will accommodate a variety of revisions to incoming PDE information, including reversals or adjustments originating from updated PDE information received from DDPS. The Primary Manufacturer is responsible for reviewing all such credit and debit amounts to confirm their accuracy.

To address adjustments and reversals, whether these occur before the 14-day prompt MFP payment window has elapsed or after the Primary Manufacturer has transmitted MFP refund payment through the MTF PM or outside of the MTF PM through an alternative payment method, the MTF DM will transmit updated claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 2) that links an adjustment to the previous MTF ICN. For adjustments, when a Primary Manufacturer participating in the MTF PM has already transmitted an MFP refund through the MTF PM, the Primary Manufacturer will identify and authorize the correct payment amount based on the reported claim adjustment in its response in the claim-level payment elements. When initiating a reversal or adjustment to claim-level payment elements, the Primary Manufacturer would update the "Transaction Code" from the claim-level data elements (see Table 4) to indicate an "adjustment" to previously transmitted claim-level payment elements. CMS has included additional claim-level data elements (i.e., "MTF ICN," "Record ID," "MTF XRef ICN," "Process Date," and "Medicare Source of Coverage") in Table 2 of section 40.4.2 of this draft guidance to support Primary Manufacturer management of claim adjustments.

Upon receiving the claim-level payment elements, the MTF DM will assess whether the claim has been previously paid and will establish a corresponding credit or debit for the Primary Manufacturer's selected drug for the specific NPI of the dispensing entity. The MTF DM's assessment will in no way constitute an endorsement or determination of the appropriateness of the adjusted MFP refund payment made by the Primary Manufacturer. The MTF DM will subsequently instruct the MTF PM to apply the specified credit or debit. The MTF PM will apply credits or debits at the dispensing entity NPI-level for each selected drug. If the claim adjustment occurs within the 14-day prompt MFP payment window and the Primary Manufacturer has not already transmitted the MFP refund, the Primary Manufacturer may transmit the MFP refund based on the adjusted claim amount. The MTF PM may require additional authorization for fund transfer from the Primary Manufacturer as technical and operational details develop.

For claims designated as full reversals from DDPS before the Primary Manufacturer has transmitted the MFP refund, the Primary Manufacturer will see the claim removed in its feed of claim-level data elements. For claims designated as a full reversal after the MFP refund has been transmitted, the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid MFP refund payment. Primary Manufacturers will not need to submit claim-level payment elements back to the MTF DM for full reversals. Neither CMS nor its MTF Contractors will independently determine, control, or verify the amount of the credit resulting from any claim reversal from DDPS. The Primary Manufacturer is responsible for reviewing all such credit amounts to confirm their accuracy.

As part of MFP effectuation, the Primary Manufacturer participating in the MTF PM will authorize the MTF PM, through transmission of the claim-level payment elements, to send to a dispensing entity, a lump sum payment equal to the total refunds to be paid as indicated when

reporting claim-level payment elements. The precise process of authorization surrounding payment transfer continues to be developed. If the Primary Manufacturer has credits accrued with respect to a selected drug for the dispensing entity NPI for which it has provided an MFP refund payment, the MTF PM will automatically credit the Primary Manufacturer and the MTF PM will indicate to the MTF DM that, for impacted claims, an accrued credit was applied. Primary Manufacturers will not need to provide authorization for the application of credits. The MTF DM will use this information to inform the ERA or remittance, as applicable, made available to the dispensing entity. The MTF DM also will update its final database with information from the MTF PM to capture whether a payment was made with credit and the amount of that credit. Primary Manufacturers will have access to the disposition of each claim-level data element claim line to which they responded with claim-level payment elements and the status of MFP refunds through the MTF DM including the result of MTF PM execution. CMS intends that dispensing entities and participating Primary Manufacturers will be able to view the status of available credits and MFP refunds through their MTF portal, however further technical specifications will be outlined in technical guidance. The MTF will not maintain a ledger of credits and debits for Primary Manufacturers that elect not to participate in the MTF PM. Additionally, for Primary Manufacturers that participate in the MTF PM, the MTF credit/debit ledger system will not track credits and debits related to claims where the MFP refund was paid outside of the MTF PM to a dispensing entity through a mutually agreed-upon process. The established MFP effectuation process between the parties will be responsible for reconciling and tracking accrued debits and credits that may result from amended claims. See section 40.4.4 of this draft guidance for additional detail.

If a Primary Manufacturer terminates participation in the MTF PM, CMS, or its designated contractor, will communicate new adjustments, including claim adjustments, reversals, and changes to MFP eligibility to the Primary Manufacturer via the claim-level data elements in the MTF DM; however, the Primary Manufacturer will no longer accrue credits and debits related to those adjustments. Additionally, CMS, or its designated contractor, will provide the Primary Manufacturer with an accounting of any outstanding credits remaining in the credit/debit ledger system as of the date of termination, at a time and in a manner to be described by CMS in upcoming guidance or technical instruction. It is the responsibility of the Primary Manufacturer to work with dispensing entities if a Primary Manufacturer believes funds are owed for the outstanding credits and to continue to make payments to dispensing entities outside of the MTF PM in order to continue to effectuate the MFP. Such outstanding credits shall not be treated as unclaimed funds under applicable guidance, regulations, and technical instructions, and claims by the Primary Manufacturer to any outstanding credits are not within the scope of the dispute or complaint process established in applicable guidance and regulations and must be taken up directly with the applicable dispensing entities.

If a Primary Manufacturer transfers ownership of a selected drug, following the process established in section 40.7 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable, and the Medicare Drug Price Negotiation Program Agreement, credits and debits will remain in the credit/debit ledger system and will be transferred to the new Primary Manufacturer.

40.4.3.3 Pass Through Payment to Dispensing Entity When Primary Manufacturer Participates in the MTF PM

Similar to other applications or mechanisms through which a Primary Manufacturer might submit its payment for delivery, the MTF PM will provide participating Primary Manufacturers with a means by which MFP refund payments can be passed through to dispensing entities at the Primary Manufacturer's election. Accordingly, the MTF PM will not require an affirmative election of participation by dispensing entities for the MTF PM to pass along MFP refund payments submitted by the Primary Manufacturer.

As outlined in section 40.4.2.2 of this draft guidance, at the time of enrollment in the MTF DM, dispensing entities will be required to register bank account information to facilitate making the ERA or remittance, as applicable, available to the dispensing entity. Also, at the time of enrollment into the MTF DM, the dispensing entity will have the opportunity to indicate whether it prefers to receive MFP refund payments through the electronic transfer of funds, which will be the default election for dispensing entities at the time of enrollment, or in the form of a paper check, if such type of payment is preferred by the dispensing entity. Due to the operational need to print, package, and mail paper checks, dispensing entities that elect to receive MFP refund payments in the form of paper checks should expect longer delivery of MFP refund payments as compared with the timing for electronic payment transmission. If the Primary Manufacturer participates in the MTF PM and transmits MFP refund payments through the MTF PM to be passed through to the dispensing entity, then the MTF PM will pass through the payment to the dispensing entity in accordance with the dispensing entity's selected payment method preference (i.e., electronic funds transfer or paper check). However, this does not preclude a dispensing entity from reaching an outside agreement with a Primary Manufacturer participating in the MTF PM for a separate arrangement to pay MFP refunds outside of the MTF PM. For MFP refund payments made by the Primary Manufacturer outside of the MTF PM—because either the Primary Manufacturer and dispensing entity have established a mutually agreed-upon process outside of the MTF PM or the Primary Manufacturer does not participate in the MTF PM—the MTF DM will include the dispensing entity's selected payment method preference among the claim-level data elements transmitted to the Primary Manufacturer. Regardless of whether the MFP refund is passed through the MTF PM or outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

If payment is passed through the MTF PM, the MTF PM's transfer of the Primary Manufacturer's authorized MFP refund payment to the dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity. Additionally, the receipt of the MFP refund payment by the dispensing entity (either electronically or via paper check) does not constitute the dispensing entity's agreement that access to the MFP has been provided by the Primary Manufacturer.

CMS received feedback from dispensing entities that they prefer having the option to identify a reconciliation vendor to access an ERA, or a remittance if payment is issued by paper check, on their behalf. Additionally, dispensing entities under the same parent organization requested the ability to receive payment through a single entity and to allow for groups of pharmacies to enroll

together instead of each pharmacy being required to enroll individually, to streamline both the disbursement of funds and the enrollment process. In response to this feedback, enrollment in the MTF DM will provide the dispensing entity with the option to have a PSAO, reconciliation contractor, or other vendor as indicated during the enrollment process, access the ERA or remittance, as applicable, and receive MFP refund payments on behalf of the dispensing entity, as well as the option for chains to designate a single or central pay option for dispensing entities under common ownership. CMS will issue detailed instructions on enrollment procedures, with considerations for the ability for chains to enroll groups of dispensing entities and functionality for integrating PSAOs, reconciliation vendors, and other third-party vendors in the enrollment process. Designation by the dispensing entity of a third-party vendor will require the dispensing entity's attestation of designation during the enrollment process in the MTF DM. CMS may provide further guidance or technical instructions to ensure effective transfer of MFP refund payments through PSAOs, reconciliation vendors, or aggregated payment to a single entity if necessitated.

For Primary Manufacturers that utilize the MTF PM, once the MTF DM has sent claim-level data elements to the Primary Manufacturer, and the Primary Manufacturer sends the claim-level payment elements to the MTF and, if applicable, pays the MFP refund amount to the dispensing entity through the MTF PM, then the MTF DM will generate an ERA or remittance for the dispensing entity for purposes of reconciling the Primary Manufacturer's retrospective MFP refunds with previously created accounts receivable. The MTF DM will produce ERAs that use the X12 835 standard adopted under HIPAA.

40.4.4 MFP Refund Payments When Primary Manufacturer Makes Payment Outside of the MTF PM

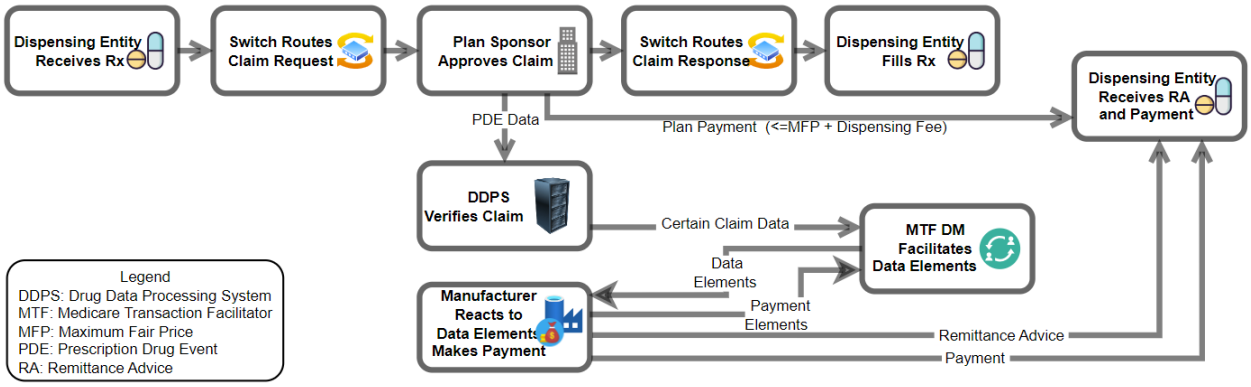
As discussed in section 40.4.3 of this draft guidance, the Primary Manufacturer may choose not to pass payment through the MTF PM for facilitation of MFP refund payments. If the Primary Manufacturer chooses not to pass payment through the MTF PM, then the Primary Manufacturer is responsible for paying the MFP refund to the dispensing entity outside of the MTF PM; as described in section 90.2.1 of this draft guidance, Primary Manufacturers are required to describe the details of their approach to MFP effectuation outside of the MTF PM, including any specific arrangements with dispensing entities outside of the MTF, in their MFP Effectuation Plans. This section discusses differences in data received from and transmitted to the MTF DM for MFP refund payments made when payments are passed through the MTF PM as compared to payments not passed through the MTF PM, such as when the Primary Manufacturer is not participating in the MTF PM or when the Primary Manufacturer is participating in the MTF PM and mutually agrees with a dispensing entity on a payment arrangement outside of the MTF.

40.4.4.1 Primary Manufacturer Payment Outside of the MTF PM

Table 2, in section 40.4.2 of this draft guidance, lists the claim-level data elements the MTF DM will send to Primary Manufacturers to start the 14-day prompt MFP payment window for each claim for an MFP-eligible drug. For Primary Manufacturers that make payments outside of the MTF PM, CMS plans to make available through the MTF DM the bank account information and designated destination for ERAs or remittances for dispensing entities enrolled in the MTF DM to support the Primary Manufacturer's creation and transmission of an ERA or remittance to the dispensing entity based on the preferred payment method indicated by the dispensing entity

during MTF DM enrollment. For electronic transfer of funds, it is the responsibility of the Primary Manufacturer to ensure that the ERA created and transmitted to the dispensing entity uses the X12 835 standard adopted under HIPAA. For funds issued via paper check, it is the responsibility of the Primary Manufacturer to ensure that the remittance is created and made available to the dispensing entity. Figure 4 represents the flow of data and payment if the Primary Manufacturer makes payment outside of the MTF PM. Although Figure 4 illustrates data flow for Part D drug claims, as discussed in section 40.4 of this draft guidance, CMS intends to use the MTF to facilitate data exchange for drugs payable under Part B that are furnished or administered to MFP-eligible individuals and is soliciting comments for how the data flow for Part B drug claims may differ from what is outlined below.

Figure 4: Diagram of MTF Data Flow when Primary Manufacturers Make Payment Outside of the MTF PM



In instances in which the Primary Manufacturer does not use the MTF PM to facilitate payments to a dispensing entity, the Primary Manufacturer must establish a process by which the MFP refund payment can be made. While CMS is not involved in the establishment or facilitation of MFP refund payment processes formed between the Primary Manufacturer and dispensing entities outside of the MTF PM, Primary Manufacturers will be required to submit reports with claim-level payment elements to the MTF DM that detail MFP refund payments made directly to dispensing entities, which CMS intends to use to monitor the Primary Manufacturer's compliance with its requirement to provide access to the MFP. The claim-level data elements the MTF DM will transmit to Primary Manufacturers include the dispensing entity's preferred method by which to receive payment (electronic funds transfer or paper check) as indicated by the dispensing entity during MTF DM enrollment. As discussed in section 40.4.2 of this draft guidance, these retrospective refund payments by the Primary Manufacturer to the dispensing entity would be provided through a process that is agreed to by the Primary Manufacturer and the dispensing entity and described in the Primary Manufacturer's MFP Effectuation Plan required under section 90.2.1 of this draft guidance.

Any payment system established by a Primary Manufacturer to facilitate these payments outside of the MTF must adhere to GAAP standards and procedures. Payments made without MTF PM facilitation are subject to the 14-day prompt MFP payment window and other applicable requirements for MFP effectuation in this draft guidance. MFP refund payments must be made in a manner that complies with applicable data privacy and security laws. As mentioned in section 40.4.2 of this draft guidance, regardless of whether the MFP refund is facilitated through the

MTF PM or made outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

40.4.4.2 Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When Primary Manufacturer Makes Payment Outside of the MTF PM
As stated in section 40.4.3 of this draft guidance, regardless of whether the Primary Manufacturer elects not to participate in the MTF PM or participates in the MTF PM and makes payment to a dispensing entity outside of the MTF PM, the Primary Manufacturer is responsible for providing claim-level payment elements to the MTF DM for each MFP-eligible claim indicating whether a refund was paid and the amount of the refund paid to make the MFP available. The following discussion outlines the reporting of claim-level payment elements to the MTF DM that is required of a Primary Manufacturer for each MFP refund payment made outside of the MTF PM. Some of the reporting requirements differ from requirements for MFP refund payments passed through the MTF PM, which are described in section 40.4.3 of this draft guidance.

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering the Negotiation Program and monitoring compliance with the requirement to provide access to the MFP, the Primary Manufacturer will be required to transmit claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer or whether access to the MFP is provided prospectively or retrospectively. Due to the anticipated high volume of claims for selected drugs, CMS anticipates that Primary Manufacturers may engage a third-party vendor and/or automate the submission of claim-level payment elements to the MTF DM. Primary Manufacturers remain responsible for ensuring that claim-level payment element information is accurate and submitted on a timely basis.

For all claims that are transmitted by the MTF DM to the Primary Manufacturer (regardless of whether an MFP refund is paid, and regardless of whether the selected drug was initially sold by the Primary Manufacturer or a Secondary Manufacturer), Primary Manufacturers, inclusive of any of the Primary Manufacturer's contracted third-party vendors, will be required to include in the claim-level payment elements: (1) the corresponding claim-level data elements previously transmitted by the MTF DM, listed in Table 2 in section 40.4.2 of this draft guidance; and (2) the claim-level payment elements listed in Table 6 below. The claim-level data elements and corresponding claim-level payment elements for each MFP eligible claim shall be returned in a single response file to the MTF DM.

Table 6: Example Manufacturer Claim-Level Payment Elements List when Primary Manufacturers Make Payment Outside of the MTF PM[73]

Payment Elements	Purpose
MTF PM Facilitation Indicator	Indicates whether transmission of the MFP refund should be facilitated through the MTF PM
MFP Refund Transmission Date and Time	Indicates when the MFP refund was transmitted by the Primary Manufacturer.[74]
Method for Determining MFP Refund Amount	Indicates the basis on which the MFP refund amount was determined (refer to Table 5 in section 40.4.3.1 of this draft guidance).
Amount of Payment Transmitted as the MFP Refund	Documents the amount of MFP refund transmitted. Payment element should be populated with the final MFP refund amount if payment was an adjustment to a previous claim.
Transaction Code[75]	Indicates if the MFP refund payment is in response to an original claim, or if it is an adjustment or reversal to a previously submitted set of claim-level payment elements.

Claim-level payment elements in common with required elements for payments made through the MTF PM include the "MTF PM Facilitation Indicator," "Method for Determining MFP Refund Amount," "Amount of Payment Transmitted as the MFP Refund," and "Transaction Code." The Primary Manufacturer would update the "Transaction Code" from the claim-level data elements (see Table 6) prior to sending claim-level payment elements to the MTF. As mentioned in section 40.4.3.1 of this draft guidance, two claim-level payment elements, NPI of the Entity Receiving the MFP Refund and Quantity of Selected Drug, proposed in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 were removed from this draft guidance to eliminate redundancy with the corresponding claim-level data elements. "MFP Refund Transmission Date and Time" is an additional claim-level payment element that is required for MFP refund payments made outside of the MTF PM. As discussed in section 40.4.3.1 of this draft guidance, for payments passed through the MTF PM, the MTF PM will timestamp the receipt of the claim-level payment elements. However, for payments made outside of the MTF PM, Primary Manufacturers will need to report the date and

[73] These elements are representative of examples and CMS will provide the exact payment elements in forthcoming guidance or technical instructions as operations develop.
[74] The recipient is the dispensing entity for MFP refund payments transmitted directly between parties outside the MTF PM. For MFP refunds paid via electronic payment, the Primary Manufacturer reports the date and time when electronic payment was transmitted to the dispensing entity. For MFP refunds paid via paper check, the Primary Manufacturer reports the date on which the paper check was mailed to the dispensing entity.
[75] Transaction Code is the same field received in the claim-level data elements from the MTF DM. Primary Manufacturers will update the Transaction Code field before submitting claim-level payment elements to the MTF DM.

time that electronic payment was transmitted or the date that a paper check was mailed to a dispensing entity.

Additional claim-level payment elements may be necessary to provide information that would otherwise be available if the MFP refund payment was made through the MTF PM, such as claim-level payment elements related to the application of credits or debits to payments, or another reconciliation method agreed to between the Primary Manufacturer and dispensing entities. Additional details on specific claim-level payment elements that may be reported to the MTF DM when the Primary Manufacturer does not use the MTF PM will be provided in future guidance or technical instructions.

The claim-level payment elements must be submitted to the MTF DM within the 14-day prompt MFP payment window, including when the claim-level payment elements indicate that no MFP refund payment is made in response to the claim-level data elements received. If an MFP refund payment is transmitted in response to the claim-level data elements received, the Primary Manufacturer should submit claim-level payment elements after sending paper check or electronic payment of the MFP refund to the dispensing entity outside of the MTF PM. Failure by the Primary Manufacturer to transmit all claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window would be a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act (see section 100 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable). While the claim-level payment elements will serve as the record of a Primary Manufacturer's response to the claim-level data elements when a refund is transmitted outside of the MTF PM, the Primary Manufacturer also is required to maintain documentation for each claim received from the MTF of either: (1) the retrospective MFP refund payment amount, and details of transmission of payment; or (2) the explanation of why the Primary Manufacturer did not provide a retrospective MFP refund. The Primary Manufacturer must make this documentation available to CMS upon request.

As discussed in section 40.4.3 of this draft guidance, CMS understands there are several reasons why a Primary Manufacturer may not pay an MFP refund or pay an MFP refund amount other than the SDRA for a given claim. To account for such scenarios, the Primary Manufacturer will report a mandatory claim-level payment element, "Method for Determining MFP Refund Amount," to be populated with one of several pre-identified justification codes indicating whether the MFP refund payment was made using the SDRA, a different amount, or the reason an MFP refund payment was not provided.[76] Examples of these justification codes, listed in Table 5 in section 40.4.3.1 of this draft guidance, include codes indicating the drug was prospectively purchased at or below the MFP, the Primary Manufacturer and dispensing entity have a separately negotiated refund amount distinct from the SDRA, the Primary Manufacturer claims an exception under section 1193(d)(1) of the Act, or credits tracked outside of the MTF for refunds paid for subsequently adjusted claims were applied in lieu of payment. CMS believes that identifying standardized justifications for the report of claim-level payment elements will

[76] Nothing in this section precludes a Primary Manufacturer and a dispensing entity from reaching agreements outside of the MTF to establish an adjusted refund amount based on the dispensing entity's acquisition costs.

allow Primary Manufacturers to establish efficient processes to provide such reports to the MTF. CMS intends to work with interested parties to add justification codes, if necessary, to meet reporting needs.

Upon CMS' request, Primary Manufacturers must provide evidence of MFP refund payments made outside of the MTF PM, which could include any number of items including paper checks, ACH transfers, wholesaler chargebacks, e-vouchers, or other electronic means of paying the dispensing entity so long as the evidence clearly supports information furnished in the claim-level payment elements. The payment approach(es) used by the Primary Manufacturer must be included in the Primary Manufacturer's plan submitted to CMS regarding effectuation of the MFP as described in section 90.2.1 of this draft guidance.

For Primary Manufacturers that make payments outside of the MTF PM, the MTF DM will receive the claim-level payment elements from the Primary Manufacturer but will not create and make available an ERA or remittance, as applicable, for the dispensing entity; in this case, it is the responsibility of the Primary Manufacturer to ensure that an ERA is created and transmitted to the dispensing entity for electronic transfer of funds. In instances where a Primary Manufacturer makes non-electronic payments outside of the MTF PM, the Primary Manufacturer must make available a remittance to the dispensing entity.

The MTF DM will maintain a record of the execution of MFP refund payments, as documented in the transmitted claim-level payment elements. Compliance with the 14-day prompt MFP payment window will be assessed using the "MFP Refund Transmission Date and Time." For electronic MFP refund payments made to dispensing entities outside of the MTF PM, this date must reflect the date that the Primary Manufacturer sent the payment to the dispensing entity. For paper checks sent outside of the MTF PM, this date must reflect the date that the paper check was mailed to the dispensing entity. In addition to monitoring for compliance with the 14-day prompt MFP payment window, this information will assist in the dispute and complaint resolution process between interested parties, described in section 90.2.2 of this draft guidance. For informational purposes, the MTF DM will issue a receipt file to Primary Manufacturers that do not elect to participate in the MTF PM. This receipt file will provide a notice to the Primary Manufacturer that acknowledges receipt and processing of claim-level payment elements by the MTF DM. CMS is soliciting comments on content for the receipt file that would be informative for Primary Manufacturers.

40.4.4.3 Dispensing Entity Receipt of Payment Outside of the MTF PM

As discussed in section 40.4.3 of this draft guidance, even if the Primary Manufacturer participates in the MTF PM, the Primary Manufacturer and dispensing entity may establish a mutually agreed-upon process for effectuating the MFP outside of the MTF PM. If the Primary Manufacturer does not participate in the MTF PM, then the Primary Manufacturer must establish its own methods of payment facilitation, which dispensing entities will be able to utilize to access the Primary Manufacturer's MFP refund payments. These MFP effectuation processes must be described in the Primary Manufacturer's MFP Effectuation Plan, as discussed in section 90.2.1 of this draft guidance. The 14-day prompt MFP payment window applies regardless of whether the Primary Manufacturer elects to use the MTF PM or not to provide access to the MFP.

The Primary Manufacturer is responsible for issuing an ERA or remittance to dispensing entities for MFP refund payments made through the Primary Manufacturer's MFP effectuation processes. For electronic fund transfers, the Primary Manufacturer must ensure that the ERA created and made available to the dispensing entity uses the X12 835 standard adopted under HIPAA and can be utilized by dispensing entities to close accounts receivable. Primary Manufacturers should have access to bank account information and designated destination for ERA transmissions for dispensing entities through the MTF DM. The MTF DM will collect this information when dispensing entities enroll, and CMS plans to make this information available through the MTF DM to support the Primary Manufacturer's creation and transmission of an ERA or remittance, as applicable.

CMS encourages the dispensing entity to work with the Primary Manufacturer to resolve any concerns regarding the availability and amount of an MFP refund. Where a payment issue cannot be resolved, either the dispensing entity or the Primary Manufacturer can use the complaint process outlined in section 90.2.2 of this draft guidance. Dispensing entities 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 the MFP may not have been made available. If a complaint is filed, CMS intends to take the steps outlined in section 90.2.2 and may issue a decision regarding whether the MFP was made available to the dispensing entity.

40.4.4.4 Primary Manufacturer and MTF PM MFP Refund Payment Adjustments due to Claim Amendments When Primary Manufacturer Makes Payment Outside of the MTF PM

For MFP refunds where payment was made outside of the MTF PM for a claim that is subsequently reversed or adjusted, the MTF will not maintain a credit/debit ledger system to address claim reversals, adjustments, and other changes in status that occur after an MFP refund payment has been made outside of the MTF PM. Primary Manufacturers may establish different methods for handling changes in payment amounts for payments made outside of the MTF PM, so long as such methods are consistent with the Primary Manufacturer's statutory obligation to make MFP available and adhere to GAAP standards and procedures. Accounting for claims reversals and adjustments must be detailed in a manufacturer's MFP Effectuation Plan, as discussed in 90.2.1 of this draft guidance, and the Primary Manufacturer has an obligation to make these processes transparent to dispensing entities that receive MFP refunds outside of the MTF PM.

As noted in section 40.4.2.1 of this draft guidance, the MTF DM will send all Primary Manufacturers claim-level data elements for all reversals and adjustments received for claims previously sent to that Primary Manufacturer. As discussed in section 40.4.2 of this draft guidance, information about previously paid MFP refunds will be included in the claim-level data elements, if applicable. For MFP refund payments made outside of the MTF PM, Primary Manufacturers must submit claim-level payment elements as described in section 40.4.4.1 of this draft guidance for these claims to provide the MTF DM with information on any changes to previously paid MFP refund amounts for purposes of program monitoring and oversight. CMS intends that the Primary Manufacturer will document adjustments through submission of their claim-level payment elements that include the final refund amount and a notation of adjustments. Credits, debits, forwarding balances, and other information should be captured in the Primary

Manufacturer's accounting ledger. Collecting this information will assist in the dispute and complaint resolution process between interested parties, described in section 90.2.2 of this draft guidance. CMS intends to conduct monitoring and oversight of these systems, including audits as appropriate. CMS may provide additional detail on reporting adjustments and reversals when the Primary Manufacturer makes payment outside of the MTF PM in future guidance or technical instructions.

40.4.5 Nonduplication with 340B Ceiling Price

In accordance with section 1193(d)(1) of the Act, the Primary Manufacturer of a selected drug is not required to provide access to the MFP for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act) is lower than the MFP for such selected drug.[77] Under section 1193(d)(2) of the Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.

A Primary Manufacturer that provides access to the MFP for a selected drug (whether via prospective discount or retrospective refund) is not required to provide a 340B ceiling price on that same selected drug claim if the MFP is lower than the 340B ceiling price. That is, these price concessions are not cumulative, but manufacturers must ensure that the appropriate price concession is honored, consistent with their obligations under section 1193 of the Act, and inclusive of their agreements under section 340B(a)(1) of the PHS Act. CMS expects that the ingredient cost component of all Part D prescriptions filled for a selected drug will be no greater than the drug's MFP, including when those prescriptions are filled at 340B covered entities and their contract pharmacies. CMS understands that 340B covered entities and their contract pharmacies currently use various inventory management processes for drugs that are subject to an agreement under section 340B(a)(1) of the PHS Act, such as separate physical drug inventories or a virtual replenishment model.

To illustrate how the 340B nonduplication provision would apply in cases where the dispensing entity's acquisition cost is not already established as being equal to or less than the MFP, CMS first reiterates the prompt MFP payment requirement under section 40.4 of this draft guidance that the Primary Manufacturer must transmit payment of an amount that provides access to the MFP within 14 days of the MTF sending claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual. Therefore, applying section 1193(d) of the Act, unless the claim for the selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the MFP for the selected drug or unless access to the MFP was provided prospectively, the Primary Manufacturer is required to transmit payment of an amount that

[77] 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.

provides access to the MFP of a selected drug to the dispensing entity within the 14-day prompt MFP payment window. Section 1193(a)(3) of the Act establishes that access to the MFP shall be provided by the manufacturer to dispensing entities, subject to section 1193(d) of the Act, which contains a limited exception to accommodate otherwise applicable 340B pricing obligations that applies only if certain express conditions are met.

In particular, section 1193(d)(1) of the Act applies only if: (1) the claim for the selected drug is a 340B-eligible claim; and (2) the 340B ceiling price is lower than the MFP for the selected drug. As described in sections 40.4.3.1 and 40.4.4.2 of this 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 section 1193(d)(1) of the Act, the Primary Manufacturer would indicate so when reporting claim-level payment elements to the MTF and declining to transmit payment in an amount that provides access to the MFP within the 14-day prompt MFP payment window. In this scenario, the Primary Manufacturer would be required to provide documentation demonstrating the claim was 340B-eligible and the 340B ceiling price was lower than the MFP upon request from CMS as described further in section 90.2 of this draft guidance. CMS also notes that an NPI alone (whether a prescriber NPI or a hospital/provider NPI) generally will not constitute sufficient evidence that a claim was 340B-eligible as not all individuals served by covered entities are necessarily eligible to receive a drug purchased at the 340B ceiling price.

CMS received requests from numerous interested parties for CMS to assume responsibility for nonduplication of the 340B ceiling price and the MFP. CMS understands that these requests for CMS to undertake nonduplication would entail CMS, via the MTF, performing a widespread, independent collection of 340B-related transactional data from 340B covered entities or their third-party administrators (TPAs)—vendors that assist some 340B covered entities in identifying 340B claims—that would then be matched on a continuous, real-time basis against PDE records transmitted to the MTF to remove claims for which a discount may be required under 340B(a)(1) of the PHS Act.[78]

Considering numerous factors such as those outlined below, CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP. As described above, CMS intends to provide Primary Manufacturers with a process to identify applicable 340B-eligible claims through the reporting of claim-level payment elements to the MTF, as described in sections 40.4.3.1 and 40.4.4.1 of this 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 is continuing to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under section 1193(d)(1) of the Act into MTF processes in the future. For example, CMS is considering ways to incorporate asynchronous 340B data into MTF processes in the future.

If it is subsequently determined that a claim for a selected drug was a 340B-eligible claim but an MFP refund was provided for that claim, and the 340B ceiling price for the selected drug is determined to be lower than the MFP, then the Primary Manufacturer may use the credit/debit

[78] The nonduplication functions described here, which reflect the requests of interested parties, would be primarily proactive in nature, and, for purposes of this discussion, are separate and distinct from any functions that may be performed in the context of the dispute or complaint process or in the enforcement context.

ledger system described in section 40.4.3.2 of this draft guidance, if the Primary Manufacturer made payment through the MTF PM for the claim, to reconcile the duplicated discounts. As detailed in section 40.4.3.2 of this draft guidance, CMS intends that dispensing entities and participating Primary Manufacturers will be able to view the status of available credits and MFP refunds through their MTF portal for payments made through the MTF PM. The MTF will provide functionality in the MTF DM for Primary Manufacturers to submit instructions for the MTF to apply a credit for the previously provided MFP refund in these scenarios such that Primary Manufacturers will have access to functionality to address duplicated discounts retroactively if needed. A Primary Manufacturer that makes payment outside the MTF PM for a claim will not have access to use the credit/debit ledger system operated by the MTF to apply a credit for that claim if it is subsequently determined to be 340B-eligible and the 340B ceiling price is lower than the MFP for the selected drug. A Primary Manufacturer that makes payment outside the MTF PM may develop its own process that may include a system to account for credits and debits to effectuate nonduplication between the MFP and 340B ceiling price. To the extent dispensing entities choose to voluntarily and proactively indicate on a submitted claim that the claim is 340B-eligible,[79] the MTF would pass along the 340B indication data as applicable to the Primary Manufacturer when the MTF shares the data elements with each Primary Manufacturer. A Primary Manufacturer could use this information to determine if the claim meets the limited exception under section 1193(d)(1) of the Act, or if the Primary Manufacturer is required to provide access to the MFP in accordance with section 1193(d)(2) of the Act.

CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is 340B-eligible. Nothing in this guidance modifies a Primary Manufacturer's statutory obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. Nothing in this guidance alters a Primary Manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the 340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11.

CMS understands that a majority of 340B claims are processed by a small number of 340B TPAs on behalf of 340B covered entities and dispensing entities. CMS also understands that 340B TPAs typically adjudicate claims to determine which claims are 340B eligible in a relatively short amount of time (often within as little as 24 hours). CMS strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price, wherever applicable. CMS anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders to ensure the process is not unduly burdensome for dispensing entities, 340B covered entities, and patients.

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[79] 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 have been added to the PDE record to indicate a 340B-eligible claim. See: https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf. See also: https://www.cms.gov/files/document/2025-pde-file-layouts.pdf.

CMS acknowledges the intersection between its requirement under the Negotiation Program for manufacturers to provide access to the MFP and Health Resources and Services Administration's (HRSA's) requirements for manufacturers to offer the 340B ceiling price to 340B covered entities. As necessary, CMS will coordinate with HRSA to provide and share information to support compliance with each agency's respective program requirements.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

Pursuant to CMS' statutory obligation under sections 1191(a)(4), 1196, and 1197 of the Act, CMS established a robust program for monitoring compliance with the Negotiation Program. After entering into an Agreement with CMS and in accordance with section 1193(a)(5) of the Act, the Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program. For example, CMS may engage in auditing processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer under the requirements of section 1193(a)(4) of the Act. CMS also may audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. CMS intends to 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 intends to consider the Primary Manufacturer in violation of the Agreement and the Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act.

As feasible, CMS intends to provide Primary Manufacturers with information on certain CMS calculations during and after the negotiation period, including: (1) following the Primary Manufacturer's submission of data that complies with the submission of data described in section 50.1 of this draft guidance, information on the agency's calculation of the ceiling and the computation of how CMS intends to apply a single MFP across dosage forms and strengths of the selected drug; and (2) following certain updates to CMS' computation of how the agency will apply a single MFP across dosage forms and strengths of the selected drug (such as to account for the addition of new NDCs), information on such updates. CMS intends to 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 intends to apply a single MFP across dosage forms and strengths to submit a suggestion of error for CMS' consideration. Comments related to statutorily required criteria or the policies adopted in Negotiation Program guidance are outside the scope of the suggestion of error process. For example, comments on calculation methodology will be considered out of scope. As feasible, CMS intends to 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 (in other words, the statutory deadline of March 1, 2026).

A Primary Manufacturer will have 21 days to submit a suggestion of error. The suggestion of error must be submitted via email to IRARebateandNegotiation@cms.hhs.gov with the subject

line "Suggestion of Error for [name of the selected drug]." This notification should include supporting information documenting why the Primary Manufacturer believes that CMS made a mathematical error in its calculations and corresponding steps that should be reviewed. A Primary Manufacturer may provide this information via a sample Excel file that CMS intends to provide to the Primary Manufacturer at the same time that CMS provides the calculation of the ceiling and the computation of how CMS intends to apply a single MFP across dosage forms and strengths to the Primary Manufacturer. CMS intends to review and respond within 21 days of receiving the suggestion of error from the Primary Manufacturer, if feasible. The suggestion of error process does not affect a Primary Manufacturer's obligation to comply with Negotiation Program requirements and will not alter or change any timelines or requirements of the Negotiation Program.

40.6 Termination of the Agreement

In accordance with section 1193(b) of the Act, when the Primary Manufacturer enters into the Agreement described in section 40.1 of this 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 nine months after the date on which CMS determines that the selected drug is no longer a selected drug under section 1192(c) of the Act or the Agreement is terminated by either party in accordance with this section (the "Termination Date").

In accordance with section 1193(a)(5) of the Act, a Primary Manufacturer may terminate its Agreement with respect to a selected drug with respect to a price applicability period, before reaching an agreement with CMS as to the MFP for the selected drug or after such an MFP is agreed to, if the Primary Manufacturer meets certain conditions for termination consistent with the provisions in 26 U.S.C. § 5000D(c). Specifically, a Primary Manufacturer seeking to terminate its Agreement with respect to a selected drug must submit to CMS a notice of request to terminate. As noted in section 40.1 of this 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 Manufacturer Discount Program. The provisions enacted in 26 U.S.C. § 5000D give the Primary Manufacturer choices with regard to the Negotiation Program. One option is that the Primary Manufacturer may participate in the Negotiation Program. Another option is that the Primary Manufacturer may opt out of the Negotiation Program, and the excise tax may be imposed under 26 U.S.C. 5000D and the Department of the Treasury regulations referenced in section 90.3 of this draft guidance. Alternatively, the Primary Manufacturer may opt out of the Negotiation Program but avoid the excise tax on sales of the selected drug during periods for which the manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of its drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act. Promoting continuity in the administration of the Negotiation Program warrants extending parallel options to a Primary Manufacturer with respect to potential CMP liability. A Primary Manufacturer with an Agreement with respect to the price applicability

period with respect to a selected drug may opt out of the Negotiation Program and pay CMPs associated with violations of program requirements. Alternatively, a Primary Manufacturer seeking to cease participation in the Negotiation Program through the end of the price applicability period for a selected drug may avoid CMP liability by terminating its Agreement if it also ceases participation in the Medicaid Drug Rebate Program and the Manufacturer Discount Program through the end of the price applicability period for the selected drug.

Thus, in accordance with section 1193(a)(5) of the Act, CMS has determined that the Primary Manufacturer's notice of termination of the Agreement must incorporate both: (1) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(A)(i); and (2) an attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer (a) shall not seek to enter into any subsequent agreement with any such program and (b) shall not seek coverage for any of its drugs under the Manufacturer Discount Program under section 1860D-14C of the Act, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(B).[80] A Primary Manufacturer later seeking to re-enter any applicable agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program would be deemed to have provided an invalid attestation that was a condition of termination, and the Agreement would once again become operative as of the date of re-entry into the applicable agreements or coverage for any of its drugs under the Manufacturer Discount Program. If a Primary Manufacturer terminated its Agreement prior to completing the negotiation process and agreeing to an MFP, such process will be initiated or resumed in accordance with the negotiation process described in section 60 of this draft guidance. In addition, the timing of the Primary Manufacturer's decision to resume participation in the Negotiation Program may implicate the renegotiation process described in section 130 of this draft guidance.

If the conditions for termination of the Agreement for the Negotiation Program described above are met, CMS will terminate such Agreement effective on the first date on which the notices of termination for all applicable agreements have been received and none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program. As is noted above, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program, and the Manufacturer Discount Program. If a Primary Manufacturer determines after executing its Agreement that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice that complies with the requirements in this section 40.6, the Primary Manufacturer's request will constitute good cause to terminate the Primary Manufacturer's agreement(s) under the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14C(b)(4)(B)(i) of the Act to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14C of the Act and thus facilitate an expedited Termination Date.

[80] 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.

Moreover, consistent with the process described in section 40.1 of this draft guidance, if a Primary Manufacturer has determined it is unwilling to continue its participation in the Negotiation Program and provides a termination notice that complies with the requirements in this section 40.6, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request for its applicable agreements under the Manufacturer Discount Program, as applicable. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

Notwithstanding any termination of the Agreement, the MFP shall continue to apply for any selected drugs that were dispensed prior to the Termination Date. Also, notwithstanding the termination of the Agreement, any confidentiality, record retention, and/or data requirements and any requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities shall continue to apply.

40.7 Other Provisions in the Agreement

Additional terms in the Agreement set forth general provisions in accordance with requirements determined by CMS to be necessary for purposes of administering or monitoring compliance with the Negotiation Program. For example, any notice required to be given by the manufacturer or CMS must be sent in writing via email to CMS- and manufacturer-designated email addresses. CMS retains the authority to amend the Agreement to reflect changes in law, regulation, or guidance, and, when possible, CMS will give the Manufacturer at least 60-day notice of any change to the Agreement.

In accordance with section 1193(a)(5) of the Act, if, after entering in an Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs / BLAs of the selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Agreement, including the requirement to provide access to the MFP, associated with the transferred NDA(s) / BLA(s) unless and until the Primary Manufacturer transfers all the NDAs / BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer. The acquiring entity's assumption of responsibility as the new Primary Manufacturer must be evidenced by a novation to the transferring Primary Manufacturer's original Agreement for the Negotiation Program. The transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the Biosimilar Delay under section 1192(f) of the Act unless and until such liabilities are transferred to the acquiring entity as the new Primary Manufacturer. The transferring Primary Manufacturer shall provide CMS at least 30 calendar days written notice before the effective date of any such transfer and, if applicable, any novation.

If the Primary Manufacturer of a selected drug transfers all NDAs / BLAs of the selected drug, and the acquiring entity assumes responsibility as the new Primary Manufacturer of the selected

drug for purposes of the Negotiation Program, CMS recognizes that this transfer of ownership could enable the original Primary Manufacturer to avoid potential excise tax liability for future sales as well as render unnecessary the efforts by the original Primary Manufacturer to comply with the statutory suspension of the excise tax and the termination process as described in section 40.6 of this 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 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) of the Act regarding therapeutic alternatives to a selected drug. CMS will consider evidence about therapeutic alternatives relevant to the factors described in section 1194(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS would be best positioned to identify all available, relevant evidence for the factors described at section 1194(e)(2) of the Act.

CMS intends to publish the Drug Price Negotiation ICR in the Federal Register for a 60-day public comment period in Summer 2025 and intends to publish a revised version of the ICR for a 30-day comment period in Fall 2025. The Drug Price Negotiation ICR for initial price applicability year 2028 will describe how CMS intends to collect the data outlined in sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act, and will include instructions on how Primary Manufacturers and members of the public may submit relevant data. The ICR incorporates lessons learned pertaining to the collection process, question format, and content received from respondents for initial price applicability years 2026 and 2027.

The definitions that CMS is adopting for the purposes of describing the data to be collected for use in the Negotiation Program under sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act are specified in Appendix A of this draft guidance.

In accordance with sections 1193(a)(4)(B) and 1194(b)(2)(A) of the Act, the data described in sections 50.1 and 50.2 of this draft guidance for drugs selected for initial price applicability year 2028 must be submitted to CMS by March 1, 2026. CMS' intention to require public submission on the same date as manufacturer submission (i.e., March 1, 2026) serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer, pursuant to general program administration authority.

CMS will also obtain new information on the factors described at sections 1194(e)(1) and 1194(e)(2) of the Act for purposes of renegotiation (as described in section 1194(f) of the Act). These requirements are described further in section 130.3 of this draft guidance.

50.1 Manufacturer-Specific Data

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as described in section 60 of this 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.

Section 1194(f)(4)(B) of the Act directs CMS to establish a renegotiation process that is, to the extent practicable, consistent with the negotiation process under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. Consistent with this directive, as described in section 130.3.2 of this draft guidance, once a renegotiation-eligible drug is selected for renegotiation, CMS will collect new information for all section 1194(e)(1) data elements from all Primary Manufacturers with a drug selected for renegotiation.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by March 1, 2026:

1. Research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s).

The Primary Manufacturer should submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to section 40.2 of this draft guidance (e.g., NDC-11s distributed by a private label distributor and NDC-11s listed as a sample package, an inner package, an outer package, and discontinued). As noted above, CMS requires the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data pertaining to market data and revenue and sales volume data for the selected drug.

See Appendix A of this draft guidance for a list of definitions that apply for purposes of describing these data to be collected for use in the Negotiation Program, including for renegotiation.

In addition to these data, CMS is soliciting comment on the collection of additional, forward-looking "market data" for the selected drug that pertain to periods that overlap with the negotiation period and/or the price applicability period. CMS suggests this data could include, for example, forecasted net revenue and volume data for the selected drug for these future periods. Specifically, CMS shares two examples to illustrate the type of data CMS believes may provide market insight for this gap in time: (1) the manufacturer's annual forecast of U.S. net revenue, volume by indication, and net pricing for the selected drug itemized by the relevant market channel (e.g., Medicare, Medicaid, commercial or other); and (2) an annual gross-to-net ratio trend for the selected drug across all market channels and market share percentages and volume, by indication. CMS believes these types of data are consistent with the section 1194(e)(1)(E) factor of "market data and revenue and sales volume data for the drug in the United States." These data could assist CMS with considering anticipated net pricing and volume changes while negotiating an MFP for the selected drug. To illustrate a practical application of how CMS could use this additional market data, consider a scenario where there is a substantial WAC price decrease planned for a selected drug to be implemented prior to the first initial price applicability year for the selected drug, which could be informative during discussions in the negotiations with a Primary Manufacturer. CMS is soliciting comments from interested parties on the types of "market data" that a Primary Manufacturer could submit to inform pricing and net revenue projections for a selected drug.

Additionally, the Primary Manufacturer has an ongoing obligation to timely report certain updates to data submissions required of Primary Manufacturers under sections 1193(a)(4)(A) and 1194(e)(1) of the Act and previously submitted to CMS through the initial response to the Drug Price Negotiation ICR Form. Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under sections 1193(a)(4)(A) and 1194(e)(1) to CMS if the data was restated due to requirements of the government entity that initially receives and oversees processing of such data. For example, under the Medicaid program, manufacturers must report revisions to best price under 42 C.F.R. § 447.510. Timely notify CMS via the IRA Mailbox at IRARebateandNegotiation@cms.hhs.gov with the subject line "Updates to 1194(e)(1) data submission for [name of selected drug]" if updates are applicable to the selected drug. CMS will provide a method and process for submission of these updates via the CMS HPMS at such time. This ongoing obligation to update the Primary Manufacturer's original data submissions is separate both from any voluntary submission of data from a Primary Manufacturer of a selected

drug to inform renegotiation eligibility and selection (see section 130.3.1 of this draft guidance) and the required submission of section 1194(e)(1) data to CMS for renegotiation of drugs selected for renegotiation (see section 130.3.2 of this draft guidance), which cover different reporting periods. CMS may also consider the Primary Manufacturer's original data submission, including any updates to such information, to inform renegotiation eligibility and selection, and to use such information during renegotiation if a drug is selected for renegotiation.

50.1.1 Non-FAMP Data

The Primary Manufacturer must submit data on non-FAMP for the selected drug for the Primary Manufacturer and any Secondary Manufacturer(s), as required under section 1193(a)(4)(A) of the Act. CMS will collect these data through the Drug Price Negotiation ICR described above. Specifically, under section 1194(c)(1)(C)(ii) of the Act, for initial price applicability year 2028, the Primary Manufacturer must submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar years 2021, as well as calendar year 2025 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2026). In the case that there is not an average non-FAMP price available for such drug for 2021, the Primary Manufacturer must submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of the first full calendar year following market entry of such drug. For purposes of determining the applicable year, CMS intends to consider the average non-FAMP price to be available for a selected drug for calendar year 2021 if the Primary Manufacturer reports at least one quarter of non-FAMP data for at least one NDC-11 of the selected drug in calendar year 2021.

As described in Appendix A, when for a given NDC-11 of a selected drug there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) or calendar year 2025, the non-FAMP reported by the Primary Manufacturer to CMS for that calendar quarter should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2025 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS. The use of these data to calculate the ceiling for the MFP is further described in section 60.2 of this 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 ICR.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

As noted above, section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;

2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, hereinafter the "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Section 1194(e)(2) of the Act additionally requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Information submitted by members of the public, including manufacturers, Medicare beneficiaries, 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.[81] CMS will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the measure used is permitted in accordance with section 1194(e)(2) of the Act as well as section 1182(e) of Title XI of the Act and other applicable law, including section 504 of the Rehabilitation Act. CMS may use content in a study that uses a cost effectiveness-measure if it determines that the cost-effectiveness measure used is permitted in accordance with the law and does not treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. In instances where some, but not all, content in a study is excluded (e.g., Quality-Adjusted Life Years (QALYs)), CMS may still consider content that is relevant and allowable (e.g., clinical effectiveness, risks, harms) under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act.

CMS will remove the requirement for respondents to the Drug Price Negotiation ICR for initial price applicability year 2028 to indicate whether their submission contains information from studies that use measures or methods that treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill and the request that respondents provide a short description of any cost-effectiveness measures included in the research they are submitting, and how they believe the data avoids treating extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Previous submissions to the Negotiation Data Elements and Drug Price Negotiation Process ICR from initial price applicability years 2026 and 2027 indicate that not all respondents are familiar with cost-effectiveness measures and, therefore, may not be able to provide relevant information to fulfill this requirement. Nonetheless, CMS reviews, and will continue to review, measures included in studies submitted by respondents through the Drug Price Negotiation ICR. CMS determines, and will continue to

[81] 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.

determine, if it is appropriate under section 1194(e)(2) of the Act for CMS to consider the information submitted.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, 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), information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, information about patient experience, and/or information on whether the selected drug addresses unmet medical need, as described in section 1194(e)(2) of the Act. Outcomes such as changes to productivity, independence, and quality of life will also be considered when these outcomes correspond with a direct impact on the individuals taking the selected drug or therapeutic alternative and are appropriately measurable and quantifiable.

CMS additionally will review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this 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 intends to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., has sufficient sample size) to answer the primary question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses.

CMS will consider research and real-world evidence relating to Medicare populations, including individuals with disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS intends to prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

All information on the factors described in section 1194(e)(2) of the Act related to drugs selected for initial price applicability year 2028 must be submitted to CMS by March 1, 2026.

See Appendix A of this 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.

Pursuant to section 1195(a)(2) of the Act and as discussed in section 60.6.1 of this draft guidance, CMS is required to publish the explanation of the MFP by March 1, 2027 for initial price applicability year 2028 selected drugs. Within the explanation of the MFP, CMS may also make public high-level comments about the section 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any PHI / PII or any proprietary information reported to CMS under section 1193(a)(4) of the Act for purposes of the negotiation.

Similar to the approach taken for publication of the public MFP explanations for initial price applicability year 2026, for each drug, CMS will make available on the CMS website redacted versions of section 1194(e)(2) data submitted by the public that are determined to be non-proprietary and will not disclose any PHI, PII, or information that is protected from disclosure under other applicable law.

60. Negotiation Process

In accordance with section 1194(b)(1) of the Act, CMS will develop and use a consistent methodology and process for negotiation with the aim of achieving agreement on "the lowest maximum fair price for each selected drug." This section 60 describes the negotiation process, including engagement with Primary Manufacturers and interested parties, the development of the written initial offer, the process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug, the process and requirements for accepting an offer or providing a statutory written counteroffer, optional negotiation meetings between CMS and the Primary Manufacturer, additional price exchange opportunities, the conclusion of negotiation, the publication of the MFP, and explanation of the MFP. The policies and procedures set forth in sections 60.1, 60.3, 60.4, 60.5, and 60.6 of this draft guidance will also apply for purposes of renegotiation such as: (1) for drugs selected for renegotiation, the renegotiation process will establish a single price based on 30-day equivalent supply, as described below for the negotiation process in section 60.1 of this draft guidance; (2) the methodology for developing an initial offer as described in section 60.3 of this draft guidance; (3) drugs selected for renegotiation will go through the same procedures, structure, and timing as selected drugs for negotiation as described in section 60.4 of this draft guidance; (4) a single MFP will apply across dosage forms and strengths of the renegotiated selected drug, for drugs payable under Part B and/or covered under Part D, as applicable as described in section 60.5 of this draft guidance; and (5) publication and explanation of the MFP as described in section 60.6 and 60.6.1 respectively of this draft guidance. Determining the ceiling for renegotiation is described in section 130.4.1 of this draft guidance.

60.1 Establishment of a Single MFP for Negotiation and Renegotiation Purposes

In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year. CMS interprets this language to refer to negotiation of a single price for a selected drug with respect to its price applicability period. Accordingly, CMS intends to 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.

Whereas for purposes of negotiation and renegotiation, the focus is on establishing the MFP, for purposes of MFP implementation, the Medicare payment will use the MFP, as applicable, within established Medicare payment methodologies. For example, in accordance with section 1847A(b)(1)(B) of the Act, Medicare payments under Part B for a selected drug shall be 106 percent of the MFP. In another example, in accordance with section 1860D-2(d)(1)of the Act, the negotiated prices used for payment under Part D for a selected drug shall be no greater than the MFP plus any dispensing fees. CMS is soliciting comments on how MFP effectuation should apply in cases where the selected drug is not paid under section 1847A of the Act, including whether it best effectuates the relevant statutory provisions in instances in which payment may be made under Part B for a selected drug on the basis of an amount other than ASP or WAC, for the Medicare Part B payment (and coinsurance) to be based on the lower of 106 percent of the MFP and the otherwise applicable payment amount.

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 intends to base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit—such as tablet, capsule, injection—or per volume or weight-based metric) for all formulations (including drugs payable under Part B and/or covered under Part D, as applicable), weighted across dosage forms and strengths. This approach of negotiating a single price across all dosage forms and strengths aligns with the statutory requirement to negotiate an MFP for a selected drug. CMS believes this will also allow for a more direct comparison with the therapeutic alternative(s), which might have different dosage forms, strengths, and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) than the selected drug.

CMS is soliciting comment on whether it should take an alternative approach to negotiating the single price for the selected drug—for example, on a per-unit basis rather than a 30-day equivalent supply basis, or on the basis of a days' supply less than 30 days—for drugs for which a 30-days' supply is not representative of the typical use of such drug (for example, drugs that have only one formulation and are indicated for administration once in a course of treatment, or drugs that are typically administered daily for a short period such as two weeks). CMS is soliciting comment on how to modify the calculation of (1) the ceiling; (2) the application of the MFP; and (3) the pricing of therapeutic alternatives if a different approach to negotiating a single price for the selected drugs for which a 30-day supply is not representative of the typical use of such drug were used.

Section 60.5 of this draft guidance describes the methodology CMS intends to use to translate the MFP once finalized (which, per above, CMS intends to be an average price per 30-day equivalent supply for the selected drug across all formulations of the drug) back into per unit (e.g., tablet) prices at the dosage form and strength level, per package (e.g., bottle), and per HCPCS code dosage, for the purposes of publishing per-unit, per-package, and per-HCPCS code dosage MFPs for the different dosage forms and strengths of the selected drug at the NDC-9, NDC-11, and HCPCS code levels, as contemplated under section 1196(a)(2) of the Act. Section

60.5.1 of this draft guidance describes the process by which CMS intends to apply the MFP to new NDAs / BLAs, NDCs, or HCPCS codes, including those added during the negotiation period or after any agreement upon MFP is reached, and to NDCs and HCPCS codes with insufficient PDE, Part B claims, or WAC data in calendar year 2025 to apply the MFP across those dosage forms and strengths. In addition to the description of that methodology included in this draft guidance, as feasible, CMS intends to share the inputs behind that methodology specific to the selected drug with the Primary Manufacturer of the selected drug during the negotiation period such that the Primary Manufacturer will have visibility into the implied unit prices, package prices, and HCPCS code dosage prices based on the MFP for the different dosage forms and strengths of the selected drug throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price would be clearly translatable to per unit, per package, and per HCPCS dosage code prices at the dosage form and strength level).

60.2 Limitations on Offer Amount

In accordance with section 1194(b)(2)(F)(i) of the Act, in negotiating the MFP of selected drugs with respect to initial price applicability year 2028, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. This section 60.2 of this 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 2028, the ceiling for the MFP for a selected drug shall not exceed the lower of the following:

- As described in section 60.2.2 of this draft guidance and section 1194(c)(1)(B) of the Act, an amount equal to one of the following, as applicable to the selected drug:
    - For a selected drug that is covered under Part D but is not payable under Part B, the sum of the plan-specific enrollment weighted amounts, as described in section 60.2.2.1 of this draft guidance; or
    - For a selected drug that is payable under Part B but is not covered under Part D, the payment amount under section 1847A(b)(4) of the Act for the year prior to the year of that selected drug's publication date with respect to the initial price applicability year for that selected drug, as described in section 60.2.2.2 of this draft guidance; or
    - For a selected drug that is payable under Part B and covered under Part D, an amount equal to the weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount (hereinafter the "combined Part B and Part D amount"), as described in section 60.2.2.3 of this draft guidance. CMS interprets the language in section 1194(c)(1)(B) of the Act to mean that it should calculate a single ceiling incorporating both of these amounts for selected drugs payable under Part B and covered under Part D.
- As described in section 60.2.3 of this draft guidance and section 1194(c)(1)(C) of the Act, an amount equal to the applicable percent, as applicable to the selected drug, of the lower of:
    - The average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for calendar year 2021 (or in the case that there is not an average non-FAMP for

such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September 2025;[82] or

- The average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for the calendar year prior to the selected drug publication date, February 1, 2026, which for initial price applicability year 2028 is 2025.

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

CMS will use information submitted by manufacturers to the CMS HPMS pursuant to section 40.2 of this draft guidance to determine which NDC-11s of the selected drug will be included in the ceiling calculations described in sections 60.2.2 and 60.2.3 of this draft guidance, based on the criteria described below.

- Sum of the plan-specific enrollment weighted amounts for the most recent year for which data is available (calendar year 2024 for initial price applicability year 2028): (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) CMS observes any PDE days' supply, PDE quantity dispensed, and PDE gross expenditures in calendar year 2024; and (4) CMS observes any associated Direct and Indirect Remuneration (DIR) amounts for the NDC-11 for calendar year 2024.
- Payment amount under section 1847A(b)(4) for the most recent year for which data is available (calendar year 2025 for initial price applicability year 2028): (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) the NDC-11 is assigned to a HCPCS code; and (4) CMS observes any Part B claims for the HCPCS code to which the NDC-11 is assigned in calendar year 2025.
- Average non-FAMP for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug): (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) CMS received non-FAMP data for the NDC-11 for at least one calendar quarter in calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for

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

such drug); and (4) CMS observes any PDE days' supply and PDE quantity dispensed or any Part B claims associated with the HCPCS code to which the NDC-11 is assigned in calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug).

- Average non-FAMP for calendar year 2025: (1) the NDC-11 is assigned to the Primary Manufacturer or marketed by Secondary Manufacturer(s); (2) the NDC-11 does not represent a sample package; (3) CMS received non-FAMP data for the NDC-11 for at least one calendar quarter in calendar year 2025; and (4) CMS observes any PDE days' supply and PDE quantity dispensed or any Part B claims associated with the HCPCS code to which the NDC-11 is assigned in calendar year 2025.

For the purposes of calculating the sum of the plan-specific enrollment weighted amounts, 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;[83] (2) total gross covered prescription drug costs on the PDE record is greater than $0; (3) the PDE record is considered final action;[84] (4) the drug coverage status code indicates the PDE record is for a drug covered under Part D; and (5) the compound code indicates the PDE record is not for a compounded drug. An additional sixth requirement specific to the sum of the plan-specific enrollment weighted amount calculation for calendar year 2024 is that the Part D plan that submitted the PDE record also included the NDC-11 associated with the PDE record in their calendar year 2024 DIR data (discussed further in section 60.2.2 of this draft guidance).[85]

For the purposes of calculating the payment amount under section 1847A(b)(4) of the Act, Part B claims will be included in the ceiling calculation for HCPCS codes to which the NDC-11s of the selected drug are assigned when the claims meet the following requirements: (1) the claim is associated with a service date between January 1, 2025, and December 31, 2025; (2) the claim type is 40, 71, 72, 81, or 82 (claim type codes associated with separately payable drugs eligible for reimbursement under Part B); (3) the total allowed charges (defined as the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service) for the HCPCS code on the claim is greater than $0; (4) the claim is considered final action;[86] and (5) the claim is not billed as a compounded drug.

60.2.1.1 Determination of the 30-Day Equivalent Supply for a Selected Drug

CMS will calculate a single ceiling per 30-day equivalent supply across all dosage forms and strengths of the selected drug. Using the price per 30-day equivalent supply to calculate this

[83] The year used for average non-FAMP for calendar year (CY) is CY 2021, CY 2024 is used for sum of the plan-specific enrollment weighted amounts, and CY 2025 is used for average non-FAMP for CY 2025 as stated in the bulleted criteria above in this section.

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

[85] 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.

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

amount facilitates aggregation across dosage forms and strengths of a selected drug where units (e.g., mg versus mL) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ.

To calculate the 30-day equivalent supply for each PDE record associated with a selected drug that is a drug covered under Part D, CMS will use the methodology as described at 42 C.F.R. § 423.104(d)(2)(iv)(A)(2). This methodology relies on the "days' supply" field in PDE records.

To calculate the 30-day equivalent supply for Part B claims associated with selected drugs that are payable under Part B, CMS must use an alternative methodology because Part B claims do not contain a "days' supply" field. CMS will conduct the following steps to determine the 30-day equivalent supply for a Part B claim:

1. For a given Part B claim for the selected drug's HCPCS code in calendar year 2025, CMS will identify any subsequent Part B claim or PDE record (if any Part D claims) that: (a) is associated with the same beneficiary and (b) is for a drug or biological product with the same active moiety / active ingredient as the selected drug.
2. CMS will calculate a "days between service" amount by counting the days between the first Part B claim's date of service and the immediately subsequent Part B claim or PDE record's date of service. For example, if the first Part B claim's date of service is January 12, 2025 and the immediately subsequent claim with the same active moiety / active ingredient is another Part B claim with a date of service of March 12, 2025, the "days between service amount" would be calculated as 59 days. This would be the same calculation if the subsequent claim was a PDE record.
    a. If the beneficiary does not have a subsequent claim or PDE record with the same active moiety / active ingredient (for example, if the Part B claim in question is the last Part B claim associated with the active moiety / active ingredient that the beneficiary received), CMS intends to assign a "days between service" amount equal to the median "days between service" amount for all other Part B claims for that selected drug associated with that beneficiary during the applicable claims period. CMS chose median as opposed to other measures because median is a common measure of central tendency that is less influenced by outlier values. If there are no other Part B claims for that selected drug associated with that beneficiary during the applicable claims period, CMS will not assign a "days between service" amount, and the claim will not be included in the calculations.

       Continuing the example above, if the beneficiary's third claim was August 1, 2025 the number of "days between service" amount, for days between March 12, 2025 and August 1, 2025, would be calculated as 142. If the beneficiary only had one claim after August, it would be assigned the median of 59 and 142, which is 100.5.
3. CMS will use the "days between service" amount calculated for each Part B claim to calculate the 30-day equivalent supply using a similar methodology to the methodology as described at 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for PDE records. If the "days between service" is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the "days between service" is greater than 34, the number of 30-day equivalent supplies is equal to the days between service divided by 30.

Because Part B claims are billed at the HCPCS code level, and some calculations using the 30-day equivalent supply of the selected drug require NDC-level 30-day equivalent supply amounts, CMS will allocate a portion of the HCPCS code's 30-day equivalent supply to each NDC within the HCPCS code for calculations that require 30-day equivalent supply at the NDC level.

To determine the total Part B 30-day equivalent supply at the NDC-level, CMS will conduct the following steps:

1. Determine the total billing units sold for each NDC-11 assigned to the HCPCS code (including NDC-11s that do not belong to the selected drug, if applicable) for each applicable quarter, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC-11 package level by the number of billing units per NDC-11 reporting unit.
2. For all NDC-11s assigned to the HCPCS code, sum the total billing units sold for such NDC-11s across all calendar quarters to calculate an annual amount.
3. For each NDC-11 associated with the selected drug, divide the total billing units sold for that NDC-11 by the total billing units sold for all applicable NDC-11s of the same HCPCS code.
4. For each NDC-11 associated with the selected drug, multiply the 30-day equivalent supply for the HCPCS code (as described above) by the quotient calculated in step 3 to yield the 30-day equivalent supply for the NDC-11.
    a. If the calculation for which CMS is using 30-day equivalent supply requires the 30-day equivalent supply at the NDC-9 level, sum the amount calculated in step 4 for all NDC-11s within the NDC-9 to calculate the total Part B 30-day equivalent supply attributed to the NDC-9.

60.2.2 Determination of the Sum of the Plan-Specific Enrollment Weighted Amounts, the Payment Amount Under Section 1847A(b)(4) of the Act, and the Combined Part B and Part D Amount

If a selected drug is covered under Part D but is not payable under Part B, as set forth in the preceding section, CMS will calculate the sum of the plan-specific enrollment weighted amounts as described in section 60.2.2.1 of this draft guidance. If a selected drug is payable under Part B but is not covered under Part D, as set forth in the preceding section, CMS will calculate the payment amount under Section 1847A(b)(4) of the Act as described in section 60.2.2.2 of this draft guidance. If a selected drug is payable under Part B and covered under Part D, as set forth in the preceding section, CMS will calculate a single amount referred to as the combined Part B and Part D amount as described in section 60.2.2.3 of this draft guidance.

60.2.2.1 The Sum of the Plan-Specific Enrollment Weighted Amounts

In accordance with section 1194(c)(1)(B)(i) of the Act, CMS will calculate for a selected drug that is covered under Part D an amount equal to the sum of the plan-specific enrollment weighted amounts determined using the methodology described in section 1194(c)(2) of the Act. Plan sponsors report Part D PDE data to CMS at the NDC-11 level. Sponsors also report DIR data to CMS at the NDC-11 level in the annual Detailed DIR Report. As directed by statute, CMS will use these reported data for plan year 2024, which is the most recent year for which data will be

available, for the purpose of determining the sum of the plan-specific enrollment weighted amounts for a selected drug that is covered under Part D for initial price applicability year 2028.

CMS will include all Part D plans[87] 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 2024.[88]

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 2024 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 remuneration at point-of-sale amounts (ERPOSA),[89] and units dispensed.
3. For each Part D plan and each NDC-9, CMS will sum the total DIR amounts found in the 2024 Detailed DIR Report and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale.
4. For each Part D plan and each NDC-9, CMS will subtract the total DIR minus ERPOSA amount calculated in step 3 from the total negotiated price amounts calculated in step 2 and then divide by the total units dispensed also determined in step 2. This calculation results in the NDC-9 price per unit, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan.
5. Separately, CMS will identify the total number of individuals enrolled in all Part D plans in December 2024 and the total number of individuals enrolled in each Part D plan in that

[87] CMS intends to identify Part D plans based on the combination of the Part D contract identifier and the plan benefit package identifier.
[88] 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.
[89] ERPOSA is the estimated amount of rebates or other price concessions that the Part D plan sponsor is required to apply, or has elected to apply, to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale (POS). For further information please see: https://www.cms.gov/files/document/erposamemo508g.pdf. or refer to 87 Fed. Reg. 27704 (May 9, 2022).

same month, for each NDC-9 of the selected drug.[90] The Part D plans included in the calculations of this step for a given NDC-9 will be restricted to Part D plans with at least one PDE record for that NDC-9 identified in step 1.

6. For each Part D plan and each NDC-9, CMS will divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2024 as identified in step 5 by the total number of individuals enrolled in all Part D plans also as identified in step 5, and multiply this quotient by the price per unit, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan, calculated in step 4, to arrive at the plan-specific enrollment weighted amount.
7. For each NDC-9, CMS will then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan-specific enrollment weighted amounts.
8. For each NDC-9, CMS will then multiply the sum of the plan-specific enrollment weighted amounts calculated in step 7, which are a per unit price, by the NDC-9 average number of units per 30-day equivalent supply calculated from PDE data for 2024 (i.e., quotient of the total quantity dispensed and the total 30-day equivalent supply) to yield the price of a 30-day equivalent supply.

Steps 9 through 10 result in the sum of the plan-specific enrollment weighted amounts across all NDC-9s of the selected drug:

9. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s of the selected drug, both calculated from 2024 PDE data, and multiply this quotient by the sum of the plan-specific enrollment weighted amounts for a 30-day equivalent supply as calculated in step 8.
10. CMS will then sum amounts calculated in step 9 across all NDC-9s of the selected drug to generate the sum of the plan-specific enrollment weighted amounts for the selected drug for a 30-day equivalent supply.

60.2.2.2 Payment Amount Under Section 1847A(b)(4) of the Act

In accordance with section 1194(c)(1)(B)(ii) of the Act, CMS will calculate for a selected drug payable under Part B an amount equal to the payment amount under section 1847A(b)(4) of the Act for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for that drug or biological product.

CMS interprets the statute to mean that the payment amount under section 1847A(b)(4) of the Act refers to the payment amount specified in section 1847A(b)(4) of the Act which is, for single-source drugs and biological products, the lesser of the annual ASP or WAC. The amount described under section 1847A(b)(4) of the Act is not adjusted to account for sequestration. Therefore, CMS does not intend to apply sequestration to the payment amount under section 1847A(b)(4) of the Act as part of the methodology to calculate the payment amount under section 1847A(b)(4) of the Act.[91] As directed by statute, CMS will use the quarterly reported

[90] 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.

[91] A sequestration payment adjustment, when applicable, is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, Merit-based Incentive Payment (MIPS) adjustments, and any applicable Medicare Secondary Payment adjustments.

ASP and WAC data for calendar year 2025, for the purpose of determining the payment amount under section 1847A(b)(4) of the Act for a selected drug or biological for initial price applicability year 2028. For single-source drugs and biological products payable under Part B for which Medicare does not pay based on section 1847A(b)(4) of the Act (for example, single-source dugs and biological products which are paid on the basis of 95 percent of Average Wholesale Price (AWP)), CMS would default to the ceiling amount determined under section 1194(c)(1)(C)(ii) of the Act. That is, for selected drugs or biologicals payable under Part B but not paid based on section 1847A(b)(4) of the Act, CMS would calculate the ceiling based on the applicable percent of average non-FAMP. CMS is soliciting comments on this approach and on other options to calculate the ceiling for MFP for selected drugs or biologicals payable under Part B that are not paid based on section 1847A(b)(4) of the Act.

Before calculating the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply across all dosage forms and strengths of a selected drug, CMS will first (1) calculate the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which NDC-11s of the selected drug are assigned, which CMS will then assign as the payment amount under section 1847A(b)(4) of the Act for each NDC-11 of the selected drug within such HCPCS code; and (2) allocate HCPCS code-level utilization from Part B claims across each NDC-11 assigned to such HCPCS code, so that CMS may then use the NDC-level utilization as weights when calculating a single payment amount under section 1847A(b)(4) of the Act across all dosage forms and strengths of the selected drug.

Calculating the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which NDC-11s of the selected drug are assigned

CMS will calculate the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which an NDC-11 of the selected drug is assigned using data from manufacturers of all NDC-11s that (1) are assigned to the HCPCS code; and (2) are part of the selected drug. CMS will separately calculate annual ASP and WAC amounts and then compare the amounts to determine the lower value for use as the payment amount under section 1847A(b)(4) of the Act, based on ASP and WAC data as reported in sections 1927(b)(3) and 1847A(f) of the Act.

CMS will convert the quarterly ASP and WAC reported by manufacturers for each NDC for a selected drug that is associated with a HCPCS code to an annual calendar year 2025 ASP or WAC amount for each HCPCS code by taking an average of the reported ASP or WAC amounts for the HCPCS code across all four quarters of calendar year 2025, weighted by the total number of billing units in the Part B claims within that HCPCS code each quarter. If the total billing units reported for all NDC-11s within the HCPCS code are negative, zero, or missing for a given quarter,[92] CMS intends to assign that quarter the total billing units of the lowest positive total billing units from the other quarters in calendar year 2025 for that HCPCS code.

For each of the ASP and WAC calculations separately, if the reported price is negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code in a given quarter, CMS will exclude that quarter from the calculation. If the WAC reported to the ASP Portal is negative,

[92] For more information on ASP, see: https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.

zero, missing for all applicable NDC-11s assigned to the HCPCS code for all four quarters, CMS will use the WAC reported by Primary Manufacturers to CMS under section 1194(e)(1) as described in section 50.1 and Appendix A of this draft guidance.

After calculating an annual ASP and an annual WAC, CMS will determine the lesser of the two to yield the payment amount under section 1847A(b)(4) of the Act for that HCPCS code. This amount will apply to all applicable NDC-11s assigned to that HCPCS code.

If both ASP and WAC are negative, zero, or missing for all applicable NDC-11s assigned to the HCPCS code for all four quarters, CMS will calculate the payment amount under section 1847A(b)(4) of the Act by taking the average of the published payment limits in the ASP pricing file (or in the Hospital Outpatient Prospective Payment System (OPPS) Addendum B file, if it is not available in the public pricing file) for the HCPCS code across all four quarters, weighted by reported ASP units following the methodology for weighting by reported ASP units described above (including the adjustments made when units are negative, zero, or missing for at least one quarter). CMS believes this approach is appropriate because the prices in these files are typically calculated following the methodology described in section 1847A(b)(4) of the Act but may be adjusted as necessary to accommodate the underlying data (e.g., negative, zero, or missing ASP and/or WAC).

Allocating HCPCS code-level utilization from Part B claims across each NDC-11 assigned to that HCPCS code

Because Part B claims are paid at the HCPCS code level and CMS uses NDC-level utilization weighting to calculate amounts for the ceiling, CMS will allocate HCPCS code-level utilization from Part B claims to NDC-9-level utilization using the proportion of ASP units reported by manufacturers to CMS for each NDC-11 that is associated with the NDC-9 and is assigned to the HCPCS code. CMS will also convert Part B unit types to be equivalent to PDE unit types to facilitate the calculation of a single amount, the combined Part B and Part D amount, that incorporates both the sum of the plan-specific enrollment weighted amounts and the payment amount under Section 1847A(b)(4) of the Act as described in section 60.2.2.3 of this draft guidance. If there is no equivalent unit type in PDE, CMS will not convert the Part B unit type to a PDE unit type. CMS believes that this circumstance typically occurs in situations where the drug is not covered under Part D (e.g., radiopharmaceuticals that use HCPCS units expressed in millicuries)—meaning CMS would not need to calculate a combined Part B and Part D amount. However, in the event that the drug is also covered under Part D, CMS would separately calculate the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act and take the average of the two total amounts (expressed in terms of a 30-day equivalent supply), weighted by the total 30-day equivalent supply of each, to yield the combined Part B and Part D amount. CMS is soliciting comments on this approach and whether there are scenarios that could result in a potential distortionary effect on the calculation of a single amount. Additionally, CMS is soliciting comments on alternative approaches to calculate a combined Part B and Part D amount.

CMS will convert Part B units to be equivalent to NCPDP units that are used in PDE records, and determine the respective share of Part B utilization for an NDC-9 within a HCPCS code (“converted Part B units attributed to the NDC-9”) using the following steps:

1. For each HCPCS code, calculate the total Part B units by multiplying the total billing units in Part B claims data reported to CMS for the HCPCS code by the standard billing unit for the HCPCS code.
2. For each NDC-11 assigned to a HCPCS code to which an NDC-11 of the selected drug is assigned for each quarter (including NDC-11s that do not belong to the selected drug, if applicable), calculate the total number of billing units for the NDC-11 by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC-11 package level by the number of billing units per NDC-11 reporting unit.
3. For each NDC-9, divide the sum of billing units, as calculated in step 2, for all NDC-11s that belong to the selected drug and are associated with that NDC-9 by the total billing units for all NDC-11s of the same HCPCS code.
4. For each NDC-9, multiply the total Part B units for the HCPCS code as calculated in step 1 by the quotient calculated in step 3 to determine the total Part B units for each NDC-9.
5. For each NDC-9, multiply the total Part B units for that NDC-9 by the billing unit to NCPDP unit conversion ratio (calculated by dividing the product of the standard package size and package quantity for an NDC-11 by the number of billing units per NDC-11 reporting unit for the NDC-11) to determine the PDE equivalent of the total Part B units for that NDC-9.

Calculating the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug

CMS will calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug in two stages. First, CMS will calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of each NDC-9 associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this draft guidance. Second, CMS will calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply across all NDC-9s for a selected drug.

To determine the payment amount under section 1847A(b)(4) of the Act for each NDC-9 and across all NDC-9s of the selected drug associated with the NDC-11s, CMS will conduct the following steps.

Steps 1 through 6 will result in the payment amount under section 1847A(b)(4) of the Act for each NDC-9 of the selected drug associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this draft guidance:

1. For each selected drug, CMS will identify the NDC-11s and the unique HCPCS code(s) associated with the selected drug using the criteria described in section 60.2.1 of this draft guidance. CMS intends to identify the annual calendar year 2025 payment amount under section 1847A(b)(4) of the Act for each HCPCS code and assign it to each NDC-9 within that HCPCS code as described earlier in section 60.2.2.2 of this draft guidance.
2. For each NDC-9, CMS will sum the converted Part B units attributed to the NDC-9 (calculated as described immediately preceding these steps in section 60.2.2.2 of this draft guidance) across all four quarters of calendar year 2025 to calculate the annual Part B units of that NDC-9.

3. For each NDC-9, CMS will calculate the total Part B 30-day equivalent supply attributed to that NDC-9 in calendar year 2025 as described in section 60.2.1.1 of this draft guidance.
4. For each NDC-9, CMS will calculate the quotient of the annual Part B units of the NDC-9 calculated in step 2 and the total Part B 30-day equivalent supply calculated in step 3 (the average number of units per 30-day equivalent supply).
5. For each NDC-9, CMS will then multiply the payment amount under section 1847A(b)(4) of the Act in step 1 by the average number of units per 30-day supply calculated in step 4 to yield the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9.

Steps 6 through 7 result in the annual calendar year 2025 payment amount under section 1847A(b)(4) of the Act across all NDC-9s of the selected drug:

6. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9, calculated in step 3, by the total 30-day equivalent supply across all NDC-9s of the selected drug and multiply this quotient by the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9 as calculated in step 5.
7. CMS will then sum the amounts calculated in step 6 across all NDC-9s of the selected drug to generate the payment amount under section 1847A(b)(4) of the Act for the selected drug for a 30-day equivalent supply.

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

CMS interprets the language in section 1194(c)(1)(B) of the Act to mean it should calculate a single amount across the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amounts for all dosage forms and strengths of a selected drug that is payable under Part B and covered under Part D. Section 1194(c)(1)(B) of the Act provides for the calculation of "an amount," in the singular, for each selected drug, even if such drug is payable under Part B and covered under Part D. It then specifies the payment amount under section 1847A(b)(4) of the Act as the amount to be calculated for selected drugs for which payment may be made under Part B and the sum of the plan-specific enrollment weighted amounts as the amount to be calculated for selected drugs covered under Part D. It does not specify that CMS should select only one when calculating the amount for a drug that fits into both categories. For such selected drugs, section 1194(c)(1)(B) of the Act's direction to calculate a single amount for each selected drug therefore means that CMS should calculate a single amount that captures both the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amounts. To calculate the subparagraph (B) amount for such a selected drug, CMS will calculate a weighted average of the payment amount under section 1847A(b)(4) of the Act as outlined in section 60.2.2.2 and the sum of the plan-specific enrollment weighted amounts, as outlined in section 60.2.2.1 of this draft guidance.

CMS will calculate a single payment amount per 30-day equivalent supply across the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act in several stages. First, CMS will separately calculate the sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act per 30-

day equivalent supply for each NDC-9, as described in sections 60.2.2.1 and 60.2.2.2 of this draft guidance, respectively. Second, CMS will calculate a weighted average of the sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act per 30-day equivalent supply for these NDC-9s, using the respective utilization for the NDC-9 in Part D and Part B as described in the following steps.

Steps 1 through 3 will result in the sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply for each NDC-9 of the selected drug associated with the NDC-11s identified based on the criteria described in section 60.2.1 of this draft guidance:

1. For all NDC-9s associated with NDC-11s of the selected drug that meet the criteria described in section 60.2.1, CMS will separately calculate the sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply. If an NDC-9 is only present in PDE data, CMS will calculate only the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply for that NDC-9. If an NDC-9 is only associated with a Part B HCPCS code that is present in Part B claims data, CMS will calculate only the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9. If an NDC-9 is both present in PDE data and is associated with a Part B HCPCS code that is present in Part B claims data, CMS intends to calculate both the sum of the plan-specific enrollment weighted amount per 30-day equivalent supply and the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC-9; however, in the utilization weighting described below, CMS will treat the NDC-9 as having two distinct versions and keep those versions separate in the utilization weighting to allow the Part D formulations and Part B formulations to contribute separately to the single amount. CMS believes this step is necessary to account for differences in the pricing data between Part D and Part B.
2. For each NDC-9 identified in step 1 present in PDE data, CMS will calculate the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply as described in steps 1 through 8 under section 60.2.2.1 of this draft guidance and the total 30-day equivalent supply.
3. For each NDC-9 identified in step 1 associated with a HCPCS present in Part B claims data, CMS will calculate the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply as described in steps 1 through 5 under section 60.2.2.2 of this draft guidance and the total 30-day equivalent supply.

Steps 4 through 5 result in the combined sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act across all NDC-9s of the selected drug:

4. For each NDC-9 identified in steps 2 and 3, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s (both those present in PDE data and those associated with HCPCS present in Part B claims data) of the selected drug, and multiply this quotient by either the sum of the plan-specific enrollment weighted amounts or the payment amount under section 1847A(b)(4) of the Act, respectively, per 30-day equivalent supply of that NDC-9. As stated above, if an NDC-9 is present in both PDE data and associated with a HCPCS code present in Part

B claims data, CMS will treat each version as a distinct NDC-9 in this step of the calculation.

5. CMS will then sum the amounts calculated in step 4 across all NDC-9s of the selected drug (including both the Part B version and the Part D version of NDC-9s that are present in both PDE records and associated with HCPCS codes present in Part B claims data), to generate the combined sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act for the selected drug for a 30-day equivalent supply.

60.2.3 Determination of the Average Non-Federal Average Manufacturer Price

In accordance with section 1194(c)(1)(C)(ii) of the Act, when comparing against the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable, to determine the ceiling for each selected drug for initial price applicability year 2028, CMS will use the lower of:

1. The calculated amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021,[93] increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September 2025;[94] or
2. The calculated amount equal to the applicable percent of the average non-FAMP price for the selected drug for calendar year 2025.

First, CMS will use the non-FAMP price and unit volume data for each NDC-11 that meets the criteria to be included in the 2021 average non-FAMP calculation as described in section 60.2.1 of this 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.

CMS will then use 2021 PDE quantity dispensed and days' supply data submitted to CMS at the NDC-11 level by Part D plan sponsors, and/or total Part B billing units and 30-day equivalent supply data at the HCPCS code level, as applicable, for calendar year 2025 for the following:

1. To calculate an annual average non-FAMP per unit for each NDC-9 of the selected drug.
2. To calculate the annual average non-FAMP per 30-day equivalent supply for each NDC-9 of the selected drug.
3. To calculate the annual average non-FAMP per 30-day equivalent supply for the selected drug.

Second, CMS will follow the same methodology that is described above for calendar year 2021 to calculate the average non-FAMP for calendar year 2025. The methodology will use the manufacturer-reported non-FAMP for 2025 and calendar year 2025 PDE quantity dispensed and days' supply and/or total Part B billing units and 30-day equivalent supply data, as applicable, in

[93] If there is not a non-FAMP (or an average non-FAMP can't be calculated) for such drug for calendar year 2021, CMS intends to use the data for the first full year following the market entry for such drug. This applies for all references of calendar year 2021 when cited for non-FAMP, average non-FAMP, and PDE in section 60.2.3 of this draft guidance.

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

the calculation for NDC-11s that meet the criteria to be included in the 2025 average non-FAMP calculation as described in section 60.2.1 of this draft guidance. As described in section 60.2.1 of this draft guidance, for initial price applicability 2028, the set of NDCs used to calculate the annual average non-FAMP calculation for calendar year 2021 may differ from the set of NDCs used to calculate the annual average non-FAMP calculation for calendar year 2025.

In order to directly compare the amount calculated based on the applicable percent of average non-FAMP and the amount calculated based on the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable, (as described in section 60.2.2 of this 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 2025 in two stages to determine which is lower. First, for each calendar year, CMS will calculate the applicable percent of the average non-FAMP for each NDC-9 of the selected drug. Second, for each calendar year, CMS will calculate the applicable percent of the average non-FAMP across NDC-9s of the selected drug. The amounts calculated in each stage are for a 30-day equivalent supply as described in section 60.2.1 of this draft guidance.

To determine the applicable percent of the average non-FAMP for each NDC-9 and across all NDC-9s of the selected drug, CMS will conduct the following steps separately for calendar year 2021 and calendar year 2025.

Steps 1 through 9 will result in the average non-FAMP, adjusted for inflation if applicable, and with the applicable percent applied, for each NDC-9 of the selected drug associated with the NDC-11s identified in section 60.2.1 of this draft guidance:

1. To calculate an average non-FAMP that is comparable to the sum of the plan-specific enrollment weighted amounts, the payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable, described in section 60.2.2 of this draft guidance, CMS will determine the total number of NCPDP units per NDC-11 package, so that the payment amounts (average non-FAMP and the sum of the plan-specific enrollment weighted amounts, payment amount under section 1847A(b)(4) of the Act, or the combined Part B and Part D amount) represent the same quantity of the selected drug.[95]
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

[95] 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.

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 units for that NDC-11 by the total units for all applicable NDC-11s of the same NDC-9 and multiply this quotient by the average non-FAMP per unit for the calendar year calculated in step 4, applying the methodology below, as applicable:
    5a. NDC-11s that are present only in PDE data: Total units are defined as the total quantity dispensed for an NDC-11 as determined using the applicable 2021 or 2025 PDE data identified in section 60.2.1 of this draft guidance.
    5b. NDC-11s that are only associated with HCPCS codes present in Part B claims data: Total units are defined as the total Part B units for an NDC-11 as determined using the unit allocation and standardization methodology described for calculating converted Part B units attributed to the NDC-9 in section 60.2.2.2 of this draft guidance, adjusted to the NDC-11 level by removing step 3, changing all references to "NDC-9" in steps 4 and 5 to "NDC-11", and changing the reference to "step 3" in step four to "step 2."
    5c. NDC-11s that are both present in PDE data and associated with HCPCS codes present in Part B claims data: Total units are defined as the sum of the total quantity dispensed for the NDC-11 and the total Part B units for an NDC-11 as determined using the unit allocation and standardization methodology described in section 60.2.2.2 of this draft guidance.
6. For each NDC-9, CMS will sum the amounts calculated in step 5 to calculate the average non-FAMP per unit for that NDC-9 for the calendar year. CMS believes steps 5 and 6 are necessary to account for fluctuations in quantity dispensed that may occur across NDC-11s of an NDC-9 in the Medicare Part D population.
7. For the calendar year 2021 calculation only: for each NDC-9, CMS will then increase the average non-FAMP per unit for calendar year 2021 calculated in step 6 by the percentage increase in CPI-U (all items; United States city average) from September 2021 to September 2025 as specified in section 1194(c)(1)(C)(ii) of the Act. CMS would not apply a CPI-U (all items; United States city average) adjustment to the average non-FAMP per unit for calendar year 2025.
    - Note: For initial price applicability year 2028, if the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 60.1.1 of this 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 2025.

8. For each NDC-9, after CMS has calculated the average non-FAMP per unit for the calendar year (step 6 for the calendar year 2025 calculation or step 7 for the calendar year 2021 calculation adjusted), adjusted for inflation if applicable, CMS will then apply the applicable percent specified in section 1194(c)(3) of the Act for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1 of this 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 percent are described below, in Table 7, for initial price applicability year 2028. CMS notes that the "extended-monopoly" type is not discussed below because the definition of extended-monopoly drug under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030. CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for purposes of calculating the ceiling prior to initial price applicability year 2030.

Table 7: Monopoly Types and Applicable Percent for Initial Price Applicability Year 2028

Monopoly Type	Definition	Applicable Percent	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[96]	For initial price applicability year 2028, a selected drug that is not a long-monopoly drug or a selected drug that is a vaccine licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	75%	The first approval date, under section 505(c) of the FD&C Act, associated with the initial FDA application number for the active moiety (or fixed combination drug) must be after January 1, 2012, and before February 1, 2019. The earliest licensure date, under section 351(a) of the PHS Act, associated with the initial FDA application number for the active ingredient (or fixed combination drug) must be after January 1, 2012, and before February 1, 2015 for drugs, or before February 1, 2015 for vaccines.

[96] Because the definition of extended-monopoly drug at section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with CMS with respect to an initial price applicability year before 2030, for initial price applicability year 2028, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

Monopoly Type	Definition	Applicable Percent	Note
Long-monopoly drug (section 1194(c)(5)(A) of the Act)	With respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term 'long-monopoly drug' does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	40%	The first approval date under section 505(c) of the FD&C Act or the earliest licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or fixed combination drug) must be on or before January 1, 2012.

9. For each NDC-9, CMS will then multiply the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied as calculated in step 8 by the quotient of total units divided by the total 30-day equivalent supply (i.e., this quotient represents the average units per 30-day supply equivalent for that NDC-9) as described in step 5 and section 60.2.1 of this draft guidance for when a selected drug is covered under either Part D, Part B, or both, respectively, to determine the average non-FAMP for a 30-day equivalent supply. As described above in section 60.2.1 of this 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 based on the methodology outlined in section 60.2.1, and multiply this quotient by the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation if applicable, and with the applicable percent applied, calculated in step 9.
11. CMS will then sum amounts calculated in step 10 across all NDC-9s of the selected drug to calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied, for the selected drug.

CMS will then compare the applicable percent of the calendar year 2021 average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, with the applicable percent

of the calendar year 2025 average non-FAMP per 30-day equivalent supply for the calendar year and determine which is lower.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS will compare the lower amount of the applicable percent of the average non-FAMP as determined in section 60.2.3 of this draft guidance to the amount calculated in section 60.2.2 of this draft guidance (sum of the plan-specific enrollment weighted amounts, the payment amount under section1847A(b)(4) of the Act, or the combined Part B and Part D amount, as applicable) to determine the lower amount, which will be the ceiling for the selected drug. Once CMS has determined the ceiling for the selected drug, CMS will ensure that the MFP per 30-day equivalent supply, as negotiated through the process described in sections 60.3 and 60.4 of this 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) of the Act that were used in developing the offer; however, CMS has the discretion to determine how and to what degree each factor should be considered.

As discussed in greater detail below, consistent with section 1194(e) of the Act, for the purpose of determining an initial offer, CMS will: (1) identify the therapeutic alternative(s), if any, for the selected drug, as described in section 60.3.1 of this draft guidance; (2) use the lower of Part D total gross covered drug cost (TGCDC) net of DIR and CGDP and/or Manufacturer Discount Program payments (hereinafter the "Net Part D Plan Payment and Beneficiary Liability"[97]) for the therapeutic alternative(s), and/or the lower of ASP or WAC for the therapeutic alternative(s),[98] or the MFP for any selected drug negotiated for a prior initial price applicability year that is a therapeutic alternative 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 comparative effectiveness of the selected drug and therapeutic alternatives, including the selected drug's impact on specific populations, the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need, the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s), and the prescribing information approved by the FDA for the selected drug and its therapeutic alternative(s), as described in section 60.3.3 of this draft guidance (resulting in the "preliminary price"); and (4) further adjust

[97] The CGDP ended on December 31, 2024 and the Medicare Part D Manufacturer Discount Program took effect January 1, 2025. As such, the Net Part D Plan Payment and Beneficiary Liability will be determined using PDE records to remove Manufacturer Discount Program payments rather than CGDP payments, as applicable and as available.

[98] For initial price applicability year 2028, when assessing a therapeutic alternative(s) payable under Part B to determine a starting point for the initial offer, CMS will use the lesser of ASP or WAC, in order to better align with the payment amount under section 1847A(b)(4) of the Act in circumstances where the WAC of a therapeutic alternative is lower than its ASP.

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

For initial price applicability year 2028, for the purpose of identifying indications[99] for the selected drug, CMS will identify the FDA-approved indication(s) of the selected drug covered under Part D or payable under Part B using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS may consider off-label use when identifying indications if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In initial price applicability year 2028, CMS will exclude from its analysis any FDA-approved indication(s) used solely in a setting in which the selected drug is not billed under Part B or Part D. Since the MFP resulting from a negotiation may only be applied in Medicare Part B and Medicare Part D, it is consistent for CMS to focus its analysis on these FDA-approved indications.

For each indication of the selected drug that is not excluded, CMS will follow the steps outlined below to identify a pharmaceutical therapeutic alternative(s), if any, for purposes of developing the initial offer. CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, consistent with past guidance, CMS will only consider therapeutic alternatives that are drugs or biological products covered under Part D or Part B for initial price applicability year 2028. CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials. For purposes of this 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.

CMS is soliciting comments on the possibility and feasibility of considering health care services payable under Medicare Part A or Part B as potential therapeutic alternatives to the selected drug for future rulemaking. Specifically, CMS is interested in whether there are specific cases where a health care service could be a relevant therapeutic alternative to a selected drug consistent with section 1194(e)(2) of the Act as well as what factors could be used to determine if a health care service could be considered a therapeutic alternative or not.

To identify potential therapeutic alternatives for the indications of a selected drug, CMS intends to use data submitted by the Primary Manufacturer and the public, prescribing information approved by the FDA, drug classification systems commonly used in the public and private

[99] For purposes of this section of this draft guidance and the Drug Price Negotiation ICR, CMS distinguishes between the use of the word "indication" and the term "FDA-approved indication" such that "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s) and "indication" refers to the condition or disease state for which the selected drug is used. CMS intends to use "indication" for purposes of this draft guidance.

sector for formulary development, CMS-recognized Part D compendia, widely accepted clinical guidelines, evidence identified through the CMS-led literature review, published drug or drug class reviews, peer-reviewed studies, and Medicare claims or other data sets. In addition to brand name drugs and biological products, CMS intends to consider generic drugs and biosimilars when identifying a potential therapeutic alternative(s) to a selected drug. CMS may consider off-label use when identifying indications for therapeutic alternatives if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication covered under Part D or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

CMS will begin by identifying potential therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action and then also consider therapeutic alternatives in different pharmacologic classes based on CMS' review of the sources noted above. Where appropriate, only certain formulations or dosage forms and strengths will be identified as the therapeutic alternative to the selected drug. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug for the purpose of developing the initial offer. For example, for a potential therapeutic alternative, CMS may consider the place in therapy based on evidence-based clinical practice guidelines, pharmacologic and therapeutic characteristics, utilization in the Medicare population, and the availability of direct and indirect comparative evidence relative to the selected drug. CMS may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same indication. CMS may also consult with clinicians, patients or patient organizations, and/or researchers, to ensure that appropriate therapeutic alternatives are identified. CMS may also consider peer-reviewed or other clinical evidence and information submitted by the Primary Manufacturer and the public to inform the selection of a therapeutic alternative(s). CMS will prioritize clinical appropriateness in the selection of therapeutic alternatives.

60.3.2 Developing a Starting Point for the Initial Offer

CMS considered several options for what price should be used as the starting point for developing the initial offer. Options considered included the use of the Part D net price(s) and/or the ASP/WAC(s) of therapeutic alternative(s), if any, to the selected drug, the unit cost of production and distribution for the selected drug, the ceiling for the selected drug (as described in section 60.2 of this draft guidance), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule[100] (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.

[100] 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.

After considering these options and in accordance with section 1194(e)(2)(A) of the Act, which directs CMS to consider the cost of therapeutic alternative(s), for initial price applicability year 2026, CMS used the Part D net price(s) ("net price(s)") and/or ASP(s) of the therapeutic alternative(s) (or a subset of clinically comparable therapeutic alternatives) for the selected drug, as applicable, as the starting point for developing the initial offer unless the net price(s) or ASP(s) was greater than the statutory ceiling and then considered adjustments based on section 1194(e)(2) data and manufacturer-submitted data per section 1194(e)(1) of the Act. For initial price applicability year 2026, CMS identified the price of each therapeutic alternative that is covered under Part D net of all price concessions received by any Part D plan or pharmacy benefit manager on behalf of the Part D plan by using PDE data and detailed DIR report data.

For initial price applicability year 2027, CMS identified the price of therapeutic alternative(s) to determine the starting point for developing the initial offer using the same approach that the agency used for initial price applicability year 2026 (described above) but also considered the CGDP and Manufacturer Discount Program payments, as applicable and available, for a therapeutic alternative(s) covered under Part D as well as the MFP in situations where a therapeutic alternative for a selected drug for initial price applicability year 2027 was itself a selected drug from initial price applicability year 2026 and has an MFP. Reducing the TGCDC by both DIR and CGDP or Manufacturer Discount Program payments permits an appropriate accounting of the price paid by the plan and beneficiary.

Building on experience from the first two cycles of negotiations, for selected drugs in initial price applicability year 2028, when assessing a therapeutic alternative(s) covered under Part D to determine the starting point for the initial offer, CMS will use the lower of either: (1) the Net Part D Plan Payment and Beneficiary Liability, which reflects TGCDC net of DIR and CGDP or Manufacturer Discount Program payments, as applicable; or (2) the MFP for selected drugs negotiated for a prior initial price applicability year, if applicable. When determining the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative, CMS will exclude PDE records for which a compound code indicates the PDE record is for a compounded drug. For initial price applicability year 2028, when assessing a therapeutic alternative(s) payable under Part B to determine a starting point for the initial offer, CMS will use the lesser of ASP or WAC, in order to better align with the payment amount under section 1847A(b)(4) of the Act in circumstances where the WAC of a therapeutic alternative is lower than its ASP.

In taking this approach, CMS acknowledges that the therapeutic alternative(s) may not be priced to reflect the clinical benefit of the selected drug, however, using Net Part D Plan Payment and Beneficiary Liability, the lower of ASP or WAC, or MFP of therapeutic alternatives enables CMS to start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), CMS will be able to focus the adjustments made to the preliminary price on section 1194(e)(2) factors by adjusting this starting point relative to whether the selected drug offers more, less, or similar benefit compared to its therapeutic alternative(s). The other options considered do not provide a starting point that reflects the cost of therapeutic alternatives in the current market, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries relative to the other drug(s) available to treat the patient's disease or condition.

To inform a starting point for the initial offer, CMS may use an alternative methodology to calculate the 30-day equivalent supply as appropriate for the therapeutic alternatives to ensure comparability with the selected drug. For example, if a therapeutic alternative has an indication for which it is typically prescribed for a period meaningfully shorter than 30 days (e.g., for a two-week period, meaning that one fill would be defined as a 30-day equivalent supply despite lasting only two weeks), and the selected drug does not have a similar prescribing pattern, CMS may use an alternative methodology to calculate 30-day equivalent supply for the therapeutic alternative to ensure that its price is expressed on comparable terms to a 30-day equivalent supply of the selected drug.

If there is one therapeutic alternative for the selected drug, CMS will use the lower of Net Part D Plan Payment and Beneficiary Liability or MFP for a selected drug negotiated for a prior initial price applicability year (regardless of whether the agreed-upon MFP for such selected drug has become effective), and/or ASP/WAC, 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 2028. If the therapeutic alternative is payable under Part B and covered under Part D, then CMS will use an approach to combine the two relevant prices to determine a starting point similar to the methodology used to combine the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act to calculate the combined Part B and Part D amount as described in section 60.2.2.3 of this draft guidance.

If there are multiple therapeutic alternatives, CMS will consider the range of Net Part D Plan Payment and Beneficiary Liability, MFP(s) for a selected drug negotiated for a prior initial price applicability year, and/or the lower of ASP/WACs, including the prices of generic and biosimilar therapeutic alternatives, as well as the utilization of each therapeutic alternative relative to the selected drug, to determine the starting point within that range. As part of its determination of a starting point within such a range, CMS will consider therapeutic alternative prices within each indication (when available and if different from therapeutic alternative prices across indications), and will consider weighing such prices by the utilization of therapeutic alternatives within and across multiple indications or other patterns of use for the therapeutic alternatives or the selected drug.

CMS understands that some therapeutic alternatives may be exposed to more competition while others are less exposed to such competition. CMS is soliciting comments on possible alternative approaches to determine a starting point for a selected drug with one or more therapeutic alternatives, including (1) considering a starting point between (a) the Part B ASP/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and D amount discussed above for the therapeutic alternatives and (b) the statutory ceiling; or (2) considering a starting point between (a) the Part B ASPs/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and Part D amount discussed above for therapeutic alternatives and (b) unit cost of production and distribution of the selected drug. CMS is soliciting comments on other starting points for the initial offer, including but not limited to other domestic reference prices, along with disadvantages and advantages to their use as the starting point.

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"[101] price ("Big Four price"), whichever is lower. If the FSS and Big Four prices are above the statutory ceiling, then CMS will use the statutory ceiling as the starting point for the initial offer. In all cases, the starting point will not exceed the statutory ceiling and will be subject to adjustments as described further below.

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

To evaluate the section 1194(e)(2) factors, including the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), CMS will broadly evaluate the body of available evidence, including information received from the public and manufacturers as described in section 50.2 of this draft guidance, and evidence identified through a CMS-led literature review. CMS may also analyze Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug versus its therapeutic alternative(s), clinical data, or other information relevant to the selected drug and its therapeutic alternative(s) and may consult with clinicians, patients or patient organizations, researchers, and/or FDA. As described in section 60.4.1 of this 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, 2026, deadline for submission of section 1194(e)(2) data (further described in section 60.4.1 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 CMS flexibility to consider a variety of aspects in its evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to use of the selected drug or therapeutic alternatives.

Once the starting point for the initial offer has been established and evidence on section 1194(e)(2) factors has been considered, CMS will adjust the starting point for the initial offer based on the review of section 1194(e)(2) factors. CMS will not, per section 1194(e)(2) of the Act, use evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. CMS considered employing both a qualitative approach (e.g., adjusting the starting point upward or downward relative to the section 1194(e)(2) factors offered by the selected drug compared to its therapeutic alternative(s)) and a more thoroughly pre-specified quantitative approach. Consistent with past guidance, CMS will use a qualitative approach to consider nuanced differences between drugs, for example interactions with other

[101] 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.

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.

CMS is soliciting comments on whether CMS should put greater emphasis on certain section 1194(e)(2) factors when adjusting the starting point to determine the preliminary price. For example, CMS is interested in which section 1194(e)(2) factors are most compelling in informing the section 1194(e)(2) adjustment and what approaches could be used to consistently apply those factors across selected drugs.

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

To consider comparative effectiveness of a selected drug and its therapeutic alternative(s), CMS will identify outcomes to evaluate for each identified indication of the selected drug. CMS will consider the identified outcomes of interest, including patient-centered outcomes,[102] and patient experience data, when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s) for those indications. When reviewing such information, as noted above, CMS will not, per section 1194(e)(2) of the Act, use evidence in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. Outcomes of interest to CMS may include direct clinical outcomes (e.g., cure, mortality) and/or validated or reasonably likely surrogate endpoints (e.g., serum hemoglobin A1c). In determining outcomes of interest, CMS will consider patient-reported outcomes and outcomes of importance to patients, if available. CMS may also consider additional outcomes and contextual factors, such as health-related quality of life or patient/caregiver preferences regarding treatment, to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternatives. CMS may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug. Relevant outcomes will be identified using the CMS-led literature review and information submitted by manufacturers and the public, including patients and caregivers, through the Drug Price Negotiation ICR described in section 50 of this draft guidance, as well as in the patient-focused events described in section 60.4.1 of this draft guidance.

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 a variety of aspects in its evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to the use of the selected drug or its therapeutic alternative(s).

CMS will also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations, such as individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations, as required by section 1194(e)(2)(C) of the

[102] A patient-centered outcome is defined as: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves. See: https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary.

Act. To do so, CMS intends to seek to identify studies focused on the conditions for which each selected drug is used and the impact of the selected drug and its therapeutic alternative(s) on such specific populations. Further, CMS will consider the extent to which the selected drug and its therapeutic alternatives address unmet medical needs. CMS will define unmet medical need as a circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition. 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,"[103] as well as any updates that may be issued by FDA in the future, when determining the extent to which a selected drug addresses an unmet medical need.

CMS will examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression) and will consider the costs of the selected drug and its therapeutic alternative(s). CMS may consider the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for an indication(s) when determining the extent to which a selected drug represents a therapeutic advance. CMS understands that a selected drug can be first in class,[104] however, other drugs may have become available since the selected drug's initial approval and therefore CMS will consider the extent to which a selected drug represents a therapeutic advance at the time the section 1194(e)(2) data is submitted. In accordance with section 1194(e)(2)(A) of the Act, CMS intends to review the analyses detailed above for each identified indication of the selected drug and its therapeutic alternative(s) to determine the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s).

As previously noted, CMS will take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s) as well as the patient population(s) taking the selected drug. For each selected drug, the applicable starting point will first be adjusted (i.e., apply an upward or downward adjustment, or no adjustment) based on the totality of the relevant information and evidence submitted and gathered through CMS' analysis based on section 1194(e)(2) factors (and then subsequently it will be adjusted by the manufacturer-submitted data described in section 60.3.4 of this draft guidance). 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).

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[103] 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.

[104] 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.

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 an identified therapeutic alternative will be adjusted based on the totality of available information relevant to the section 1194(e)(2) factors as detailed above, including information received from Primary Manufacturers and the public as described in section 50.2 of this draft guidance, and evidence identified through a CMS-led literature review.

CMS will consider the extent to which the selected drug addresses an unmet medical need separately for each indication. CMS defines unmet medical need as a circumstance in which the relevant disease or condition is one for which no treatment options exist, or existing treatments do not adequately address the disease or condition. As noted previously, CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics," as well as any updates that may be issued by FDA in the future, when considering the extent to which a drug addresses an unmet medical need for the purpose of the Negotiation Program.

CMS will examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance. CMS may consider the extent to which a selected drug represents a therapeutic advance by examining the magnitude of differences in outcomes of interest conferred by the selected drug for an indication(s).

60.3.3.3 Preliminary Price
After the starting point has been adjusted, as appropriate, based on section 1194(e)(2) factors, evaluated using data submitted by manufacturers and the public through the Drug Price Negotiation ICR and gathered through CMS-led analyses and literature review, the resulting price is referred to as "the preliminary price." As described in section 60.3.4 of this 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 Section 1194(e)(1) Factors[105]
CMS must also consider the factors listed in section 1194(e)(1) of the Act and described in section 50.1 of this draft guidance, which will be reported by each Primary Manufacturer. The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or downward as needed to account for these manufacturer-specific data elements. The section 1194(e)(1) factors are: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

[105] CMS notes that the title of this subsection has been revised to reference "section 1194(e)(1) factors" in place of "manufacturer-specific data" to align more closely with the title of section 60.3.3. This revision does not indicate a change in approach or factors considered for adjusting the preliminary price.

CMS will consider the five factors outlined in section 1194(e)(1) of the Act in totality and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price. CMS provides illustrative examples for the manufacturer-specific data elements below. However, the overall adjustment, inclusive of all five elements taken together, may differ from the example adjustment for any single element viewed in isolation.

In considering factor (1) above on R&D costs, CMS will consider the extent to which the Primary Manufacturer has recouped its R&D costs. CMS will compare the R&D costs with the global and U.S. net revenue for the selected drug reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its R&D costs. For example, if a Primary Manufacturer has not recouped its R&D costs, CMS may consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its R&D costs, CMS may consider adjusting the preliminary price downward or apply no adjustment. CMS may use the R&D costs reported by the Primary Manufacturer and the calculated recouped costs, including the assumptions and calculations in the accompanying narrative text, and/or other factors as described in the Drug Price Negotiation ICR and in Appendix A of this draft guidance to adjust the preliminary price.

In considering factor (2) on current unit costs of production and distribution, CMS will consider the relationship between the preliminary price and the unit costs of production and distribution. For example, CMS may consider adjusting the preliminary price downward if the unit costs of production and distribution are lower than the preliminary price, or upward if the unit costs of production and distribution are greater than the preliminary price. Again, CMS may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug to determine if an adjustment is appropriate.

In considering factor (3) on prior Federal financial support, CMS will consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

In considering factor (4) on patent applications, exclusivities, and applications and approvals for the selected drug, CMS will review the patents and exclusivities reported as it develops its initial offer. CMS believes that this information will support CMS' consideration of the 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 the extent to which the selected drug represents a therapeutic advance or the extent to which the selected drug addresses an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a disease or condition, and consideration of such information would be relevant to CMS' consideration of the extent to which the selected drug addresses an unmet medical need for that disease or condition.

Finally, in considering factor (5) on market data and revenue and sales volume data for the U.S., CMS will consider how the data compare to the preliminary price. For example, if the average

commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward. If the average commercial net price is greater than the preliminary price, CMS may consider adjusting the preliminary price upward.

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.

CMS seeks comment on possible alternative approaches, for example, whether CMS should put greater emphasis on certain section 1194(e)(1) factors when adjusting the preliminary price, or whether CMS should consider and potentially adjust the preliminary price based on pending and approved patent applications, exclusivities recognized by FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act independent of considering other section 1194(e)(1) factors in totality.

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 2028, February 28, 2026. CMS will implement the negotiation process consistent with the requirements of the statute, with the aim of achieving "the lowest maximum fair price for each selected drug" consistent with section 1194(b)(1) of the Act.

The negotiation process may include the following steps, as discussed in detail in the subsections of this section:

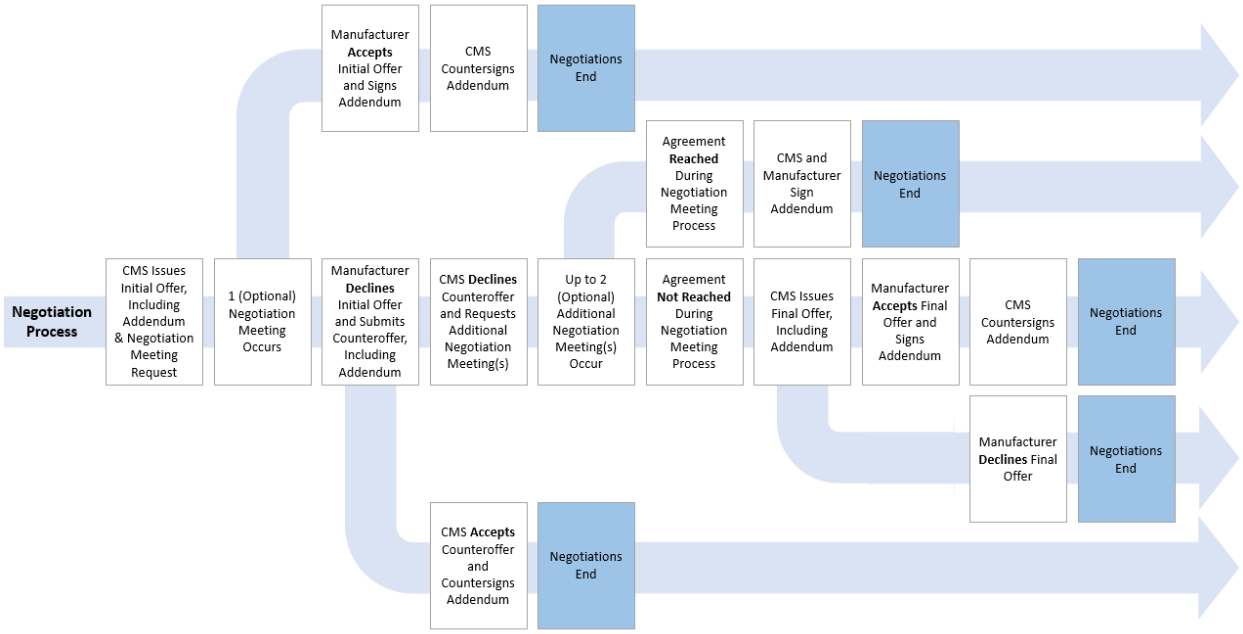
1. Section 60.4.1: CMS will host meetings with Primary Manufacturers of selected drugs that have entered into agreements with CMS and submitted section 1194(e) data, as well as public engagement events to seek input from patients and other interested parties.
2. Section 60.4.2: In accordance with section 1194(b)(2)(B) of the Act, CMS will provide a written initial offer and concise justification to the Primary Manufacturer with CMS' proposal for the MFP for a selected drug for initial price applicability year 2028 no later than June 1, 2026. This written initial offer will be accompanied by an Addendum to the Agreement populated with the proposal for the MFP, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP if such agreement is reached at this stage. CMS also will offer the Primary Manufacturer an optional negotiation meeting that would occur after CMS provides the written initial offer to the Primary Manufacturer and before the deadline for the Primary Manufacturer's statutory written counteroffer described in section 1194(b)(2)(C) of the Act.
3. Section 60.4.3: In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will respond to CMS' written initial offer no later than 30 days after the date of receipt of the written initial offer from CMS. If the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer will submit a written counteroffer (hereinafter the "statutory written counteroffer"), including an Addendum

populated with the proposal for the MFP. In accordance with section 1194(b)(2)(D) of the Act, CMS will provide a written response to the statutory written counteroffer. CMS will provide this response within 30 days of receipt or within 60 days of sharing the written initial offer, whichever is later.

4. Section 60.4.4: If the Primary Manufacturer's statutory written counteroffer is not accepted by CMS, CMS will host up to two additional in-person, virtual, or hybrid (where a portion of attendees are in-person and a portion of attendees are virtual) negotiation meeting(s) between the Primary Manufacturer and CMS.
5. Section 60.4.5: During the period between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the MFP, or one week before final offers are due to be sent by CMS (October 15, 2026), whichever is earlier, CMS and Primary Manufacturers can choose to initiate additional, written offers or counteroffers via the additional price exchange module in the CMS HPMS.
6. Section 60.4.6: If no agreement is reached during the processes described above, CMS will provide to the Primary Manufacturer a final written offer, including an Addendum containing the final proposal for the MFP, as described in section 60.4.6 of this draft guidance.

Every written offer and counteroffer will include an Addendum populated with the proposal for the MFP. If an agreement on the MFP is reached at any point during the negotiation process as described in this section, the Addendum to the Agreement, as described in section 40.3 of this draft guidance, will be executed by both parties and will constitute agreement on the MFP. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2028, subject to the conditions and timing described in section 70 of this draft guidance and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. Refer to section 60.6 of this draft guidance for information on how the MFP will be updated for subsequent years in the price applicability period. The diagram below provides a non-exhaustive list of possible paths the negotiation process could take after CMS' initial offer, for a process taking place within the statutorily specified timelines.

Figure 5: Possible Negotiation Paths[106]



During the entire negotiation process, CMS cannot propose an MFP or agree to any Primary Manufacturer proposal for the MFP that exceeds the statutorily-determined ceiling as defined in section 1194(c) of the Act and as described in section 60.2 of this 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 statutory written counteroffer, CMS will continue to engage in the negotiation process and will take the time to complete the established process as described in this section. For example, if a Primary Manufacturer does not submit required data, CMS may be delayed in sending the initial offer by the statutory deadline. During the period of time from when the Primary Manufacturer fails to meet a deadline until the date the Primary Manufacturer comes into compliance with the negotiation process, CMS will consider the Primary Manufacturer in violation of the Agreement and the Primary Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act. Section 90.3 and section 100 of this draft guidance further describe possible actions to address noncompliance.

60.4.1 Engagement with Primary Manufacturers and Interested Parties Prior to Initial Offers
After the submission of the section 1194(e) data by Primary Manufacturers and other interested parties by March 1, 2026, CMS will host meetings with Primary Manufacturers of selected drugs that have submitted section 1194(e) data. CMS will invite the Primary Manufacturer for each selected drug to one meeting in Spring 2026 after the data submission deadline. The purpose of this meeting will be for the Primary Manufacturer to provide additional context on its data submission and share new section 1194(e)(2) data, if applicable, as CMS begins reviewing the

[106] Mention of the "negotiation meeting process" in this figure is inclusive of the additional price exchange functionality described in section 60.4.5.

data and developing an initial offer. While Primary Manufacturers may share new information on section 1194(e)(2) data during meetings before the initial offer, new manufacturer-specific data (described in section 1194(e)(1) of the Act) will not be considered; rather, any information shared during these meetings and materials shared afterwards should only contextualize the Primary Manufacturer's March 1, 2026 submission of manufacturer-specific data. The Primary Manufacturer may bring materials to facilitate discussion, and CMS may request any presented or discussed materials afterwards. Each Primary Manufacturer is limited to sharing 50 pages (or a combination of pages, slides, and/or charts and graphs totaling 50 pages) of material in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting. CMS anticipates that these materials may contain cross-references to other material, particularly other material already submitted to CMS.

CMS acknowledges that a Primary Manufacturer may benefit from having access to the section 1194(e)(2) data submitted by other interested parties during the negotiation period. In addition to offering the meetings described below, CMS will aim to share redacted section 1194(e)(2) data with the Primary Manufacturer of a selected drug during the negotiation process when feasible. The data will be redacted as per the confidentiality standards described in section 40.2 of this draft guidance and will not include proprietary information, PHI / PII, or information that is protected from disclosure under other applicable law.

CMS also will host public engagement events to seek input from patients and other interested parties. These events are intended to bring together patient-focused interested parties to share feedback with CMS on patient experiences with the conditions or diseases treated by the selected drugs, as well as with the selected drugs and therapeutic alternatives to the selected drugs, and other information as CMS reviews section 1194(e)(2) data submissions and develops an initial offer for each selected drug. CMS will use information shared during these patient-focused events to better understand patients' experiences with the conditions and diseases treated by the selected drugs and their experiences with the selected drugs themselves, as well as to inform CMS' identification of therapeutic alternatives, key outcomes, and adjustment of the starting point to develop the initial offer. For patient-focused events for initial price applicability year 2028, CMS will host up to 15 patient-focused roundtable events, which will be open to patients, patient advocacy organizations, and caregivers and will allow for discussion among speakers. These patient-focused roundtable events will group selected drugs by condition when appropriate as determined by CMS. CMS will host one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register to participate. CMS will have the opportunity to ask follow-up questions of participants at the town hall meeting. CMS will engage a moderator to facilitate discussions for both the patient-focused roundtable events and the town hall meeting. These events will be held in Spring 2026. CMS may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for negotiation or host separate events specifically for drugs selected for renegotiation, as described in section 130.4.4 of this draft guidance. More information about these events will be forthcoming.

Both the patient-focused roundtable events and the town hall meeting will be held in a virtual environment. The patient-focused roundtable events will not be livestreamed; however, CMS will make the transcripts public after all the events have ended, with individual identifiable

information redacted. The town hall meeting will be livestreamed, and CMS also will release a redacted transcript after the meeting concludes. These redacted transcripts will omit names and other identifying information for patients, according to the Safe Harbor de-identification method under the HIPAA Privacy Rule,[107] as well as omit identifying information for patient advocacy organization representatives and family members/caregivers. More information on these events and how interested parties can participate is forthcoming.

60.4.2 Provision of CMS' Initial Offer and Concise Justification

In accordance with section 1194(b)(2)(B) of the Act, the written initial offer from CMS, provided no later than June 1, 2026, must include a concise justification for the offer based on the data described in section 50 of this draft guidance. The justification will include a qualitative description of the factors from section 1194(e) of the Act (further described in sections 50 and 60.3 of this draft guidance) and a description of the methodology that CMS used to develop the initial offer (described in section 60.3 of this draft guidance). The information contained in the concise justification will provide the Primary Manufacturer with information on the range of evidence and other information considered pursuant to section 1194(e) of the Act that CMS found compelling during the development of the initial offer, which includes the identification of therapeutic alternatives. CMS believes this will provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the initial offer. The initial offer and justification will not include information that CMS determines to be third-party proprietary pricing information, information that could lead to the calculation of a third party's proprietary pricing information, PHI / PII, other information that is protected from disclosure under other applicable law, or the starting point. This written initial offer will be accompanied by an Addendum to the Agreement populated with the proposal for the MFP, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP if such agreement is reached at this stage.

No offer can exceed the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this 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

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

the ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths for CMS' consideration.

In addition to the initial offer and concise justification, CMS will provide an attachment to the initial offer which applies the single initial offer price at the NDC-9 unit price, NDC-11 package price, and HCPCS code dosage price levels, as applicable, to demonstrate how this initial offer price will apply to the dosage forms and strengths as identified on the list of National Drug Codes of the selected drug. The initial offer consists of a single proposal for the MFP and the provision of these NDC-level price applications does not constitute a separate offer. These calculations may also be updated during the negotiation process, for example, to reflect new NDCs of the selected drug or new information informing the NDC-level price applications.

CMS will reach out to the Primary Manufacturer of a selected drug and offer to schedule an optional negotiation meeting during the time period after the initial offer is issued and before the statutory written counteroffer is due, which CMS believes will allow CMS and the Primary Manufacturer to begin negotiation discussions early in the negotiation period. The purpose of this meeting is to allow both parties to begin discussion related to negotiating an MFP for the selected drug, including with respect to CMS' initial offer for the MFP. CMS anticipates that such discussion might focus on CMS' initial offer and the evidence CMS used to develop the initial offer; nevertheless, as applicable, both CMS and the Primary Manufacturer could discuss other potential offers or counteroffers during this meeting, including discussion of the Primary Manufacturer's forthcoming statutory written counteroffer, should the Primary Manufacturer choose to make one. Consistent with the statutory framework, CMS anticipates that any oral potential counteroffers discussed during this meeting might be provided later in writing consistent with section 1194(b)(2)(C) of the Act. Accordingly, while CMS may engage in discussion about an oral potential counteroffer, CMS does not intend to accept or reject any such oral potential counteroffer in this first meeting and intends to respond to any later statutory written counteroffer consistent with the agency's obligations to respond in writing under section 1194(b)(2)(D) of the Act. CMS will provide information on the timing for developing the agenda and submitting meeting materials when CMS invites the Primary Manufacturer to this first negotiation meeting. This first negotiation meeting will follow the same standards around meeting length and number of attendees as the post-statutory written counteroffer negotiation meetings described in section 60.4.4 of this draft guidance. If a Primary Manufacturer declines this optional first negotiation meeting, CMS will not increase the number of negotiation meetings it offers in a subsequent stage of the negotiation process, but the Primary Manufacturer and CMS may still conduct up to two negotiation meetings if CMS rejects the Primary Manufacturer's statutory written counteroffer.

60.4.3 Required Components of Primary Manufacturers' Statutory Written Counteroffer and CMS Response in Writing

In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a statutory written counteroffer and providing a justification for such counteroffer based on the data described in section 50 of this draft guidance. Any statutory written counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the

factors described in section 1194(e) of the Act and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the data in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) of the Act, supports the Primary Manufacturer's statutory written counteroffer or otherwise does not support CMS' written initial offer. Primary Manufacturers may also include in their statutory written counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) of the Act that supports the counteroffer.

The Primary Manufacturer should provide a proposal for the MFP for the selected drug in its statutory written counteroffer. As described in section 60.1 of this draft guidance, the proposal for the MFP should be made consistent with the manner that CMS' written initial offer was made; that is, a single proposal for the MFP for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. In accordance with section 1194(b)(2)(F) of the Act, CMS cannot accept a statutory written counteroffer from a manufacturer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this draft guidance.

As described in section 50 of this draft guidance, CMS intends to publish a Drug Price Negotiation ICR for initial price applicability year 2028 in the Federal Register for a 60-day public comment period during Summer 2025. CMS intends to publish the Drug Price Negotiation ICR for a 60-day comment period to capture information related to the statutory written counteroffer that a Primary Manufacturer may submit after receiving CMS' initial offer. This ICR will include instructions and a form for a Primary Manufacturer to submit a statutory written counteroffer in the case where the Primary Manufacturer does not accept CMS' written initial offer.

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

In accordance with section 1194(b)(2)(D) of the Act, CMS will respond in writing to a statutory written counteroffer made by the Primary Manufacturer. Although the statute does not specify a timeframe for CMS' response to the Primary Manufacturer's statutory written counteroffer, negotiations for initial price applicability year 2028 must end prior to November 1, 2026, i.e., an agreement on MFP for the selected drug must be reached no later than October 31, 2026, for the Primary Manufacturer to avoid potential excise tax liability under section 5000D(b)(2) of the IRC.

In the case CMS' written initial offer is not accepted and the Primary Manufacturer submits a statutory written counteroffer, CMS will consider the statutory written counteroffer and either accept or reject it in writing within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later. When considering a statutory written counteroffer, CMS will evaluate whether accepting the counteroffer is consistent with the

statutory directive to aim to arrive at an agreement that achieves the lowest possible MFP for the selected drug.

60.4.4 Negotiation Meetings for CMS and Primary Manufacturers
As described in section 60.4.2 of this draft guidance, CMS will offer each Primary Manufacturer of a selected drug one optional negotiation meeting after CMS provides the written initial offer and before the statutory written counteroffer is due. In addition, if CMS' written response to the statutory written counteroffer described in section 60.4.3 of this draft guidance rejects the Primary Manufacturer's statutory written counteroffer, CMS will extend an invitation to the Primary Manufacturer for an optional negotiation meeting. If agreement upon an MFP is not reached in that meeting, CMS will extend an invitation for an additional optional meeting.

The scope for these negotiation meetings will focus on the section 1194(e) data, including the therapeutic alternative(s) for the selected drug, how these data should inform the MFP, and other topics aimed at working towards an agreement on an MFP. During these negotiation meetings, discussion of disputes and program policies regarding the negotiation process will be considered out of scope. CMS and the Primary Manufacturer will each be permitted to bring up to eight meeting attendees and both parties must share their participant lists ahead of each meeting. CMS arrived at this meeting attendee number after considering the roles from each party that would be critical to the conversation while ensuring that the meeting is sized appropriately to encourage active discussion. Each meeting will last no more than two hours and may be conducted in-person at CMS or Department of Health and Human Services (HHS) facilities in the Washington-Baltimore area. CMS believes two hours per negotiation meeting (of which there can be up to three meetings, as applicable) is sufficient for a fruitful discussion and is appropriate considering time and scheduling constraints. If necessary, due to distance or scheduling challenges, meetings may be held virtually or may accommodate a hybrid arrangement. CMS' notes from negotiation meetings will be retained as part of the meeting record in compliance with applicable federal law including the Federal Managers' Financial Integrity Act and the Federal Records Act and will be subject to the confidentiality policy described in section 40.2.1 of this 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 at least one week ahead of the meeting. While the agency intends to limit substantive discussion to the negotiation meetings, CMS anticipates there may be some opportunity for exchange of additional

information related to the section 1194(e) data on an ad hoc basis via email after receipt of a statutory written counteroffer and before the end of the statutory negotiation period.

These meetings will occur between the time the Primary Manufacturer's statutory written counteroffer is not accepted by CMS, which will be within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later, if applicable, and September 30, 2026. As described in section 60.4.2 of this draft guidance, an optional negotiation meeting occurring after the initial offer is issued and before the statutory written counteroffer is due may precede these meetings. There would be about two months' time between CMS' rejection of the Primary Manufacturer's statutory written counteroffer (approximately July 31, 2026), if applicable, and the deadline for negotiation meetings to conclude (September 30, 2026). CMS requires that all negotiation meetings end no later than September 30, 2026, the last business day that is 15 days prior to October 15, 2026, to allow CMS sufficient time to prepare a final offer (if an MFP was not reached during the negotiation meeting process or via the additional price exchange functionality), send that final offer to the Primary Manufacturer by October 15, and allow the Primary Manufacturer time to consider the final offer and accept or reject the final offer by October 31, 2026, as all negotiations must be concluded prior to November 1, 2026. These dates assume that a Primary Manufacturer is timely in entering into an Agreement, submitting information, and meeting deadlines related to the Negotiation Program.

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.

60.4.5 Additional Price Exchange Opportunities

CMS is providing additional price exchange opportunities through which CMS and Primary Manufacturers can initiate additional, written offers and counteroffers via the CMS HPMS during the period between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the MFP, or one week before final offers are due to be sent by CMS (October 15, 2026), whichever is earlier. CMS believes this functionality will enable both parties to have additional flexibility to extend and consider offers and counteroffers during this time period. If an agreement on the MFP is not reached earlier, this time period will conclude on October 8, 2026, one week before CMS intends to issue final offers to provide CMS the time necessary for adequate consideration of any outstanding counteroffers. As described in section 60.4.4 of this draft guidance, CMS and the

Primary Manufacturer can participate in up to two negotiation meetings per selected drug during this period, and the opportunity for additional written offers and counteroffers during this period will not replace an optional negotiation meeting. CMS believes that if a Primary Manufacturer or CMS makes an offer or counteroffer via the additional price exchange functionality, the negotiation meetings will provide an opportunity for both parties to discuss their justifications for the offer or counteroffer and rationale for determinations with respect to the offer or counteroffer. The additional price exchange functionality in the CMS HPMS will include an optional text field to enable either party to include additional contextual information for the offer or counteroffer. Only one offer or counteroffer per selected drug may be active at a time in the CMS HPMS as part of the additional price exchange functionality. An offering/counteroffering party may revise its offer/counteroffer in the period before the other party accepts or rejects it, but not afterwards. Parties do not need to alternate making offers and counteroffers.

As described in section 60.6.1 of this 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.

60.4.6 Notification of Final Offer and Determination that Negotiations Have Finished
In accordance with section 1194(b)(2)(E) of the Act, all negotiations between CMS and the Primary Manufacturer of the selected drug must end prior to November 1, 2026, for initial price applicability year 2028 to avoid potential excise tax liability.

In the event neither CMS' initial offer nor the Primary Manufacturer's statutory written counteroffer were accepted, and an MFP was not agreed to during the negotiation meeting process or via the additional price exchange functionality, CMS will send the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" and an Addendum with the final offer MFP by October 15, 2026. This will serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. This final offer will be sent only if, by October 15, 2026, neither CMS nor the Primary Manufacturer has accepted the latest offer or counteroffer made in writing or agreed upon an MFP during the negotiation meeting process or via the additional price exchange functionality. If a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by October 31, 2026. Table 8 details CMS' timing for the negotiation process for initial price applicability year 2028.

Table 8: Negotiation Process Milestones for Initial Price Applicability Year 2028

Date[108]	**Milestone**
June 1, 2026	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer

[108] 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 intends to continue to engage in the negotiation process and will take the time to complete the established process as described

Date[108]	**Milestone**
Date after CMS issues the initial offer and before the response to the initial offer and any manufacturer statutory written counteroffer is due, if applicable (After June 1st and before July 1st if the offer is made by CMS on June 1, 2026)	Optional negotiation meeting (in-person, virtual, or hybrid), if applicable
30 days after receipt of written initial offer from CMS (July 1st if the offer is made by CMS on June 1, 2026)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a statutory written counteroffer to CMS
30 days after receipt of the manufacturer statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later (July 31st if the initial offer is made on June 1, 2026 and manufacturer statutory written counteroffer is made on July 1, 2026)	Date by which CMS will provide a written response accepting or rejecting the manufacturer statutory written counteroffer
Date that the Primary Manufacturer's statutory written counteroffer is not accepted by CMS through September 30, 2026 (the last business day that is 15 days prior to October 15, 2026) or the day an MFP is agreed upon, whichever is earlier	Optional negotiation meetings (in-person, virtual, or hybrid; maximum of two possible meetings), if applicable
Date that the Primary Manufacturer's statutory written counteroffer is not accepted by CMS through October 8, 2026 (the last business day that is 7 days prior to October 15, 2026) or the day an MFP is agreed upon, whichever is earlier	Additional price exchange, if applicable
October 15, 2026	Date by which CMS will issue a "Notification of Final Maximum Fair Price Offer" to the Primary Manufacturer, if the written initial offer or Primary Manufacturer statutory written counteroffer was not accepted and an MFP was not agreed upon during the negotiation meeting process or via the additional price exchange functionality
October 31, 2026	Date by which the Primary Manufacturer must respond to (i.e., accept or reject) CMS' "Notification of Final Maximum Fair Price Offer," if applicable

in this section. If a statutory deadline is missed, the Primary Manufacturer may be subject to a civil monetary penalty or excise tax, as applicable.

Date[108]	Milestone
October 31, 2026	Statutory deadline for all negotiations to end; CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences thereof if agreement upon the MFP is not reached by October 31, 2026
November 1, 2026	Statutory end of negotiation period

In all instances, to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Agreement (described in sections 40.3 of this draft guidance) that sets forth the agreed-upon MFP. For example, when CMS prepares a written offer, CMS also completes the Addendum with the offered MFP and sends the Addendum along with the written offer to the Primary Manufacturer via the CMS HPMS. If the Primary Manufacturer accepts the written offer, it will sign the Addendum after which CMS will countersign the Addendum. Similarly, a Primary Manufacturer's statutory written counteroffer is not considered complete unless the Primary Manufacturer submits a complete response using the Statutory Written Counteroffer Form (as described in the Drug Price Negotiation ICR) in the CMS HPMS, submits an Addendum for the MFP consistent with the counteroffer proposal for the MFP in the CMS HPMS, and signs that Addendum. If CMS accepts the statutory written counteroffer, CMS will countersign the Addendum. Further, for any additional offers and counteroffers exchanged in the negotiation meetings described in section 60.4.4 of this draft guidance or via the additional price exchange functionality described in section 60.4.5 of this draft guidance, an Addendum would be populated consistent with CMS HPMS functionalities to allow for signature by the Primary Manufacturer and countersignature by CMS.

If CMS and the Primary Manufacturer do not agree to an MFP by the statutory end of the negotiation period, the Primary Manufacturer will enter a period during which the excise tax may be imposed on certain sales of the selected drug. As described in 26 U.S.C. § 5000D(b)(2) and § 5000D(c), the Primary Manufacturer can end the period during which the excise tax may apply by: agreeing to an MFP, as described in section 60.8 of this draft guidance; meeting the statutory criteria for the suspension of tax; or terminating its Agreement in the manner described in section 40.6 of this draft guidance, which includes sending a notice terminating all of its applicable agreements under the Medicare and Medicaid programs and establishing that none of the Primary Manufacturer's drugs are covered by an agreement under section 1860D-14C of the Act.

60.5 Application of the MFP Across Dosage Forms and Strengths

An MFP that is agreed upon as described in section 60.4 of this 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 dispensing entities and Part B providers), however, CMS will publish the MFP at the per-unit (e.g., tablet) level for each NDC-9, at the

package (e.g., bottle) level for each NDC-11, and per billing unit for each HCPCS (hereinafter the "billing unit") associated with the selected drug based on the list of NDCs and HCPCS codes determined pursuant to section 40.2 of this draft guidance. CMS advises supply chain entities to use the NDC-9 per unit price when effectuating the MFP for a selected drug with a formulation covered under Part D to ensure accuracy (e.g., in the event of partial package dispense). This draft guidance does not address the effectuation of the MFP for drugs payable under Part B in 2028; CMS will describe how the MFP will be effectuated for drugs payable under Part B (for example, whether all selected drugs will be granted a unique HCPCS code or Part B providers will bill for a selected drug using a combination of HCPCS code and claim modifier—or some other mechanism) in the future.

The following methodology will be used to apply the single MFP across NDC-9s and/or HCPCS codes for a 30-day equivalent supply and to calculate an MFP per unit for each NDC-9 of the selected drug and/or an MFP per billing unit associated with the selected drug. CMS will use a methodology that scales the MFP per unit and/or the MFP per billing unit based on price differentials across different dosage forms and strengths. For initial price applicability year 2028, CMS will use the Primary Manufacturer reported WAC from CMS HPMS (see section 40.2 of this draft guidance) of the selected drug in this calculation. CMS will first calculate annual calendar year 2025 WAC per unit cost for each of the NDC-11s for the selected drug (including NDC-11s payable under Part B—which are assigned to HCPCS codes in NDC-HCPCS crosswalk files published by CMS—as well as NDC-11s covered under Part D) from the manufacturer-submitted quarterly WAC per unit and unit volume data to account for potential variation in unit volume across quarters. The annual calendar year 2025 WAC per unit for each NDC-11 will then be converted into an amount for a 30-day equivalent supply (using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for PDE records or the methodology described in section 60.2.1 of this draft guidance for Medicare fee-for-service Part B claims), so that the WAC will be comparable to the negotiated single MFP. CMS intends to then aggregate the WAC per 30-day equivalent supply for each NDC-11 into a WAC per 30-day supply for each NDC-9 of the selected drug. The WAC per 30-day equivalent supply for each NDC-9 will then be used to calculate a WAC price ratio for each NDC-9 of the selected drug. The ratio derived from the WAC per 30-day equivalent supply for each NDC-9 will then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each NDC-9 of the selected drug. Lastly, to determine the per unit MFP for an NDC-9, CMS will convert from an MFP for a 30-day equivalent supply to an MFP per unit based on the average number of units in a 30-day equivalent supply. For selected drugs payable under Part B, CMS will further convert the MFP per unit of each NDC-9 into an MFP per billing unit by converting the per-unit amount into an amount per billing unit as necessary (to account for any differences in the NDC-9 unit versus the billing unit, e.g., if the NDC-9 unit is per mL and the billing unit is 5mL), then taking an average of the MFP per billing unit across all NDC-9s belonging to the selected drug in the HCPCS code, weighted by the ASP units reported as sold for each NDC-9 as reported by manufacturers for each NDC-11 within an NDC-9 in the ASP portal.

For the process described above, CMS will apply the MFP to any NDCs of the selected drug assigned to the Primary Manufacturer and/or Secondary Manufacturer(s) where such NDCs do not represent sample packages and where the Primary Manufacturer reported a non-zero WAC

for at least one calendar quarter of calendar year 2025. For such NDCs of selected drugs covered under Part D, CMS would use calendar year 2025 PDE records where (1) the PDE record is associated with a prescription filled between January 1, 2025, and December 31, 2025; (2) total gross covered prescription drug costs on the PDE record are greater than $0; (3) the PDE record is considered final action; (4) the drug coverage status code indicates the PDE record is for a drug covered under Part D; and (5) the compound code indicates the PDE record is not for a compounded drug. For such NDCs of selected drugs payable under Part B, CMS would use calendar year 2025 Part B claims where (1) the claim is associated with a service date between January 1, 2025, and December 31, 2025; (2) the claim type is 40, 71, 72, 81, or 82; (3) the total allowed charges (defined as the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service) for the HCPCS code on the claim is greater than $0; (4) the claim is considered final action; and (5) the claim is not billed as a compounded drug. CMS also will apply the MFP to any new NDCs or NDCs with insufficient PDE or WAC data in calendar year 2025 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, 2025, and ending December 31, 2025, for purposes of this calculation because it will be the most recent period of data available.
2. For each NDC-11, CMS will then sum the amounts calculated in step 1 to calculate the annual WAC per unit.
3. For each NDC-11, CMS will divide the total units dispensed/administered by the total 30-day equivalent supply, summed across 2025 PDE data and 2025 Part B claims data, to calculate the average number of units per 30-day equivalent supply.
    - For NDCs present only in PDE data: total units dispensed/administered are defined as the total quantity dispensed for an NDC-11.
    - For NDCs only associated with HCPCS codes present in Part B claims data: total units dispensed/administered are defined as the total billing units sold for an NDC-11 as determined using the unit allocation and standardization methodology described in section 60.2.2.2 of this draft guidance, adjusted to the NDC-11 level by removing step 3, changing all references to “NDC-9” in steps 4 and 5 to “NDC-11”, and changing the reference to “step 3” in step four to “step 2”.
    - For NDCs that are both present in PDE data and associated with HCPCS codes present in Part B data: total units dispensed/administered are defined as the sum of the quantity dispensed for the NDC-11 and the total billing units sold for the NDC-11 as determined using the unit allocation and standardization methodology described in section 60.2.2.3 of this draft guidance, adjusted to the NDC-11 level by removing step 3, changing all references to “NDC-9” in steps 4 and 5 to “NDC-11”, and changing the reference to “step 3” in step four to “step 2”.

4. For each NDC-11, CMS will multiply the WAC per unit calculated in step 2 by the average number of units per 30-day equivalent supply calculated in step 3 to calculate the WAC per 30-day equivalent day supply for that NDC-11.
5. For each NDC-11, CMS will divide the total 30-day equivalent supply for that NDC-11 across both PDE data and Part B claims data as applicable by the total 30-day equivalent supply across all applicable NDC-11s within an NDC-9 (across both PDE data and Part B claims data as applicable) and then multiply this quotient by the amount calculated in step 4.
6. For each NDC-9, CMS will then sum amounts calculated in step 5 across all NDC-11s to calculate the WAC per 30-day equivalent supply for that NDC-9.
7. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s and then multiply this quotient by the amount calculated in step 6.
8. CMS will then sum amounts calculated in step 7 across all NDC-9s of the selected drug to calculate the WAC per 30-day equivalent supply for the selected drug.
9. For each NDC-9, CMS will then divide the WAC per 30-day equivalent day supply for that NDC-9 calculated in step 6 by the WAC per 30-day equivalent supply for the selected drug calculated in step 8 to calculate the WAC per 30-day equivalent supply ratio for that NDC-9.
10. For each NDC-9, CMS will multiply the single MFP for the selected drug by the relative WAC per 30-day equivalent supply ratio for that NDC-9 calculated in step 9 to calculate the MFP per 30-day equivalent supply for that NDC-9.
11. For each NDC-9, CMS will divide the MFP per 30-day equivalent supply for that NDC-9 calculated in step 10 by the quotient of the total number of units dispensed divided by the total 30-day equivalent supply to calculate the MFP per unit (e.g., tablet).

For NDC-11s associated with HCPCS codes present in Part B claims data, CMS will further convert the MFP per unit of each NDC-9 into an MFP per billing unit using the following steps:

12. For each NDC-9, CMS will convert the MFP per unit as calculated in step 11 to an MFP per billing unit, as necessary. For example, if the unit of the NDC in PDE data is 1 mL but the billing unit associated with which that NDC is 5 mL, CMS would multiply the MFP per unit calculated in step 11 by 5.
13. For each NDC-9, CMS will sum the units reported by manufacturers in the ASP portal for all quarters in 2025 for all NDC-11s associated with that NDC-9 within a given HCPCS code.
14. For each NDC-9, CMS will divide the amount calculated in step 13 by the sum of units reported by manufacturers in the ASP portal for all quarters in 2025 for all NDC-11s that share the same HCPCS code and belong to the selected drug.
15. For each NDC-9, CMS will multiply the MFP per billing unit calculated in step 12 by the quotient calculated in step 14.
16. For each HCPCS code, CMS will sum the value calculated in step 15 across all NDC-9s for which the corresponding NDC-11 is associated with the HCPCS code to yield the MFP per billing unit.

CMS will include the MFP per billing unit, calculated in step 16 above, and the MFP per-unit price for each NDC-9 of the selected drug, calculated in step 11 above, 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 2028 and CMS may consider additional policies for future years of the Negotiation Program. Due to potential for confusion arising from differences between the NDC-11 package price as published by CMS (calculated without rounding any values in interim steps) and the NDC-11 package price that would result if another entity were to take the product of the published NDC-9 unit price (rounded to six decimals) and the package size, CMS is soliciting comments on removal of the NDC-11 package price from the public pricing file.

60.5.1 Application of the MFP to New NDAs / BLAs or NDCs and to NDCs with Insufficient PDE, Part B Claims, or WAC Data in Calendar Year 2025

Consistent with CMS' process for identifying a qualifying single source drug described in section 30.1 of this draft guidance, if the Primary Manufacturer for an initial price applicability year 2026, 2027, or 2028 selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient (or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients) as the selected drug, CMS will include the NDCs associated with the new NDA or BLA, as appropriate, on the list of NDCs of the selected drug determined pursuant to section 40.2 of this draft guidance and require that the MFP apply to such NDCs. If the new NDA or BLA is associated with NDCs that are assigned to a HCPCS code that is not already included on the list of HCPCS codes of an initial price applicability year 2028 selected drug determined pursuant to section 40.2 of this draft guidance, CMS will include the new HCPCS code, as appropriate, on the list of HCPCS codes of the selected drug and require that the MFP apply to such HCPCS codes. Similarly, after the drug is selected for an initial price applicability year 2026, 2027, or 2028, if the Primary Manufacturer for such drug receives approval or licensure for a new drug or biological product that is marketed pursuant to a supplement to an existing NDA or BLA, or otherwise launches a new NDC for the selected drug or (for initial price applicability year 2028 selected drugs only) is assigned a new HCPCS code for the selected drug, CMS will include such NDCs and HCPCS codes, as appropriate, on the list of NDCs and HCPCS codes of the selected drug determined pursuant to section 40.2 of this draft guidance and require that the MFP apply to such NDCs and HCPCS codes.

Additionally, an NDC (or all NDCs assigned to a HCPCS code, for initial price applicability year 2028 selected drugs) that has been included on the list of NDCs of the selected drug pursuant to section 40.2 of this draft guidance may lack sufficient PDE, Part B claims, or WAC data in the calendar year used to apply the MFP across that dosage form and strength during the negotiation period as described above. For such NDCs and HCPCS codes described above, CMS will determine whether there is an existing NDC that is comparable to such NDC (or comparable to the NDCs associated with such HCPCS code) and to which the MFP for the selected drug has been applied. CMS will determine which existing NDC is comparable based on review of the FDA-approved label of the selected drug and other relevant sources. If an existing, comparable NDC exists, CMS will use the quotient of total units dispensed/administered to 30-day equivalent supply (adjusted as necessary to reflect dosing or unit type differences between the

NDCs) and the WAC ratio that was calculated for the existing, comparable NDC to apply the MFP to the new NDC or NDC that lacks sufficient data to be used in the calculation. If a comparable NDC does not exist, CMS will impute the quotient of total units dispensed/administered to 30-day equivalent supply using sources such as the FDA-approved label and other sources associated with the NDC that lacks sufficient PDE, Part B claims, and/or WAC data but will use a WAC ratio of 1.0 to apply the MFP to the NDC that lacks sufficient PDE, Part B claims, and/or WAC data. If a new NDC (or NDC that lacks sufficient PDE, Part B claims, or WAC data) is assigned to a HCPCS code for which CMS has already calculated an MFP per billing unit, the MFP per billing unit for that HCPCS code will not change, and the new NDC (or NDC that lacks sufficient PDE, Part B claims, or WAC data) will be subject to that existing MFP per billing unit.

As described in section 40.5 of this draft guidance, as feasible, CMS will provide Primary Manufacturers with information on certain CMS calculations, including updates to CMS' computation of how the agency will apply a single MFP across dosage forms and strengths of the selected drug such as to account for the addition of new NDCs, and CMS will allow a Primary Manufacturer that believes in good faith that CMS has made an error in this computation to submit a suggestion of error for CMS' consideration. Comments related to statutorily-required criteria or the policies adopted in Negotiation Program guidance are outside the scope of the suggestion of error process. For example, comments on calculation methodology will be considered out of scope.

CMS will adjust the MFP application by updating the quotient of total quantity dispensed to 30-day equivalent supply based on observed PDE data and Part B claims for existing NDCs and HCPCS codes that lacked sufficient WAC, PDE data, or Part B claims to be included in the initial calculation of WAC ratios (described in section 60.5, step 9), and new NDCs and HCPCS codes launched after the initial calculation of WAC ratios, when CMS accrues sufficient data for such NDCs and HCPCS codes. Specifically, for these NDCs and HCPCS codes, CMS will monitor total quantity dispensed and 30-day equivalent supply from PDE data and Part B claims over time, beginning when these NDCs and/or HCPCS codes are first added to CMS' computation of how the agency will apply a single MFP across dosage forms and strengths of the selected drug. CMS will update the total quantity dispensed and 30-day equivalent supply values and recompute the application of the single MFP across dosage forms and strengths for these NDCs and/or HCPCS codes (but only for such NDCs and/or HCPCS codes, not for all NDCs and/or HCPCS codes of the selected drug) based on which of the following situations occurs first: (1) CMS determines the variation in average total quantity dispensed and 30-day equivalent supply is stable over time; (2) a year has elapsed since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B claims; or (3) the NDC or HCPCS code has accrued the same number of units dispensed/administered as the NDC-11 that had the fewest units dispensed/administered at the time that the WAC ratios were originally calculated.

60.6 Publication of the MFP

In accordance with section 1195(a)(1) of the Act, CMS will publish by November 30, 2026, the MFP for each drug selected for initial price applicability year 2028 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS

will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file, and the explanation for the MFP (published at a later date – see section 60.6.1 of this draft guidance). The MFP file[109] will contain the single MFP for a 30-day equivalent supply of the selected drug, NDC-9 per unit price, NDC-11 per package price, and HCPCS code dosage price and will be updated annually to show the inflation-adjusted MFP for the selected drug. CMS will also update the file as needed if any NDC-9s, NDC-11s, or HCPCS codes are added or removed for the selected drug, or if the NDC-9 per unit price, NDC-11 per package price, or HCPCS code dosage price is updated as a result of additional data. Further, CMS will publish on the CMS website when a drug is no longer a selected drug and the reason for that change, and when an MFP between a Primary Manufacturer and CMS is not agreed upon.

In accordance with section 1195(b)(1)(A) of the Act, for each selected drug, for each year subsequent to the first initial price applicability year of the price applicability period (unless renegotiation occurs), CMS will publish an updated MFP no later than November 30 of the year that is two years prior to such subsequent year. The updated MFP for each selected drug will be equal to the MFP that was published for such drug for the previous year, increased by the annual percentage increase in the CPI-U for the 12-month period ending with the July immediately preceding such November 30. For example, no later than November 30, 2026, CMS will publish on the CMS website updated amounts for any MFPs for initial price applicability year 2027 selected drugs for which a manufacturer agreement is in effect. Those updated MFPs will take effect in 2028 and will be equal to the initial price applicability year 2027 MFP for the selected drug increased by the percent increase in CPI-U from July 2025 to July 2026. In accordance with section 1192(c)(2) of the Act and subject to the timeline and situations discussed in section 70 of this draft guidance, a selected drug with an agreed-upon MFP may cease to be a selected drug and no longer subject to an MFP if CMS determines that a generic drug or a biosimilar for the reference drug is approved or licensed by the FDA and—as discussed in section 70 of this 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), as discussed in section 130 of this draft guidance.

60.6.1 Explanation for the MFP

Section 1195(a)(2) of the Act requires CMS to publish public explanations for the MFPs no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2027, for initial price applicability year 2028. CMS will strive to publish these public explanations earlier than March 1, 2027, if feasible. The public explanations will focus on the section 1194(e) data that had the greatest impact in determining the MFPs and include a discussion of the other section 1194(e) data, as applicable. It may also note any data or circumstances that may be unique to the selected drug. Alongside the narrative explanation, CMS will release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers,

[109] The Maximum Fair Price Layout file will display the NDC-9 per unit price to six decimal places. Publishing an NDC-9 per unit price rounded to the sixth decimal point place aligns with how CMS publishes other prices. Furthermore, publishing an NDC-9 per unit price rounded to the sixth decimal place would also result in the same agreed-upon MFP per 30-day equivalent when reversing the application of the single MFP across dosage forms and strengths calculations.

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 of this draft guidance, a selected drug will no longer be subject to the negotiation process, with respect to its initial price applicability year, if CMS determines that at least one generic drug or biosimilar satisfies the following criteria: (1) it is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product; and (2) it is marketed pursuant to such approval or licensure. The approach CMS will take to make this determination is described in section 70 of this 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 2028 by November 1, 2026 in order to avoid potential imposition of an excise tax. If negotiations have not ended by this date, the Primary Manufacturer may be subject to an excise tax. As a general matter, if the Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, CMS will continue to engage in the negotiation process described in section 60.4 of this 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) of the Act, when CMS initiates or resumes the negotiation process, CMS will apply the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including beginning in 2028, which may have potential implications with respect to the renegotiation process as discussed in section 130 of this draft guidance.

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) FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or FDA has licensed a biosimilar under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and (2) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure.

The approval (or licensure, as applicable) and marketing of an authorized generic drug (which includes authorized generic drugs and certain biological products as defined in section 1192(e)(2) of the Act) would not qualify as meeting the statutory requirement that a generic drug or a biosimilar is being marketed. In accordance with section 1192(e)(2)(B)(i) of the Act, an authorized generic drug as defined in section 505(t)(3) of the FD&C Act is treated as the same qualifying single source drug as a qualifying single source drug that is the listed drug, for the purposes of the Negotiation Program. Likewise, section 1192(e)(2)(B)(ii) of the Act indicates that the same rule applies to a biological product that is approved under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark.

The determination whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list will be informed by CMS' review of PDE and AMP data (as well as any other data CMS reviews, such as ASP data, Medicaid SDUD, and/or data from a nationally representative and commercially available database) for the generic drug or biosimilar for which the selected drug is the listed drug or reference product on a monthly basis as described below. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry based on the totality of the circumstances. The sources

of data described in this section 70 will be informative for that inquiry, but CMS' determination will not necessarily turn on any one source of data.

After the selected drug is removed from the selected drug list, CMS will monitor the manufacturers of such generic drugs or biosimilars to ensure they continue to engage in bona fide marketing of the generic or biosimilar based on the process described in section 90.4 of this draft guidance.

Starting in March 2026, and repeated each month thereafter, for the applicable selected drugs, CMS will take the following approach in its review of data to inform its determination whether the statutory criteria in sections 1192(c)(1)(A) and 1192(c)(1)(B) of the Act for an approved generic drug or licensed biosimilar to be marketed pursuant to such approval or licensure are being met.

First, CMS will use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar is approved or licensed for any strength(s) or dosage form(s) of a selected drug for initial price applicability year 2028.

Second, if CMS determines that a generic drug or biosimilar has been approved or licensed, CMS will begin by reviewing the PDE and AMP data (as well as any other data CMS reviews, such as ASP data, Medicaid SDUD, and/or data from a nationally representative and commercially available database) with dates of service or sales during the most recent 12-month period available for that data source to determine if the manufacturer of the generic drug or biosimilar has engaged in bona fide marketing of that drug or product. For example, when CMS performs this assessment in March 2026, CMS intends to use PDE data with dates of service from April 2025 through mid-March 2026 and AMP data with sales from February 2025 through January 2026 (submitted to CMS by February 28, 2026). When CMS performs this assessment in April 2026, CMS intends to use PDE data with dates of service from May 2025 through mid-April 2026 and AMP data with sales from March 2025 through February 2026 (submitted to CMS by March 31, 2026).

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 intends to consider a generic drug or biosimilar to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product. Additional relevant factors may include whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar, as articulated further in section 90.4 of this 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 2028, if CMS makes this determination between the date that the selected drug list for initial price applicability year 2028 is published and November 1, 2026, the drug will remain a selected drug through 2028, but no MFP will apply, and the drug will not be replaced with another selected drug.

In accordance with section 1192(c)(1) of the Act, a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) of the Act are met. Accordingly, if CMS makes this determination between November 2, 2026 and March 31, 2028, for a drug selected for initial price applicability year 2028, then the drug will cease to be a selected drug on January 1, 2029 and the MFP will apply for 2028. If CMS makes this determination between April 1, 2028 and March 31, 2029, then the selected drug will cease to be a selected drug on January 1, 2030, and the MFP will apply for 2028 and 2029. These results are summarized in Table 9.

Table 9: Removal from the Selected Drug List Following Generic Drug or Biosimilar Approval and Marketing

Date on which CMS determines that a generic drug or biosimilar is approved and marketed	**Result with respect to selected drug for the Negotiation Program**
The date that the selected drug list for initial price applicability year 2028 is published through November 1, 2026 (the end of the Negotiation Period for the initial price applicability year 2028)	Selected drug remains a selected drug for initial price applicability year 2028, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2029.
November 2, 2026 through March 31, 2028	Selected drug remains a selected drug and MFP applies for initial price applicability year 2028; selected drug ceases to be a selected drug on January 1, 2029.
April 1, 2028 through March 31, 2029	Selected drug remains a selected drug and MFP applies for initial price applicability year 2028 and calendar year 2029; selected drug ceases to be a selected drug on January 1, 2030.

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) of the Act for generic competition are met for a selected drug, CMS will publish such information on the CMS website.

80. MFP-Eligible Individuals in 2026, 2027, and 2028

For 2026, 2027, and 2028, in accordance with section 1191(c)(2)(A) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" means, with respect to a selected drug, the following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispensing entity, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan), if Part D coverage is provided under such plan for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who only uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash,[110] and for whom no PDE record is produced for the claim.

For 2026 and 2027, CMS does not expect Primary Manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in a Medicare Advantage plan under Part C. For 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, CMS expects Primary Manufacturers to provide access to the MFP of a selected drug to hospitals, physicians and other providers of services and suppliers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in a Medicare Advantage plan under Part C. CMS is soliciting comments in section 40.4 of this draft guidance related to the effectuation of the MFP for drugs payable under Part B and will address policies related to the effectuation of the MFP for drugs payable under Part B to Part B providers in the future.

For 2028, in accordance with section 1191(c)(2)(B) of the Act, the term "maximum fair price eligible individual" or "MFP-eligible individual" also means, with respect to a selected drug, the following: in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under Medicare Part B or in a Medicare Advantage plan under Medicare Part C, if payment may be made under Part B for such selected drug. CMS anticipates that Medicare Advantage plan requirements under 42 C.F.R. Part 422 will apply to selected drugs. CMS is soliciting comments on how best to monitor MA plans' use of Part B step therapy practices to ensure compliance with program rules and any data or policy clarifications that may be needed for implementation.

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

Direct member reimbursement (DMR) requests are requests for reimbursement submitted by eligible individuals to Part D plan sponsors to be reimbursed for a claim in which the individual paid the cash price out-of-pocket for the drug at the dispensing entity and did not use Part D coverage when receiving the drug. While Part D plan sponsors generally may charge the enrollee for the difference between the cash price paid to the dispensing entity and the plan allowance (if out-of-network) or negotiated price (if in-network) for drugs covered under Part D accessed from

[110] 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.

both out-of-network and in-network dispensing entities, neither 42 C.F.R. § 423.124(b) nor Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual's guidance on DMRs directly addresses drugs covered under Part D that have an MFP in effect.[111]

One situation in which an individual may submit a DMR request is if they are on vacation and need a medication, but there is no network pharmacy nearby, so they fill a prescription at an out-of-network pharmacy. Another situation where an individual may submit a DMR request is if they visit a network pharmacy, but the pharmacy's technology system is temporarily not functioning and the pharmacy is unable to adjudicate the claim online. In these two scenarios, the individual may elect to pay the cash price at the pharmacy and later submit a DMR request to their Part D plan sponsor for the prescription to apply towards their out-of-pocket expenses for purposes of moving through the benefit and to potentially receive reimbursement from the plan for accessing a drug that is covered under their Part D benefit. CMS notes that DMR requests are exceedingly rare. In a recent internal analysis, less than one-hundredth of a percent of final action claims submitted in 2024 for the ten drugs selected for initial price applicability year 2026 were submitted as DMR requests. An individual who submits a DMR request for a selected drug accessed at either an out-of-network (in accordance with 42 C.F.R. § 423.124(a) and (c)) or at an in-network dispensing entity, when the selected drug is covered under the Part D benefit (e.g., utilization management requirements have been met) (hereinafter a "covered DMR request") and a PDE record is generated for the claim, is an MFP-eligible individual under the definition in section 1191(c)(2)(A) of the Act and section 80 of this draft guidance.

Sections 1196(a)(1) and (a)(3)(A) of the Act direct the Secretary to establish procedures to ensure that the MFP for a selected drug is applied before any coverage or financial assistance under other health benefit plans or programs or other discounts, as well as to establish procedures to carry out the provisions of the IRA with respect to MFP-eligible individuals who are enrolled in a Part D plan. As discussed above, DMR requests are unique from typical claims for selected drugs and, therefore, warrant procedures to facilitate access to the MFP for MFP-eligible individuals that differ from how the MFP is normally effectuated for selected drugs. For example, when an eligible individual submits a DMR request, the Part D benefit is not used at the point of sale, the dispensing entity does not bill the individual's Part D plan but rather charges the individual the cash price established by the dispensing entity, and the individual's status as an MFP-eligible individual is not determined until after the point of sale when the individual submits the DMR request to their Part D plan. While a Primary Manufacturer of a selected drug that is participating in the Negotiation Program and reaches agreement upon an MFP remains responsible for providing access to the MFP to MFP-eligible individuals who are dispensed that selected drug during a price applicability period, CMS believes that, in light of

[111] 42 C.F.R. § 423.124(b) establishes that a Part D plan sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs at out-of-network pharmacies to assume financial responsibility for any differential between the out-of-network dispensing entity's usual and customary price and the Part D sponsor's plan allowance (as defined at 42 C.F.R. § 423.100). Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual provides detailed guidance on how Part D plan sponsors must process DMR requests that are submitted by enrollees that paid the dispensing entity's cash price (i.e., the pharmacy did not submit a claim to the Part D plan sponsor) at both out-of-network and in-network pharmacies. Chapter 14 of the Medicare Prescription Drug Benefit Manual is available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter-14-coordination-of-benefits-v09-17-2018.pdf.

these unique aspects of DMRs, it is necessary to establish a procedure that leverages existing Part D plan sponsor procedures for DMRs to help ensure that the MFP is available to an MFP-eligible individual that submits a covered DMR request.

For 2026, 2027, and 2028, access to the MFP for an MFP-eligible individual that submits a covered DMR request for a selected drug will be facilitated by the Part D plan sponsor. For DMRs involving in-network claims, the plan sponsor is responsible for reimbursing the individual at least the difference between the cash price paid by the enrollee to the dispensing entity and the negotiated price (which, in accordance with section 1860D-2(d)(1)(D) of the Act, shall be no greater than the MFP plus any dispensing fees for such selected drug). For DMRs involving out-of-network claims, the plan sponsor is responsible for reimbursing the individual at least the difference between the cash price paid by the enrollee to the dispensing entity and the MFP plus any dispensing fees, since there is not a negotiated price for the out-of-network dispensing entity. Accordingly, MFP-eligible individuals that submit a covered DMR request for a selected drug must not pay more than the MFP plus any dispensing fees if the individual is in the deductible phase of the benefit or their copayment or coinsurance if they are in other phases of the benefit. Primary Manufacturers and Part D plan sponsors may establish a reimbursement process related to DMR requests for MFP-eligible claims as necessary to ensure MFP effectuation for these MFP-eligible individuals.

As discussed above, a covered DMR request for a selected drug presents a unique circumstance where the dispensing entity and the plan sponsor do not have insight to the MFP eligibility of the individual at the point of sale and therefore require an alternate procedure to effectuate the MFP for the MFP-eligible individual. In DMR situations, the dispensing entity has already received the cash payment from the individual at the point of sale, at the cash price established by the dispensing entity, and is not involved in the submission of the claim to the Part D plan or the transaction to reimburse the MFP-eligible individual. In such cases, CMS will consider the MFP to have been made available to the dispensing entity through the cash payment by the individual and, as a result, will not require the Primary Manufacturer to pay an MFP refund to the dispensing entity in connection with a covered DMR request.

90. Manufacturer Compliance and Oversight

In accordance with section 1196(b) of the Act, CMS will monitor compliance by a Primary Manufacturer with the terms of the Agreement and establish a mechanism through which violations of such terms shall be reported.

90.1 Monitoring of Manufacturer Compliance

CMS will closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program, including all processes related to renegotiation. Following the publication of selected drugs for negotiation and renegotiation for each initial price applicability year, CMS intends to provide information about the negotiation or renegotiation process, as applicable, 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 and renegotiation periods, CMS will track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. CMS may require additional information from the Primary Manufacturer to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. This may include requiring recurring reporting (for example, providing evidence that MFP is being made available), or making specific ad hoc requests to the Primary Manufacturer for information related to targeted monitoring, auditing, or investigation efforts. When applicable, CMS will provide a written request to the Primary Manufacturer detailing such requests, including a date by which any requested information must be submitted. CMS is committed to providing Primary Manufacturers with reasonable timeframes to accommodate these information requests. CMS intends to consider written requests for deadline extensions submitted no later than three calendar days prior to the initial deadline. Extension requests must include a reasonable basis for requiring the extension as determined by CMS. CMS will only grant very limited extension requests and may be unable to fully grant requested extensions due to statutory timelines or other operational considerations.

To facilitate program operations and support manufacturer compliance, CMS may provide the Primary Manufacturer with written reminders of impending submission deadlines, with warnings of potential applicability of the excise tax (see 26 U.S.C. § 5000D for additional information regarding the excise tax) or of potential liability for a CMP for submission violations (see section 100 of this draft guidance). CMS may also provide written requests for clarifications, corrections, and/or additional information following data submissions; written notification that a Primary Manufacturer may be subject to enforcement action, as applicable; written reminders that potential compliance concerns are ongoing, as applicable; and written confirmation that potential compliance concerns have been mitigated, as applicable. As appropriate, CMS communications may take the form of Requests for Corrective Action Plans, Notifications of Potential Noncompliance, and/or Violation Notices. If CMS makes a determination to assess a CMP, CMS intends to follow the procedures outlined in section 100.5 of this draft guidance to notify the Primary Manufacturer and initiate the CMP process.

Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program may result in potential excise tax liability (see 26 U.S.C. § 5000D). Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in CMPs. If the Primary Manufacturer submits information that is required under the Agreement and CMS determines the information is false, the Primary Manufacturer will be determined to be noncompliant with the requirement to submit information and may be subject to a CMP. The start and end date of CMP accrual as well as the total amount accrued will be noted on the CMP Notification sent by CMS, following the process established in section 100.5 of this draft guidance.

90.2 Monitoring of Access to the MFP in 2026, 2027, and 2028

In accordance with section 1193(a)(3) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP – whether agreed upon during a negotiation or a renegotiation process – with respect to a selected drug shall be provided by the Primary

Manufacturer to MFP-eligible individuals at the pharmacy, mail order service, or other dispensing entity at the point-of-sale, to dispensing entities with respect to such MFP-eligible individuals who are dispensed the selected drug and, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, to Part B providers with respect to such MFP-eligible individuals who are furnished or administered the selected drug. Although the Primary Manufacturer is obligated to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug that are dispensed, furnished, or administered to MFP-eligible individuals as described above, the Primary Manufacturer is not obligated to make any sales of the selected drug.

Further, in accordance with section 1193(a)(5) of the Act, which requires that the Primary Manufacturer comply with requirements determined by the Secretary to be necessary for purposes of administering and monitoring compliance with the Negotiation Program, and section 40.4 of this draft guidance, CMS requires that the Primary Manufacturer establish processes to ensure the MFP is available as described in section 40.4 on units of the selected drug for which there are Secondary Manufacturers. CMS reiterates that the requirement for the Primary Manufacturer to provide access to the MFP applies to all sales of the selected drug by a Secondary Manufacturer to MFP-eligible individuals and to dispensing entities and Part B providers that dispense, administer, or furnish the selected drug to an MFP-eligible individual, as discussed in section 80 of this draft guidance. Unless otherwise specified, the MFP effectuation policies described in this draft guidance apply only to Part D. CMS is not at this time including detailed policy on monitoring access to the MFP for drugs payable under Part B but intends to align the policies for Part B with the policies for Part D discussed in this section 90.2 of this draft guidance to the extent appropriate and feasible.

The MFP effectuation policies established for 2026 and 2027 in final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 are final policies that remain in effect for 2026 and 2027. In this draft guidance, CMS makes updates and includes supplemental information regarding these policies for 2026 and 2027 and is extending these same policies to 2028 for drugs covered under Part D. For ease of reference, CMS is restating the MFP effectuation sections from final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 in this draft guidance so that the draft changes and updates to those policies can more easily be read in context with the policies in the prior final guidance that CMS is modifying or supplementing. In this section, CMS adds clarifying language about the factors that will be considered when assessing MFP availability during case-specific monitoring and investigation activities.

If CMS determines through audits, investigations, or complaints from dispensing entities or other market participants, that a Primary Manufacturer has not consistently fulfilled its obligation to make the MFP available by transmitting payment of an amount that provides access to the MFP within the 14-day prompt MFP payment window (unless the MFP was provided prospectively or, as detailed in section 40.4.5 of this draft guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies) for drugs covered under Part D, CMS will notify the Primary Manufacturer of its noncompliance and encourage the Primary Manufacturer to adopt process changes to address deficiencies in its MFP effectuation policies and practices as soon as possible. Failure to make the MFP available promptly may result in

CMS imposing the appropriate CMPs as set forth in section 100.1 of this draft guidance. Further, dispensing entities are encouraged to review their accounts receivable to determine whether a Primary Manufacturer has accurately paid all the claims the dispensing entity believes are MFP-eligible claims and to work with the Primary Manufacturer to resolve discrepancies. The dispensing entity may use the complaint and dispute process set forth in section 90.2.2 of this draft guidance to alert CMS of remaining discrepancies.

As described in section 40.4 of this draft guidance, CMS has engaged an MTF Contractor for the MTF DM to facilitate the exchange of data between Primary Manufacturers and dispensing entities to support the verification that the selected drug was dispensed to an MFP-eligible individual. As described in section 40.4.3 of this draft guidance, CMS has also engaged an MTF Contractor for the MTF PM to provide optional facilitation of retrospective MFP refund payments from participating Primary Manufacturers to dispensing entities to help effectuate access to the MFP.

Under section 1195(a) of the Act, the MFP for a selected drug and the explanation for each MFP will be published by CMS, giving the public and other interested parties an opportunity to know the MFP for each selected drug, and will be updated as needed if any NDC-9s or NDC-11s are added or removed for the selected drug and annually to show the inflation-adjusted MFP for the selected drug (see section 60.6 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance, as applicable, for additional details). Under section 1195(a)(1) of the Act, the MFPs for selected drugs for initial price applicability year 2028 must be published by November 30, 2026.[112] In addition, CMS anticipates it is likely that pharmaceutical database compendia will publish the MFPs for selected drugs such that they would become easily accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they were provided access to the MFP.

As described in sections 40.4.1 through 40.4.4 of this draft guidance, the Primary Manufacturer is responsible for calculating a refund amount for each MFP-eligible claim and reporting claim-level payment elements with a justification code indicating the method of calculation of that refund amount for Part D claims. This includes the reasons considered in section 40.4.3 and 40.4.4 of this draft guidance for an MFP refund payment amount that differs from the SDRA, including adjustments for differing acquisition costs, prospective purchasing by a dispensing

[112] Section 40.2 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance describes the Primary Manufacturer's ongoing obligation to timely report any changes to the NDC-11s for the selected drug. Section 60.5.1 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this 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, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance describes CMS' publication of and updates to the MFP file. Section 60.8 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this draft guidance describes the MFP publication timeline that CMS will follow in the event of late action from the Primary Manufacturer.

entity at or below MFP, or the claim being excluded from MFP refunds under section 1193(d)(1) of the Act.

As related to the exclusion of a claim from MFP refunds under section 1193(d)(1) of the Act, section 40.4.5 of this 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 furnished, dispensed, or administered such selected drug at the 340B covered entity if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price is lower than the MFP for such selected drug. In accordance with section 1193(d)(2) of the Act, if the MFP for the selected drug is below the 340B ceiling price in effect on the date on which the MFP-eligible individual is furnished, dispensed, or administered such selected drug by the 340B covered entity, the Primary Manufacturer is required to provide access to the MFP to the 340B covered entity with respect to such an MFP-eligible individual in a nonduplicated amount to the 340B ceiling price.

CMS recognizes that the data elements from PDE records transmitted by the MTF to Primary Manufacturers may include those from claims that should be subject to a different refund amount than the SDRA, claims for selected drugs prospectively purchased at or below MFP, or claims for which the Primary Manufacturer may claim an exception under section 1193(d)(1) of the Act. As noted in section 40.4.3 and 40.4.4 of this draft guidance, CMS expects Primary Manufacturers to indicate such claims in the reported claim-level payment elements, and to maintain documentation justifying the indication and MFP refund payment, if applicable.

When assessing whether a Primary Manufacturer provided access to the MFP to a dispensing entity with respect to a selected drug, CMS will undertake a fact-specific assessment that will consider the following, among other factors, as applicable: whether the retrospective refund amount authorized for payment or paid by the Primary Manufacturer is sufficient to account for commercially reasonable costs the dispensing entity is likely to encounter in the supply chain, the invoice amount from the dispensing entity (if available), the delta between the MFP refund amount provided and the SDRA (if available), and any agreements or communications between the dispensing entity and the Primary Manufacturer regarding the availability of the MFP to the dispensing entity. Consistent with section 1193(a)(5) of the Act, in the course of these assessments, CMS may request information to further its inquiry into whether MFP was made available, as evaluated according to the above listed factors, from relevant parties such as Primary Manufacturers, dispensing entities, or other involved supply chain entities (e.g., documentation related to a complaint or dispute submission; banking or other transaction records from the dispensing entity or other stakeholders). For example, documentation or data related to the Primary Manufacturer's MFP refund calculation may inform CMS' assessment of whether the amount provided by the Primary Manufacturer was sufficient to make MFP available to the dispensing entity. CMS expects such information to be maintained and made available from Primary Manufacturers when requested, and CMS may also request any relevant documentation from dispensing entities, wholesalers, or other supply chain entities to better evaluate whether MFP was made available. Evaluation of any submitted documentation as relevant to these factors, as part of an investigation, audit, and/or enforcement action will be considered as part of CMS' fact-specific assessment of whether MFP was made available based on the factors

described in this paragraph. CMS is soliciting comments on these factors, and other considerations CMS may take into account when assessing whether MFP was made available.

When a refund amount other than the SDRA is paid, Primary Manufacturers will be required to maintain supporting documentation demonstrating why MFP refunds were provided at an amount other than the SDRA, or were not provided, for applicable claims. CMS expects Primary Manufacturers to maintain documentation that includes evidence reflecting the dispensing entity's actual acquisition cost or demonstrating a better approximation than WAC of the dispensing entity's acquisition cost. This could include, but would not be limited to, invoices from the dispensing entity, a contractual agreement with the dispensing entity establishing an acquisition cost agreed to between the Primary Manufacturer and the dispensing entity, or other evidence of the dispensing entity's acquisition cost for the selected drug. For claims filled with selected drugs prospectively purchased at or below MFP, documentation could include, but would not be limited to, invoicing documentation of the drug purchased at or below MFP or an agreement between the Primary Manufacturer and dispensing entity establishing prospective purchasing of the selected drug.

Specifically for claims subject to the exception under section 1193(d)(1) of the Act, to avoid duplication of discounts between MFP and the 340B ceiling price, Primary Manufacturers may identify Part D claims from the data elements transmitted by the MTF that are 340B-eligible (as defined in section 40.4.5 of this draft guidance) and for which the 340B ceiling price is lower than the MFP. If a Primary Manufacturer determines that it will not issue an MFP refund related to a given Part D claim for which the Primary Manufacturer has received data elements from the MTF, the Primary Manufacturer must indicate in the report of claim-level payment elements that it is not paying an MFP refund for each applicable claim within the 14-day prompt MFP payment window because the Primary Manufacturer has determined, or reasonably believes, that the specified claims meet the exception described in section 1193(d)(1) of the Act. In conjunction with this indication, the Primary Manufacturer must maintain documentation demonstrating its justification of nonpayment due to the 340B eligibility of these claims and the 340B ceiling price being lower than the MFP for these claims. Documentation demonstrating that the claim is 340B-eligible should include, at a minimum, either the Primary Manufacturer's process and conclusion from its 340B nonduplication process, or confirmation from a 340B covered entity or any vendor the 340B covered entity employs to determine 340B status, that the Part D claim was 340B-eligible. CMS notes that an NPI alone (whether a prescriber NPI or a hospital/provider NPI) generally will not constitute sufficient evidence that a Part D claim was 340B-eligible as not all individuals served by covered entities are necessarily eligible to receive a drug purchased at the 340B price. If the MTF claim-level data elements include the 340B Claim Indicator, the Primary Manufacturer need only maintain documentation showing that the 340B ceiling price is lower than the MFP for the applicable claim.

If a covered entity believes that certain dispenses should have been purchased at the 340B ceiling price and the Primary Manufacturer did not make the 340B ceiling price available, then the covered entity would be able to utilize the HRSA enforcement mechanisms outside of the complaint and dispute process described in section 90.2.2 of this draft guidance to pursue corrective action to receive the 340B ceiling price. If the Primary Manufacturer submits the indication in the claim-level payment elements and maintains adequate documentation to justify

its nonpayment and promptly transmits payment for the remaining claims on its MTF data elements file within the 14-day prompt MFP payment window, then the Primary Manufacturer will have met its obligation to transmit payment within the 14-day prompt MFP payment window for Part D claims.

CMS will monitor the status of the unpaid claims and claims paid at a refund amount other than the SDRA that the Primary Manufacturer identified in the claim-level payment elements for Part D claims. Primary Manufacturers must maintain the documentation that justifies its nonpayment, or its payment of a refund amount other than the SDRA, and deliver documentation to CMS, if requested, for the purposes of auditing and monitoring compliance with the Negotiation Program. CMS will monitor the status of claims paid at the SDRA and may require documentation confirming MFP refund payment and payment amount, including if CMS receives a complaint related to these claims (e.g., indicating that the dispensing entity's acquisition cost was greater than WAC, and therefore, the MFP was not made available to that dispensing entity). If CMS determines upon further investigation—whether through audits of this documentation, voluntary outreach from covered entities or their TPAs, complaints from dispensing entities, or other mechanisms including the complaint process described in section 90.2.2 of this draft guidance—that the Primary Manufacturer has not transmitted payment to make the MFP available within the 14-day prompt MFP payment window for Part D claims, CMS may issue the Primary Manufacturer a Notice of Potential Noncompliance, allowing 10 business days to respond with additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration consistent with the process outlined in section 100.1 of this draft guidance. In the event CMS determines the Primary Manufacturer is noncompliant with the requirement to effectuate the MFP, CMS may pursue CMPs as set forth in section 100.1 of this draft guidance.

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 40.4.5 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) prospectively ensuring that the price paid by the dispensing entity or Part B provider when acquiring the drug is no greater than the MFP; or (3) using some combination of these two approaches.

CMS is not at this time including detailed information on the requirements of the MFP Effectuation Plan for selected drugs payable under Part B, and, unless otherwise specified, the policies in section 90.2.1 of this draft guidance apply only to Part D at this time. However, CMS intends to align the policies for Part B with the policies for Part D discussed in this section of the draft guidance to the extent appropriate and feasible. CMS is soliciting comments on the types of information that should be included in MFP Effectuation Plans for drugs payable under Part B, and how requirements for MFP Effectuation Plans for drugs payable under Part B should differ from what is outlined in this section.

Starting with initial price applicability year 2027, CMS will split the MFP Effectuation Plan into two sections, with the Primary Manufacturer's election whether or not to use the MTF PM, the

Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they anticipate having material cashflow concerns at the start of the initial price applicability year, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM, required to be submitted via the MTF DM by June 1 of the calendar year before the MFP goes into effect, and the remainder of the information in the MFP Effectuation Plan due September 1 of the calendar year before the MFP goes into effect. This approach is intended to allow CMS time to evaluate information on the MFP Effectuation Plan that will most directly impact dispensing entities and conduct outreach if important information, as discussed throughout this section, is missing, while also allowing Primary Manufacturers time to finalize plans for making the MFP available. This update does not impact MFP Effectuation Plans for initial price applicability year 2026, which, as established in the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, are due in writing to CMS at least four months before the start of the first initial price applicability year for the selected drug.

To provide a clear, concise method of collecting the requested information, CMS included an MFP Effectuation Plan form in the Medicare Transaction Facilitator for Initial Price Applicability Year 2026 and 2027 ICR, published for a 60-day public comment in Fall 2024, and for a 30-day public comment period in Spring 2025; CMS anticipates this ICR will be finalized and published by Summer 2025. If needed, CMS intends to publish a revised version of this ICR to address any evolving data collection needs for initial price applicability year 2028. CMS developed a standardized method of data collection to promote the Primary Manufacturer's development of a robust plan for making MFP available within the MTF DM that can be populated by a Primary Manufacturer during its enrollment and subsequently updated as needed.

For selected drugs with a first initial price applicability year of 2026, CMS required in the revised guidance for initial price applicability year 2026 that a Primary Manufacturer of a selected drug send its plan for ensuring MFP availability to CMS in writing by December 2, 2025; however, CMS revised this deadline to September 1, 2025 in the final guidance for initial price applicability year 2027 and manufacturer effectuation of the maximum fair price in 2026 and 2027. For selected drugs with a first initial price applicability year of 2027, sections of the plan related to the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they expect to experience cash flow concerns, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM will be due by June 1, 2026, with the remainder of the plan due by September 1, 2026. Likewise, for selected drugs with a first initial price applicability year of 2028, the initial sections of the plan will be due by June 1, 2027, and the remainder of the plan will be due by September 1, 2027. Upon receiving the plans for making MFP available from Primary Manufacturers, CMS will conduct a risk assessment for each submission using risk assessment criteria consistent with the requirements set forth in section 40.4 of this draft guidance. Primary Manufacturers with plans that CMS identifies as having a greater risk of failing to make the MFP consistently available will be subject to increased scrutiny through CMS' monitoring and oversight activities. CMS intends to allow dispensing entities to access these plans through the MTF user interface and will redact proprietary information in those plans. In addition, CMS may release these redacted plans to other applicable stakeholders (e.g., supply chain entities) upon request.

A Primary Manufacturer must notify CMS in writing of any changes to its MFP Effectuation Plan as soon as practicable, regardless of whether the notice is provided before a selected drug's first initial price applicability year or thereafter, and subject to the terms, if applicable, of a signed MTF DM User Agreement. If the Primary Manufacturer of a selected drug with a first initial price applicability year of 2026 is also the Primary Manufacturer of a selected drug with a first initial price applicability year of 2027, then the Primary Manufacturer is not required to submit a new written plan to make MFP available for the selected drug with a first initial price applicability year of 2027 by September 1, 2026. Instead, the Primary Manufacturer may amend its previously submitted plan for the selected drug with a first initial price applicability year of 2026 to include the newly selected drug, as long as the Primary Manufacturer aligns the amendment with the new due dates for different sections of the plan established in the preceding paragraph. That is, any amendments to sections of the plan related to the Primary Manufacturer's election whether or not to use the MTF PM, the Primary Manufacturer's communication plan, the Primary Manufacturer's approach to dispensing entities who indicate they expect to experience material cash flow concerns, and information about the Primary Manufacturer's plan if they do not intend to use the MTF PM will be due by June 1, 2026, with any amendments to the remainder of the plan due by September 1, 2026.

A Primary Manufacturer may update its MTF account information over time using functionality available in the MTF DM user interface. For any changes to general enrollment information (e.g., points of contact), the Primary Manufacturer must notify CMS of any change to its MTF enrollment information no later than 30 calendar days following the change taking effect by updating the information in the MTF DM. In circumstances where a Primary Manufacturer has elected to use the MTF PM, the Primary Manufacturer may update its bank account and financial information at any time; however, the MTF will require up to a 30-day transition period from the date the Primary Manufacturer submits the updated information during which the MTF will continue operating with the previous information while integrating and testing the updated information into system operations to facilitate a successful transition in payment processing. The Primary Manufacturer must maintain availability of the off-boarding bank account, with sufficient funds to process MFP refunds, for the full duration of the 30-day transition period. A Primary Manufacturer may also elect to terminate use of the voluntary passing of payments through the MTF PM at any time after submission of its MFP Effectuation Plan, but must provide notice at least 90 calendar days before withdrawing from MTF PM participation, and must provide a revised MFP Effectuation Plan containing its alternative method for making MFP available. Conversely, a Primary Manufacturer may amend its plan to begin voluntarily passing payments through the MTF PM at any time, though it may take up to 30 calendar days following the Primary Manufacturers election to use the MTF PM and submission of banking information for the Primary Manufacturer to begin utilizing the MTF PM during which time the Primary Manufacturer must continue making MFP available using their previous approach without the MTF PM.

The contents of the Primary Manufacturers' plans are, in part, related to their decisions pertaining to participation in the MTF PM. While the plans will require baseline information from all Primary Manufacturers as part of their participation in the MTF DM, those that choose not to use the MTF PM, or choose to establish alternative reimbursement mechanisms, will be

required to provide additional details on their approach for effectuating the MFP. A Primary Manufacturer that chooses not to use the MTF PM or that chooses to establish alternative reimbursement mechanisms must also provide a detailed plan for internal auditing to ensure all transactions effectuate MFP in compliance with this guidance and Negotiation Program requirements. The remainder of this section details the content requirements for the MFP Effectuation Plans.

All Primary Manufacturers' plans must include description(s) of the types of documentation and data they anticipate collecting, maintaining, and delivering to CMS, if requested, for the purposes of auditing and compliance with the requirement to make the MFP available. Each Primary Manufacturer's MFP Effectuation Plan will also need to indicate its general plan and procedures for contacting and receiving communications from dispensing entities. CMS understands that the Primary Manufacturer and dispensing entities may pursue alternative methods of MFP effectuation outside of retrospective reimbursements (e.g., prospective purchase agreements), and having a clear communication method between the parties may facilitate such arrangements. In addition, CMS encourages Primary Manufacturers and dispensing entities to work together to resolve potential issues related to payments (e.g., insufficient refund amount, late payments, etc.) prior to using the complaint and dispute process set forth in section 90.2.2 of this draft guidance. Further, each Primary Manufacturer's plan shall include details of its process for deduplicating 340B covered units (pursuant to section 1193(d) of the Act and section 40.4.5 of this draft guidance) for the selected drug. Further, beginning with initial price applicability year 2027, if a Primary Manufacturer intends to utilize the SDRA, at least in some cases, for effectuating the MFP, the Primary Manufacturer's MFP Effectuation Plan must also include information about the Primary Manufacturer's approach for calculating MFP refund amounts, if applicable, for MFP-eligible claims in the rare cases where the MTF DM will not provide the Primary Manufacturer a calculated SDRA, as discussed in section 40.4.1 of this draft guidance. Primary Manufacturers are encouraged to include this information in the Primary Manufacturer's MFP Effectuation Plan for initial price applicability year 2026, as feasible.

As discussed in section 40.4.2.2 of this draft guidance, CMS will allow dispensing entities to identify themselves as anticipating material cashflow concerns at the start of a price applicability period with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. In its MFP Effectuation Plan, a Primary Manufacturer must include a process for mitigating material cashflow concerns for dispensing entities. For Primary Manufacturers' consideration in developing their mitigation processes, CMS will make the list of the self-identified dispensing entities available to Primary Manufacturers in the MTF DM prior to Primary Manufacturers' submission of MFP Effectuation Plans for 2026, 2027, and 2028, and will provide updates to the list on an ongoing basis as other dispensing entities enroll in the MTF DM and self-identify as anticipating having material cashflow concerns or as dispensing entities update their self-identification over time. Primary Manufacturers will not need to update their MFP Effectuation Plans in response to updates to the list of dispensing entities who have self-identified as anticipating having material cashflow concerns. CMS views sharing this list as informational but recognizes a Primary Manufacturer may establish its own eligibility criteria for determining which dispensing entities are included in its mitigation approach; any such eligibility criteria should be outlined in the Primary Manufacturer's mitigation process. Examples of processes to

mitigate material cashflow concerns for identified dispensing entities may include, but are not limited to, prospective purchasing agreements or accelerated MFP refund timelines. CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP Effectuation Plan. As stated earlier in section 90.2.1, Primary Manufacturers with plans that CMS identifies as having a greater risk of failing to make the MFP consistently available will be subject to increased scrutiny through CMS' monitoring and oversight activities. If a Primary Manufacturer makes a material change to its eligibility criteria or its mitigation approach, then it would be required to update its MFP Effectuation Plan with the changes and submit it to CMS as soon as practicable, and in any event, within 90 days of the change.

As discussed in sections 40.4.3 and 40.4.4 of this draft guidance, a Primary Manufacturer's MFP Effectuation Plan must indicate whether it will participate in the MTF PM. If a Primary Manufacturer chooses to use the MTF PM, then the MFP Effectuation Plan will indicate this decision, and the Primary Manufacturer will acknowledge that it understands and will meet the participation requirements set forth in section 40.4.3 of this draft guidance and any applicable participation agreements. If the Primary Manufacturer elects to participate in the MTF PM as its payment method, then no alternative plan to effectuate payment of MFP refunds is required. As a result of this election, and the Primary Manufacturer's timely submission of its applicable claim-level payment elements identified in section 40.4.3 of this draft guidance, the MTF PM will maintain a ledger system of credits and debits, provide the ERA and electronic transfers to dispensing entities that receive electronic transfer of funds through the MTF PM, and provide the remittance and paper checks to dispensing entities that receive MFP refunds through the MTF PM via paper check. A Primary Manufacturer's decision to participate in the MTF PM does not preclude it from negotiating separate agreements with dispensing entities to provide access to the MFP outside of the MTF PM; however, the Primary Manufacturer is required to ensure that its MFP Effectuation Plan's description of these alternative arrangements is kept up-to-date, including through submission of updates, and is consistent with the requirements described below. Similarly, a dispensing entity is free to approach a Primary Manufacturer with a request to create an alternative arrangement separate from the Primary Manufacturer's choice of MTF PM participation.

If a Primary Manufacturer declines to use the MTF PM, then it is required to provide, at a minimum, a functionally equivalent electronic reimbursement mechanism to that offered by the MTF PM. In addition, the Primary Manufacturer will be responsible for ensuring that paper checks are provided as a reimbursement mechanism for dispensing entities that do not wish to be reimbursed electronically. As discussed in section 40.4.2 of this draft guidance, the MTF DM will include the preferred payment method for the dispensing entity among the claim-level data elements transmitted to the Primary Manufacturer. The Primary Manufacturer is required to provide the electronic reimbursement mechanism for dispensing entities that have indicated their preference to receive electronic transfer of funds and the paper check reimbursement mechanism for dispensing entities that have indicated their preference to receive payment via paper check. The Primary Manufacturer's electronic and paper check payment facilitation methods will be assessed for their consistency with the requirements set forth in sections 40.4 through 40.4.5 of this draft guidance. CMS requires that the Primary Manufacturer's MFP Effectuation Plan would include, at a minimum, information regarding its plan to meet the 14-day prompt MFP payment

window for transmitting payment of an amount that provides access to the MFP, its policies and procedures for determining the methodology it will use to calculate the amount of each reimbursement due to the dispensing entity (e.g., when the Primary Manufacturer will use the applicable dispensing entity's actual acquisition cost or a standardized pricing metric, such as WAC, to calculate the MFP refund amount), confirmation that it will use a GAAP system that can be audited, and confirmation that it will submit verification of reimbursement to the MTF via the report of claim-level payment elements discussed in sections 40.4.3 and 40.4.4 of this draft guidance, as required for purposes of administering and monitoring compliance with the Negotiation Program consistent with section 1193(a)(5) of the Act. In addition, the Primary Manufacturer must describe its method of reconciling over- or under-payments arising from situations such as adjusted or updated claim information (e.g., 340B, reversals, revisions, etc.); and must provide information about their processes for creating and making available remittances for each payment made to dispensing entities (remittances for electronic payments must use the X12 835 standard adopted under HIPAA). If a Primary Manufacturer elects to operate its own system to account for this information, it must provide information regarding its method of maintaining a comprehensive, GAAP-compliant, system.

There are other specific examples of criteria CMS has identified as important to make MFP available and that a Primary Manufacturer should consider including in its electronic and paper check payment facilitation methods if: (1) it chooses not to participate in the MTF PM; or (2) has, or plans to have, alternative arrangement with certain dispensing entities even if the Primary Manufacturer will ordinarily use the MTF PM to pass through MFP refund payments to dispensing entities. These examples include, but are not limited to, a Primary Manufacturer's data transmission method to return its Table 6 data to the MTF DM, frequency of returning its Table 6 data to the MTF DM, payment method, procedures for making payment of MFP refunds, calculation of refund amounts for reimbursements not consistent with the SDRA, and 340B nonduplication method. In addition, this includes information on a Primary Manufacturer's plans for meeting the 14-day prompt MFP payment window, as well as the specifics of how a Primary Manufacturer will work with Secondary Manufacturers to ensure the MFP will be passed through by Secondary Manufacturers for selected drugs dispensed to MFP-eligible individuals.

If a Primary Manufacturer and dispensing entity maintain a separate reimbursement or purchasing arrangement that changes after the submission of the plan and exists outside of the MTF PM (e.g., prospectively purchased units), then the Primary Manufacturer must update the MFP Effectuation Plan within 90 days of the creation of the new or updated unique arrangement. If a Primary Manufacturer fails to provide an updated MFP Effectuation Plan within the 90-day period, the Primary Manufacturer may be considered out of compliance with the terms of its Agreement. In such cases, the Primary Manufacturer should notify CMS as soon as possible to enable CMS to coordinate with the Primary Manufacturer regarding necessary updates to its plan.

Consistent with the standard business practices of each dispensing entity, dispensing entities should review their accounts receivable and determine whether a Primary Manufacturer has paid all the claims the dispensing entity believes are MFP-eligible claims, in the amounts the dispensing entity believes are sufficient to effectuate the MFP. Further, dispensing entities should understand that alternative arrangements made with a Primary Manufacturer outside of the MTF

PM are private contracts between the Primary Manufacturer and the dispensing entity; thus, any disputes arising under or related to such private contracts may be subject to various laws and should be resolved between the parties. However, dispensing entities may use the complaint and dispute process described in section 90.2.2 of this draft guidance to raise any identified issues with the MFP refund payment amount or suspicion that MFP has not been made available. Both Primary Manufacturers and dispensing entities should maintain documentation of their communications and agreements and CMS may request this documentation as part of the complaint and dispute process set forth in section 90.2.2 of this draft guidance.

In accordance with its oversight responsibilities under section 1196(b) of the Act, CMS will monitor for compliance, and will audit as needed, to ensure that the Primary Manufacturer is complying with the terms of its Agreement and that the MFP is being made available for the selected drug. A Primary Manufacturer must retain for at least 10 years from the date of sale any records relating to sales of the selected drug to wholesalers and entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensing entities for Part D. By submitting its MFP Effectuation Plan, the Primary Manufacturer acknowledges it will use the processes outlined in the plan to effectuate MFP consistent with the statute. A Primary Manufacturer's MFP Effectuation Plan describing its plan to ensure MFP availability is considered in effect until it is superseded by the submission of a new MFP Effectuation Plan, or is considered terminated because the submitting entity is no longer the Primary Manufacturer of a selected drug (e.g., a drug is removed from the selected drug list, divestiture, etc.), subject to the requirements of section 40.4 of this draft guidance. A Primary Manufacturer may submit a new MFP Effectuation Plan at any time and, in conjunction with this submission, must also provide CMS with a summary of the changes contained in its updated plan.

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

In accordance with sections 1196(a)(3)(A) and 1196(b) of the Act, which require in part that the Secretary establish procedures to carry out the Negotiation Program with respect to MFP-eligible individuals and monitor compliance with the terms of the Agreement, CMS will establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and the pharmacies, mail order services, and other dispensing entities that provide drugs to MFP-eligible individuals. This system is intended to address complaints and disputes related to MFP availability and MTF functionality and is not intended to receive general comments or feedback related to the implementation of the Negotiation Program as a whole. Any issues unrelated to MFP availability and MTF functionality will be directed to the appropriate review mechanism. This intake system will include an avenue to report difficulty using, or errors related to, MTF data and/or payment system functionality. Further, the complaints process described in this section and referenced in this draft guidance will be available to parties notwithstanding their degree of participation in any aspect of the MTF. Primary Manufacturers and dispensing entities will be able to access the complaint and dispute process directly from the MTF DM user interface. Those outside the MTF will be able to access the complaints process via a publicly accessible portal. At this time, CMS is not including detailed information on the complaints and disputes process for selected drugs payable under Part B but intends to align the policies for Part B with the policies for Part D discussed in this section of the draft guidance to

the extent appropriate and feasible. Unless otherwise specified, these policies only apply to Part D at this time for 2028. CMS is soliciting comments on how the complaints and disputes process for drugs payable under Part B should differ from what is outlined in this section, and is particularly interested in receiving comments about the types of documentation that CMS should consider when a complaint is filed regarding a selected drug payable under Part B.

Complaints and disputes must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute. Upon timely receipt of a reported issue, an initial triage will be conducted to route the concern to the appropriate track, as described below. While the MTF may be involved in facilitating the resolution of complaints and disputes related to its data exchange and payment facilitation functions as discussed below, under no circumstance will the MTF determine whether the Primary Manufacturer has provided access to the MFP or otherwise met its obligations under the Negotiation Program. Complaints that present evidence of potential noncompliance will be referred to CMS so they can be effectively and timely remediated.

The complaint and dispute process will be set up with two "tracks" within one overall system. The first track is a dispute functionality within the MTF for qualifying disputes from Primary Manufacturers or dispensing entities, and, beginning in 2028, Part B providers regarding a technical aspect of the MTF process. The second track is a complaint process that will intake complaints and will be available to the public as well as Primary Manufacturers and dispensing entities, and, beginning in 2028, Part B providers regardless of their degree of participation in any aspect of the MTF and will encompass any issues that do not qualify as disputes under the definition set forth below.

Under the Negotiation Program, CMS considers a dispute to be a specific, identifiable challenge to a technical aspect of the MTF system and process (e.g., claims included as potentially requiring an MFP refund). CMS will evaluate disputes and issue findings as appropriate based on available relevant factual information. This category of review will apply to circumstances such as a Primary Manufacturer suggesting an error in its MTF claims data or dispensing entities suggesting an error in the calculation of the SDRA. The disputing party will need to submit evidence supporting its position when making the report. To resolve disputes, CMS will consider information from the party submitting the dispute as well as any other relevant or underlying information and issue a finding resolving the dispute (either favorably or unfavorably) based upon the facts and data present for the particular situation.

CMS will also collect complaints. Under the Negotiation Program, CMS considers a complaint as any issue brought forward by an individual or entity that does not fall under the above definition of dispute; this covers a wide range of concerns from a broad range of interested parties. Below, CMS has provided two examples of types of complaints; however, CMS understands that the types of complaints likely to be received would not be limited to the examples below.

One type of complaint may include operational issues with the MTF system originating from MTF system users participating in the MTF DM or the MTF PM. For this type of complaint, CMS will provide (through a CMS contractor(s)) help desk support to resolve these types of

issues promptly to ensure that the system operates smoothly. The MTF help desk will be accessible to quickly provide answers to Primary Manufacturers and dispensing entities regarding daily operations of the MTF.

A second type of complaint may include reports that the MFP was not made available, including instances where a dispensing entity expresses concern that they have not received a timely retrospective refund payment that effectuates the MFP or that the Primary Manufacturer did not transmit payment within the 14-day prompt payment window. This may also include instances where an agreed-upon MFP after renegotiation is not made available. This type of complaint could also originate from manufacturers, beneficiaries, or other interested parties, and should include supporting documentation, such as an open accounts receivable demonstrating that the Primary Manufacturer did not provide access to a price for the selected drug that is equal to or less than the MFP. Dispensing entities and Primary Manufacturers may also use the complaint process if they have a concern regarding the credit/debit ledger system established in section 40.4.3 of this draft guidance. Before submitting a complaint to CMS, CMS encourages dispensing entities and Primary Manufacturers to work together in good faith to resolve any issues regarding MFP availability. Contact information for dispensing entities and/or Primary Manufacturers will be made available to facilitate these efforts. Proof of any efforts to resolve the issue should be submitted once the complaint is filed. All complaints submitted will receive a response from CMS explaining the next steps that CMS may take.

Complaints related to a lack of MFP availability may not always require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability. Investigations may lead to enforcement action, as described in section 100 of the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, or this 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 documentation related to the Primary Manufacturer's attempts to make the MFP available. CMS intends to respond as quickly and efficiently as practicable to address concern(s) raised in a complaint or dispute and seeks to gain more practical experience implementing the complaint and dispute process before establishing further timelines.

CMS intends to track complaints and disputes over time to monitor overall trends, including those related to entities other than Primary Manufacturers and dispensing entities and emerging compliance issues, and to make process improvements in the implementation of the MTF complaint and dispute process.

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

The IRS is responsible for administering and enforcing the excise tax, not CMS. The Department of the Treasury has established regulations that govern the administration of the excise tax.[113]

[113] See Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507, available at https://www.federalregister.gov/documents/2024/07/05/2024-14706/excise-tax-on-designated-drugs-procedural-

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar

If CMS determines that either:

1. a potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2028 because any strength or dosage form of 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 monitoring by CMS may include, but is not limited to, whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar.

CMS is aware that marketing or other agreements between the Primary Manufacturer and generic drug or biosimilar manufacturers may limit the availability of the generic drug or biosimilar for purchase through the pharmaceutical supply chain, and CMS will attempt to identify when such agreements exist as a factor in determining whether bona fide marketing exists, although such agreements would not by themselves be dispositive of that determination. CMS notes that any agreements limiting the availability of a generic drug or biosimilar may be subject to scrutiny and potential enforcement under antitrust laws (including laws prohibiting unfair methods of competition) as well as laws prohibiting unfair or deceptive acts or practices in or affecting commerce.

In addition, CMS will analyze the share of generic drug or biosimilar units identified in PDE data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the generic drug or biosimilar as part of their AMP reporting responsibilities under section 1927(b)(3)(A) of the Act, and the trend in reporting of such AMP units. CMS reserves the right to also use other available data and informational sources on market share and

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requirements; *See also:* Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax, available at https://www.irs.gov/pub/irs-drop/n-23-52.pdf. *See also:* Excise Tax on Designated Drugs; Notice of Proposed Rulemaking, available at https://www.federalregister.gov/documents/2025/01/02/2024-31462/excise-tax-on-designated-drugs.

relative market competition of the generic drug or biosimilar, for example, but not limited to, the sources included in section 70 of this draft guidance. CMS requested comments on the review of specific additional sources in section 30.1 of this draft guidance.

100. Civil Monetary Penalties

In accordance with section 1197 of the Act, Primary Manufacturers of selected drugs that enter into an Agreement may be subject to CMPs for: (1) failure to ensure access to a price that is less than or equal to the MFP, as described in section 40.4 of this guidance, for MFP-eligible individuals and pharmacies, mail order services, and other dispensing entities and to hospital, physicians or other providers of services or suppliers that dispense, furnish or administer the selected drug with respect to MFP-eligible individuals; (2) failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act; (3) violation of certain terms of the Agreement; and (4) the provision of false information as described in section 1197(d) of the Act.

CMS' primary goal is to successfully administer all aspects of the Negotiation Program; CMS intends to exercise the authority to impose CMPs for instances of noncompliance that substantively obstruct Negotiation Program processes and/or availability of the MFP. Such instances may include, but are not limited to, the examples shown in Table 10 below, such as failure to make the MFP available to MFP-eligible individuals; failure to provide timely, complete, and accurate information that is necessary to execute the negotiation process or other administrative or monitoring functions of the Negotiation Program; repeated violations of the Agreement or other Negotiation Program requirements; or egregious and/or knowing violations of Negotiation Program requirements. Note that these examples are not an exhaustive list of violations that could warrant CMPs. CMS reserves the authority to issue CMPs for other violations as required to effectively administer and monitor the Negotiation Program.

Table 10: Examples of Substantive Violations

Category	Example of Substantive Violations
Violations of the Agreement	• Failure to submit data required under section 1194(e)(1) of the Act, including failure to engage in requested corrective action to mitigate such failures. • Omission or inaccuracy of manufacturer-submitted information that is critical to the negotiation and/or renegotiation processes (e.g., non-FAMP data from the Primary Manufacturer, including non-FAMP data for a selected drug sold by any Secondary Manufacturer(s), required for ceiling calculation) or other efforts to administer or monitor the Negotiation Program (e.g., reporting new NDC-11s, information requested during an audit), including failure to engage in requested corrective action to mitigate such omissions or inaccuracies. • Failure to meet the MTF reporting requirements (see section 40.4) within the 14-day prompt MFP payment window. • Failure to enroll in the MTF DM (see section 40.4.2).

Category	Example of Substantive Violations
	• Failure to submit a plan for making the MFP available (see section 90.2.1). • Submission of false information that interferes with the negotiation process (e.g., submission of false data on unit costs of production or research and development costs). • Knowing submission of false information to CMS for use in applying the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception. • Knowing provision of false information to CMS for use in applying the aggregation rule in section 1192(f)(1)(C) of the Act of the Biosimilar Delay. • Failure to submit data requested by CMS in accordance with its oversight responsibilities under section 1196(b) of the Act. • Failure to provide information required as part of the renegotiation process (see section 130.3)
MFP Availability	• Failure to make the MFP available to MFP-eligible individuals, and to pharmacies, mail order services, or other dispensing entities, and, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, hospitals, physicians and other provider of services and suppliers (see section 100.1). • Failure to process timely and complete reimbursement under a retrospective reimbursement structure (see section 40.4).
Biosimilar Delay Rebates	• Failure to pay a biosimilar delay rebate by the deadline established by CMS in future rulemaking.

Broadly, CMS is establishing a structure for enforcement actions that:

1. Is within CMS' statutory authority;
2. Is not punitive in response to immaterial noncompliance, or other instances of noncompliance that are not substantive;
3. Can be applied consistently across applicable instances of Primary Manufacturer noncompliance; and
4. Facilitates the ability to successfully engage in all components of the negotiation process within the established statutory timeframes.

This 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 for the SBE and the Biosimilar Delay. CMS provides details about the process for CMP imposition in section 100.5 of this draft guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP in 2026, 2027, and 2028

In accordance with section 1197(a) of the Act, CMS may impose a CMP on a Primary Manufacturer of a selected drug that has entered into an Agreement with CMS upon failure to

provide access to a price that is less than or equal to the MFP to MFP-eligible individuals dispensed the selected drug and to dispensing entities, or, beginning in 2028, for drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, Part B providers with respect to MFP-eligible individuals who are furnished or administered the selected drug. This includes failure to provide access to a price that is less than or equal to the MFP in connection with sales of the selected drug by a Secondary Manufacturer.

As described in section 40.4 of this 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 and, starting in 2028 as applicable, the Part B provider when acquiring the drug, is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's, and starting in 2028 as applicable, the Part B provider's, acquisition cost and the MFP. Although CMP liability may be imposed if a Primary Manufacturer fails to provide such access to the MFP, the statute does not obligate a Primary Manufacturer to make sales of selected drugs. Upon discovery and confirmation of a failure to make the MFP available, CMS intends to send the Primary Manufacturer a Notification of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS intends to establish a process in which the Primary Manufacturer will have 10 business days to respond to the Notice of Potential Noncompliance to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration. CMS intends to consider the materials provided by the Primary Manufacturer when determining the Primary Manufacturer's CMP liability, including any technical failures outside the control of the Primary Manufacturer related to the transmission of payment.

If the Primary Manufacturer fails to ensure access to a price less than or equal to the MFP, the statute provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed, furnished, or administered (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals or dispensing entities and, beginning in 2028 as applicable, Part B providers that dispense, furnish, or administer the selected drug with respect to MFP-eligible individuals and the MFP for such drug for such year. For the purposes of calculating this CMP, CMS will use the amount that is equal to the required pass through of the MFP described in section 40.4 of this final guidance. As described in sections 40.5 and 90.2 of this draft guidance, CMS intends to 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. CMS is soliciting comments on considerations the agency should take into account when calculating CMPs in this circumstance, including on factors related to accurately capturing the price made available to dispensing entities given complexities in the drug acquisition process and acquisition pricing schemas.

In an instance where an updated MFP is reached through renegotiation as described in section 130 of this draft guidance, CMS may impose a CMP if the Primary Manufacturer fails to make the renegotiated MFP available in accordance with sections 40.4 and 130 of this draft guidance. The calculation for this CMP would follow the same formula established above, i.e., a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed, furnished, or administered (during such year) and the difference between the price for

such drug made available to the MFP-eligible individual, the dispensing entity or Part B provider and the renegotiated MFP for such drug for such year.

100.2 Violations of the Agreement

Pursuant to section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS under section 1193 of the Act that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program pursuant to section 1193(a)(5) of the Act or fails to provide the information required under section 1193(a)(4) of the Act, including data required to carry out the renegotiation process (see section 130.3 of this draft guidance), may be subject to a statutorily-specified CMP for each day of such violation. The amount of $1,059,232 a day is applicable for any CMP that may be assessed under this provision in 2025 and will be updated yearly per the Federal Civil Penalties Inflation Adjustments Improvements Act of 2015.[114] In applying CMPs for Primary Manufacturer violations of the Agreement, CMS intends to use discretion such that CMPs are reserved for instances of substantive noncompliance.

One example of when CMS may impose a CMP is if a Primary Manufacturer fails to provide data required under the Drug Price Negotiation ICR Forms, such as information on non-FAMP for each applicable quarter (as described in section 50.1.1 of this draft guidance) for each NDC-11 of the selected drug for the applicable period, by March 1, 2026 for initial price applicability year 2028. In this example, when the Primary Manufacturer failed to submit timely non-FAMP, CMS would engage in outreach that would include a Request for Corrective Action Plan to address the failure and a Violation Notice. If the issue is not mitigated following this outreach and corrective action process, CMS may choose to assess a CMP. In a case where a CMP is pursued, CMS intends to send a written CMP Notification that reflects the number of days in which the Primary Manufacturer is in violation of the Agreement, which may initiate on the day after the applicable submission deadline (e.g., March 2, 2026) depending on the manufacturer's engagement in corrective action. The CMP will accrue for each day of the violation thereafter until the day the Primary Manufacturer demonstrates compliance and provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. The CMP will not include the day 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 plans to adopt the same approach to enforcement in a circumstance where a Primary Manufacturer failed to provide data for a drug

[114] This CMP amount, set forth in the statute as $1,000,000 is updated to reflect required annual inflation-adjusted increases to civil money penalty amounts under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of P.L. 114-74) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (P.L. 401-410, 104 Stat 890 (1990)), which is intended to improve the effectiveness of civil monetary penalties (CMPs) and to maintain the deterrent effect of such penalties, requires agencies to adjust the CMPs for inflation annually. In accordance with the Office of Management and Budget (OMB) Memorandum for the Heads of Executive Agencies and Departments, M-25-02, "Implementation of Penalty Inflation Adjustments for 2025, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015," the cost of living multiplier for 2025 is 1.02598.

selected for renegotiation, with a violation accruing each day after the deadline established for provision of the data (see section 130 of this draft guidance) until the Primary Manufacturer provided the data. In the event the Primary Manufacturer never provides the required data, the CMP will continue to accrue until the end of the renegotiation process (i.e., the final deadline for reaching an agreed upon renegotiated MFP). Upon reaching that deadline, certain sales of the selected drug may be subject to a potential excise tax as the result of the Primary Manufacturer failing to reach an agreed-upon renegotiated MFP (see 26 U.S.C. § 5000D(b)(3)). The imposition of a CMP related to failure to provide required data for the renegotiation process does not negate the Primary Manufacturer's ongoing obligation to provide access to the previously negotiated MFP. Primary Manufacturers continue to have the obligation to make the previously negotiated MFP available and may be assessed a CMP under section 100.1 of this draft guidance for failure to do so, until a renegotiated MFP takes effect.

Another example of when CMS may impose a CMP for violation of the Agreement is if the Primary Manufacturer submits information that is required under the Agreement and CMS determines the information is false. In this example, the Primary Manufacturer will be determined to be noncompliant with the requirement to submit information and may be subject to a CMP. In instances of a Primary Manufacturer submitting false information that is required under the Agreement, CMS intends to determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the established deadline for submission of information under the Agreement as the first day of violation, with each additional day of violation thereafter counted until the day the Primary Manufacturer provides a complete and accurate submission of the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. The start and end date of CMP accrual as well as the total amount accrued will be noted on the CMP Notification sent by CMS, following the process established in section 100.5 of this draft guidance.

100.3 Provision of False Information Related to the SBE and the Biosimilar Delay

In accordance with section 1197(d) of the Act, if CMS determines that any manufacturer knowingly provides false information to CMS for use in applying the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception, such manufacturer may be subject to a statutorily-specified CMP for each item of such false information. Likewise, if CMS determines that any Biosimilar Manufacturer knowingly provides false information to CMS for use in applying the aggregation rule in section 1192(f)(1)(C) of the Act for the Biosimilar Delay, such manufacturer may be subject to a statutorily-specified CMP for each item of such false information. The amount of $105,923,201 per item is applicable for any CMP assessed in 2025 and will be updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.[115]

CMS adopts a standard for "knowingly" that conforms with the Office of Inspector General definition at 42 C.F.R. § 1003.110 in the application of other CMPs. Knowingly means that a manufacturer, for purposes of section 1197(d) of the Act for the Small Biotech Exception or a Biosimilar Manufacturer under section 1192(f)(1)(c) of the Act for the Biosimilar Delay: (1) has

[115] The CMP amount authorized by section 1197(d) of the Act is set forth in the statute as $100,000,000 and is updated to reflect required annual inflation-adjusted increases to civil money penalty amounts under the Federal Civil Penalties Inflation Adjustments Act Improvements Act of 2015.

actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. Upon identifying instances of knowing submission of false information under either of these provisions, CMS intends to provide the Manufacturer with a CMP Notification detailing the final CMP amount and the basis for that amount, requesting payment, outlining the payment process, outlining the available appeals process, and establishing applicable deadlines for resolution.

100.4 Failure to Pay a Biosimilar Delay Rebate

Where a Manufacturer, pursuant to section 1192(f)(4) of the Act and section 30.3.1.5 of this draft guidance, owes a rebate to CMS on the basis of a biological product for which inclusion on the selected drug list was delayed and with respect to which the biosimilar product that was the subject of the successful Initial Delay Request or Additional Delay Request has failed to be licensed or marketed, and the Manufacturer fails to pay the rebate by the deadline, to be established by CMS in future rulemaking, in accordance with section 1197(b) of the Act, the Manufacturer may be subject to a CMP equal to 10 times the amount of the rebate the Manufacturer failed to pay. When CMS makes a determination to assess a CMP under this section of the Act, CMS intends to follow the procedures established in section 100.5 of this draft guidance.

100.5 Notice and Appeal Procedures

Where CMS makes a determination to assess a CMP, CMS intends to provide a written CMP Notification that the manufacturer has engaged in a substantive compliance violation and is subject to a CMP. As required by section 1128A of the Act, the CMP Notification will include the following:

- A description of the basis for the determination;
- The basis for the penalty;
- The start date of the penalty (if applicable);
- The end date of the penalty (if applicable);
- The total amount of the penalty assessed;
- Instructions for submitting the CMP payment;
- The Primary Manufacturer's right to a hearing (see below); and
- Information about where to file the request for a hearing.

In the case of violations associated with CMPs with daily accruals (e.g., failure to provide required information as described in section 100.2 of this draft guidance), CMS intends to send the CMP Notification after the noncompliance has ended in order to reflect both the start date, end date, and total amount of penalty assessed within the notice as required by section 1128A of the Act.

Per section 1128A of the Act, CMPs are due 60 calendar days after the receipt of the CMP Notification, unless the Primary Manufacturer chooses to initiate an appeal. At the conclusion of any appeal process initiated by the Primary Manufacturer, where there is still a CMP amount owed, the CMP is due within 60 calendar days of the appeal decision. CMS intends to send a reminder notice to the Primary Manufacturer, including the date the penalty is due and will restate the instructions for submitting the CMP payment.

To operationalize the CMP appeal process in the Negotiation Program, CMS is adopting the existing procedures as codified in C.F.R. Part 423 Subpart T: Appeal Procedures for Civil Money Penalties (see § 423.1000 through § 423.1094) that currently apply to Part D sponsors and to manufacturers under the Manufacturer Discount Program. Pursuant to this appeals process, the manufacturer will have 60 calendar days from the date of receipt of the CMP Notification to request a hearing (§ 423.1020). The date of receipt is defined as the calendar day following the day on which the CMP Notification is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by 42 C.F.R. Part 423 Subpart T will apply. As set forth in section 1128A(f) of the Act, if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds will be deposited in accordance with section 1128A(f) of the Act.

110. Part D Formulary Inclusion of Selected Drugs

In accordance with section 1860D-4(b)(3)(I) of the Act, and except as permitted under section 1860D-4(b)(3)(I)(ii) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies during contract year 2026, if an MFP is in effect for that drug with respect to that year, and during each subsequent year for which the MFP of the selected drug is in effect during the price applicability period. Section 1860D-4(b)(3)(I)(ii) of the Act specifies that nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation).[116]

For contract year 2028, CMS will continue the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 and final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 (described further below in this section). At this time, CMS does not have sufficient information to determine whether changes to these formulary inclusion policies are warranted. The formulary inclusion requirement in section 1860D-4(b)(3)(I) of the Act has not taken effect yet, and plan sponsors will not submit their formularies for the first contract year in which MFPs are in effect (i.e., contract year 2026) until June 2, 2025. For these reasons, CMS will continue monitoring Medicare Part D plans' compliance with all applicable formulary requirements and treatment of drugs and may further address formulary inclusion policies in the future.

Because the selected drug includes all dosage forms and strengths to which the MFP applies for initial price applicability year 2028, the statute requires that formularies include all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. For contract year 2028, CMS will not implement explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies but will apply the process described below.

[116] See section 110.1 for additional detail related to the identification of the successor regulation to § 423.120(b)(5)(iv) for purposes of the exception to the formulary inclusion requirement for selected drugs in section 1860D-4(b)(3)(I)(ii) of the Act.

CMS understands that not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics Committees with the same formulary considerations and the same formulary placement might not be warranted in all situations. However, CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.

CMS reminds Part D sponsors of the existing statutory and regulatory restrictions on formulary design. Sections 1860D-2(b)(2)(B) and 1860D-4(c)(1)(A) of the Act permit Part D sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and require them to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate. Under section 1860D-11(e)(2)(D)(i) of the Act, CMS may approve a prescription drug plan only if the agency "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." In addition, § 423.272(b)(2)(i) states: "CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Further, § 423.120(b)(2)(iii) requires each Part D plan formulary to "include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines." In addition, § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must "base clinical decisions on the strength of scientific evidence and standards of practice." CMS maintains a robust clinical formulary review process to ensure that all Medicare Part D plans meet these and other applicable requirements. CMS reviews all formularies annually to ensure that each formulary meets the agency's clinical review criteria, which include comprehensive evaluation of tier placement and all utilization management restrictions and criteria.

Given CMS' statutory obligation to monitor Medicare Part D plans' compliance with all applicable formulary requirements, CMS will use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (e.g., step therapy and/or prior authorization) for a selected drug compared to a non-selected brand drug in the same class.

For this review, CMS will consider class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action. Specifically, as part of the contract year 2028 Part D formulary review and approval process, CMS will expect Part D sponsors to provide a reasonable justification to support the submitted plan benefit design and formulary design that includes any of the practices noted above during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan

design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D sponsor only if the plan benefit design and formulary design complies with those requirements.

CMS is aware that there are concerns that Part D plan sponsors could broadly shift access with respect to a drug selected for negotiation after the drug has been announced as a selected drug, i.e., in the contract year prior to the selected drug's MFP taking effect. While CMS did not see this occur in contract year 2025 with respect to selected drugs for initial price applicability year 2026, CMS will continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year (e.g., contract years 2026, 2027, 2028, and each additional year in the selected drug's price applicability period, if an MFP is in place with respect to that year).

110.1 Formulary Inclusion Exception Successor Regulation for 2027 and 2028

Section 1860D-4(b)(3)(I)(ii) of the Act specifies that nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) (or any successor regulation). As described in the Final CY 2026 Part D Redesign Program Instructions, issued on April 7, 2025, CMS identified § 423.120(e)(2)(i), and the corresponding notice requirements at § 423.120(f)(2), (3), and (4), as the successor regulation.[117] Under § 423.120(e)(2)(i), Part D sponsors may, as an immediate substitution, remove a selected drug from the formulary and replace it with a new generic or interchangeable biological product of the selected drug if such sponsor meets the regulatory notice and timing requirements. Specifically, any such substitution of a selected drug would be subject to the timing requirements specified in § 423.120(e)(2)(i) and notice requirements specified in § 423.120(f)(2), (3), and (4). CMS will incorporate section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extend the policies therein to 2027 and 2028.

Section 70 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, and this draft guidance specify that, in accordance with section 1192(c)(1) of the Act, a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) of the Act are met. For example, CMS stated in the revised guidance for initial price applicability year 2026 that if CMS makes this determination between April 1, 2026 and March 31, 2027 for a drug selected for initial price applicability year 2026, then the selected drug will cease to be a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027.

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[117] See Final CY 2026 Part D Redesign Program Instructions (April 7, 2025), available at https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf. CMS notes that prior to finalizing this policy, CMS voluntarily solicited public comment through the Draft CY 2026 Part D Redesign Program Instructions, issued on January 10, 2025, available at https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf.

As CMS stated in the Final CY 2026 Part D Redesign Program Instructions, a Part D sponsor is permitted to remove the selected drug from its formulary for the remainder of 2026, if such removal meets the requirements specified in § 423.120(e)(2)(i) and the notice requirements specified in § 423.120(f)(2), (3), and (4). Additionally, in accordance with section 1192(c) of the Act and section 70 of the revised guidance for initial price applicability year 2026, CMS may make a determination with respect to such selected drug that the statutory criteria in section 1192(c) of the Act have been met. For the purposes of this example, if such a determination were made between April 1, 2026 and December 31, 2026, then the MFP for such selected drug would continue to apply through 2027. CMS is clarifying here that removals under the formulary inclusion exception cannot be carried over to subsequent years within the price applicability period simply because a selected drug was removed in a preceding year during the price applicability period. Instead, any removal must independently meet the immediate substitution requirements for each plan year because, consistent with CMS' longstanding policy, CMS considers each plan year's formulary to be separate and distinct from the prior year. Therefore, a removal could only apply to multiple plan years in a price applicability period if it independently meets the immediate substitution requirements for each applicable plan year. For example, removal in accordance with section 1860D-4(b)(3)(I)(ii) of the Act of the selected drug in its price applicability period from a formulary could apply to 2026 and 2027 plan years if the requirements under § 423.120(e)(2)(i) and § 423.120(f)(2), (3), and (4) permitting immediate substitutions are met with respect to both 2026 and 2027.

120. Application of Medicare Part B and Part D Drug Inflation Rebate Programs to Selected Drugs

This section of the guidance describes the application of Medicare Part B and Part D drug inflation rebates to selected drugs. As background, section 11101 of the IRA added a new section 1847A(i) to the Act to require that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Likewise, section 11102 of the IRA added a new section 1860D-14B to the Act, which requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare for certain Part D rebatable drugs based on specific requirements and formulas.[118]

The Medicare Part B and Part D Drug Inflation Rebate Programs apply to selected drugs, regardless of the status of the drug as a selected drug. Alternatively said, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Medicare Part B and Part D Drug Inflation Rebate Programs, as applicable. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated as discussed further below.

The Medicare Part B Drug Inflation Rebate Program is applicable to certain drugs that meet the definition of a Part B rebatable drug and are furnished or administered under Part B and paid under Part B for each calendar quarter, starting with the applicable calendar quarter beginning

[118] See: https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other.

January 1, 2023. These rebates are paid by manufacturers to the Federal Supplementary Medical Insurance Trust Fund.

The Part B drug inflation rebate calculation is based on changes in the lower of ASP or WAC over time.[119]

The statutory formula to determine the Part B drug inflation rebate amount owed by manufacturers for each Part B rebatable drug consists of various components, including the calculation of an "inflation-adjusted payment amount." The inflation-adjusted payment amount for a Part B rebatable drug for an applicable calendar quarter is calculated by dividing the rebate period CPI-U by the benchmark period CPI-U and multiplying the quotient by the payment amount in the payment amount benchmark quarter. The "payment amount in the payment amount benchmark quarter" is calculated based on the published payment limit for the billing and payment code in the "payment amount benchmark quarter" for each Part B rebatable drug as established at section 1847A(i)(3)(D) of the Act for drugs first approved or licensed on or before December 1, 2020, and at section 1847A(i)(4)(A) of the Act for drugs first approved or licensed after December 1, 2020. The "benchmark period CPI-U" for a Part B rebatable drug is established at section 1847A(i)(3)(E) of the Act for drugs first approved or licensed on or before December 1, 2020, and at section 1847A(i)(4)(A) for drugs first approved or licensed after December 1, 2020. These definitions are codified at 42 C.F.R. § 427.20.

For each applicable calendar quarter before a Part B rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part B drug inflation rebate amount (which may equal $0) based on the Part B rebatable drug's payment amount benchmark quarter and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, the statute at section 1847A(i)(4)(C) of the Act specifies a different "payment amount benchmark quarter" and a "benchmark period CPI-U" for each Part B rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part B rebatable drug is no longer a selected drug, the payment amount benchmark quarter is reset as the calendar quarter beginning January 1 of the last year during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the July of the year preceding such last year beginning during such price applicability period. Identification of the payment amount benchmark quarter and identification of the benchmark period CPI-U are codified at 42 C.F.R. § 427.302(c) and (e), respectively.

The Medicare Part D Drug Inflation Rebate Program is applicable to certain drugs that meet the definition of a Part D rebatable drug and are dispensed under Part D and covered by Part D plan sponsors for each 12-month applicable period, starting with the applicable period beginning October 1, 2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

[119] The calculation of the Part B rebate amount is codified at 42 C.F.R. § 427.301.

The Part D drug inflation rebate calculation is based on changes in the AMP over time.[120] MFP is excluded from AMP and thus does not affect the rebate calculation.[121]

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) of the Act for drugs first approved or licensed after October 1, 2021. The "benchmark period CPI-U" for a Part D rebatable drug is established at section 1860D-14B(g)(4) of the Act for drugs first approved or licensed on or before October 1, 2021, and at section 1860D-14B(b)(5)(A) of the Act for drugs first approved or licensed after October 1, 2021. These definitions are codified at 42 C.F.R. § 428.20.

For each applicable period before a Part D rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part D drug inflation rebate amount (which may equal $0) based on the Part D rebatable drug's payment amount benchmark period and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, section 1860D-14B(b)(5)(C) of the Act specifies a different payment amount benchmark period and benchmark period CPI-U for a Part D rebatable drug in the case where such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period will be reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U will be the January of the last year beginning during such price applicability period. Identification of the payment amount benchmark period and identification of the benchmark period CPI-U are codified at §§ 428.202(c) and (e), respectively.

130. Renegotiation of a Maximum Fair Price for Initial Price Applicability Year 2028

Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs, the selection of drugs for renegotiation, and the renegotiation process. CMS will identify renegotiation-eligible drugs in accordance with section 1194(f)(2) of the Act, as described in section 130.1 of this draft guidance. Next, CMS will select certain

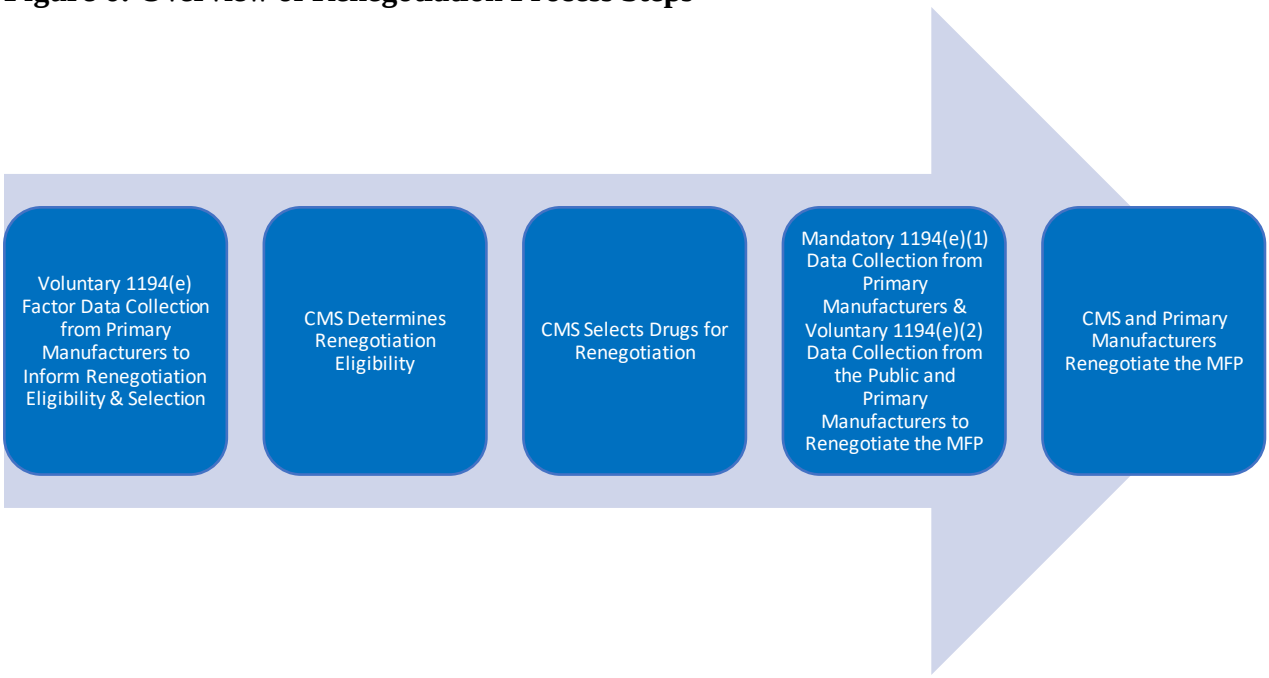
[120] Section 1860D-14B(g)(6) of the Act defines AMP to have the meaning, with respect to a Part D rebatable drug of a manufacturer, given in section 1927(k)(1) with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Section 1927(k)(1) defines AMP, with respect 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.

[121] Section 1927(k)(1)(B)(i)(VI), as amended by section 11001(b)(3) of the IRA.

renegotiation-eligible drugs for renegotiation in accordance with section 1194(f)(3) of the Act, as described in section 130.2 of this draft guidance. Finally, CMS will renegotiate MFPs for such drugs selected for renegotiation, in accordance with section 1194(f)(4) of the Act, as described in section 130.4 of this draft guidance. Figure 6 depicts an overview of this process.

CMS notes that renegotiation is a component of the Negotiation Program. A Primary Manufacturer that has an Agreement in effect, as discussed in section 40 of this draft guidance, will be required to adhere to the process and deadlines described in this section 130 of this draft guidance as well as previous sections. For example, the policies described in sections 40.5, 90, and 100 of this draft guidance are applicable to renegotiation. The renegotiation process will conclude with an agreed-upon MFP (the "renegotiated MFP"), unless the Primary Manufacturer chooses not to participate or chooses not to agree upon a new MFP. To meet their MFP effectuation obligations, Primary Manufacturers must make the initial agreed-upon MFP available as set forth in section 40.4 of this draft guidance, for all dispenses on or before December 31, 2027 (including based on any claim adjustments to previously processed claims); and Primary Manufacturers must make the renegotiated MFP available, if applicable, as set forth in section 40.4 of this draft guidance, when their selected drug is dispensed, furnished, or administered to MFP-eligible individuals on or after January 1, 2028.

Figure 6: Overview of Renegotiation Process Steps



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

Section 1194(f)(2) of the Act establishes the definition of a "renegotiation-eligible drug" as a selected drug for which (1) a new indication is added to the drug; (2) the drug monopoly status was not that of an extended-monopoly or a long-monopoly drug and changes to that of an extended-monopoly drug; (3) the drug monopoly status was not that of a long-monopoly drug; and changes to that of a long-monopoly drug; or (4) the Secretary determines there has been a

material change to any section 1194(e)(1) or (e)(2) factor. In accordance with section 1198(4) of the Act, there will be no administrative or judicial review of CMS' determinations of renegotiation-eligible drugs under section 1194(f)(2) of the Act and the selection of renegotiation-eligible drugs under section 1194(f)(3) of the Act.

In accordance with section 1194(f)(1) of the Act, CMS will review selected drugs from initial price applicability years 2026 and 2027 for renegotiation eligibility in initial price applicability year 2028. CMS interprets section 1194(f)(1) of the Act to mean that the Secretary must provide for a process of renegotiation for years during the selected drug's price applicability period. Because calendar year 2028 will be a year within the price applicability period for drugs selected for initial price applicability years 2026 and 2027, such selected drugs may be eligible for renegotiation in calendar year 2026 (i.e., for initial price applicability year 2028) and may be selected for renegotiation if certain criteria are met (as discussed in sections 130.1 and 130.2 of this draft guidance). Renegotiation eligibility will be based on the four eligibility categories in section 1194(f)(2) of the Act and as described in sections 130.1.1 through 130.1.4 of this draft guidance.

As a matter of operations, first, CMS will identify selected drugs which are renegotiation-eligible due to a change in monopoly status. Then, CMS will review the remaining selected drugs and identify those for which a new indication has been added. Next, CMS will review the remaining selected drugs (excluding those which are already eligible due to a change in monopoly status or the addition of a new indication) for a material change in any section 1194(e) factor. CMS' approach to a selected drug that becomes renegotiation-eligible more than once over multiple renegotiation cycles will be discussed in future rulemaking.

Selected drugs negotiated in initial price applicability years 2026 and 2027 were limited to those covered under Part D per section 1192(d)(2)(A) of the Act. For purposes of initial price applicability year 2028, CMS does not expect Primary Manufacturers to provide access to the MFP of a selected drug negotiated for initial price applicability years 2026 or 2027 to Part B providers for Part B utilization with respect to a drug furnished or administered to MFP-eligible individuals and payable under Part B; rather we anticipate that selected drugs from initial price applicability years 2026 and 2027 with Part B utilization are likely to be determined to be renegotiation-eligible drugs, pursuant to section 1194(f)(2) of the Act and as discussed in this section 130.1 of the draft guidance; selected for renegotiation, pursuant to section 1194(f)(3) of the Act and as discussed in section 130.2 of the draft guidance; and there is an agreed-upon renegotiated MFP. For such renegotiation-eligible drugs that are selected for renegotiation and for which a renegotiated MFP is agreed upon, the renegotiated MFP will apply for initial price applicability year 2028 and will apply to claims payable under Part B and dispenses covered under Part D, as applicable. For drugs selected for renegotiation for initial price applicability year 2028, any renegotiated MFP will apply to all formulations across dosage forms and strengths of the selected drug, which will include when the selected drug is payable under Part B only, covered under Part D only, and when the drug is payable under Part B and covered under Part D.

130.1.1 Selected Drugs for Which There is a Change in Status to an Extended-Monopoly Drug
Section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer

has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030 from the definition of an "extended-monopoly drug."[122] CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for initial price applicability year 2028, and therefore no selected drug will have a monopoly status change to extended-monopoly for purposes of renegotiation-eligibility under section 1194(f)(2)(B) of the Act.

130.1.2 Selected Drugs for Which There is a Change in Status to a Long-Monopoly Drug
Section 1194(c)(5) of the Act defines a long-monopoly drug as, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term "long-monopoly drug" does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section. To meet the definition of a long-monopoly drug for initial price applicability year 2028, the first approval date under section 505(c) of the FD&C Act or the earliest licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients)[123] must be on or before January 1, 2012 (see Table 7 in section 60.2.3 of this draft guidance for more information on monopoly types). Therefore, in accordance with section 1194(f)(2)(C) of the Act, a selected drug that meets this definition and that did not qualify as a long-monopoly drug when the drug was selected for negotiation will be determined to be renegotiation-eligible due to a change in status to a long-monopoly drug.

130.1.3 Selected Drugs for Which a New Indication is Added
Section 1194(f)(2)(A) of the Act identifies a selected drug for which a new indication is added as a renegotiation-eligible drug. For consistency with CMS' approach to identifying indications for selected drugs during the negotiation process (as described in section 60.3.1 and as further defined in Appendix A of this draft guidance), CMS will consider an "indication" to be the condition or disease state that the selected drug treats.

As described in section 130.3.1 of this draft guidance, CMS will collect voluntary information submissions from Primary Manufacturers of selected drugs to inform renegotiation drug eligibility and selection.

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[122] Section 1194(c)(4)(A) of the Act defines an extended-monopoly drug, for an initial price applicability year, as "a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable," excluding vaccines licensed and marketed per section 351 of the PHS Act as described in section 1194(c)(4)(B) of the Act. See sections 30.1 and 60.2.3 of this draft guidance for more information about extended-monopoly drugs.

[123] As noted in section 30.1 of this draft guidance, for biological products whose applications were previously submitted as NDAs and approved under section 505 of the FD&C Act but subsequently deemed to be approved biologics license applications (BLAs) under section 351 of the PHS Act, effective March 23, 2020, pursuant to section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

To identify whether a new indication has been added to the FDA approved labeling[124] for a selected drug, CMS will use publicly available information from the Drugs@FDA database and relevant databases maintained by the Center for Biologics Evaluation and Research.[125] CMS will also review voluntary submissions from Primary Manufacturers. CMS will deem a drug renegotiation-eligible based on the addition of a new indication if the FDA approved labeling has been updated to include treatment or prevention of a new disease or condition.[126] Conversely, CMS will not deem a selected drug to be renegotiation-eligible under section 1194(f)(2)(A) of the Act based on FDA labeling updates within a previously indicated disease or condition. This approach complements the requirement in section 1194(f)(2)(D) of the Act for CMS to consider any material change in a section 1194(e)(2) factor, which includes "prescribing information" (see section 1194(e)(2)(B) of the Act). As part of that inquiry, CMS will review the FDA-approved labeling for a material change in prescribing information per section 130.1.4 of this draft guidance and, in doing so, would also capture the impact of labeling updates within a previously indicated disease or condition during such review (e.g., expansion of an existing indication to include an additional age group(s)). That is, labeling updates within a previously indicated disease or condition will not be regarded as a "new indication" for renegotiation eligibility under section 1194(f)(2)(A) of the Act, but will be considered as part of the review of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act, as discussed in section 130.1.4 of this draft guidance.

CMS will review off-label uses when identifying indications for renegotiation eligibility and selection if the Primary Manufacturer of a selected drug submits the off-label use through the voluntary information submission process. CMS will apply the standards outlined in section 60.3.1 of this draft guidance when reviewing an off-label use submitted by a Primary Manufacturer for consideration as a new indication for the purpose of renegotiation eligibility. That is, CMS will only consider an off-label use when identifying indications for purpose of renegotiation eligibility under section 1194(f)(2)(A) of the Act if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. Should a Primary Manufacturer of a selected drug decide to submit information about off-label use of the selected drug, through this process, the Primary Manufacturer should indicate in their submission if the referenced off-label use is included in evidence-based clinical practice guidelines, and if the off-label use is a medically-accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical

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

[125] Available at www.fda.gov/drugsatfda, https://www.fda.gov/vaccines-blood-biologics/cber-regulated-products-supporting-documents, and https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year.

[126] CMS clarifies that "new" in the renegotiation context means not considered in the negotiation process to achieve an agreed upon MFP. For example, in the event CMS previously considered an off-label use during negotiation because such off-label use was , at that time, included in evidence-based clinical practice guidelines and considered to be a medically-accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice, and then the Primary Manufacturer received FDA approval for that off-label use, CMS would not consider the now on-label use to be a new indication in accordance with section 1194(f)(2)(A) of the Act.

literature, and/or accepted standards of medical practice. New off-label uses identified in a voluntary submission from a Primary Manufacturer for a selected drug within a previously indicated disease or condition will not be regarded as a "new indication" for renegotiation eligibility under section 1194(f)(2)(A) of the Act, but will be considered as part of the review of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act, as discussed in section 130.1.4 of this draft guidance.

130.1.4 Selected Drugs for Which There is a Material Change in a Section 1194(e) Factor
Section 1194(f)(2)(D) of the Act directs CMS to identify a selected drug for which there has been a material change to any factor listed in section 1194(e) as a renegotiation-eligible drug and provides CMS with the discretion to determine what constitutes a "material change."

CMS will consider a change to a section 1194(e) factor for a selected drug to be material if the change would reasonably be expected to impact CMS' holistic consideration of the (e)(1) or (e)(2) factors collectively, by meaningfully increasing or decreasing the adjustment for section 1194(e)(1) factors and/or section 1194(e)(2) factors during initial offer development by CMS for renegotiation and/or, had such changes to a section 1194(e) factor been present in the prior completed negotiation, they would have meaningfully changed the negotiation process (i.e., subsequent offers or counteroffers) (see section 60.3 of this draft guidance regarding initial offers and section 60.4 regarding negotiation process). Table 11 provides a few illustrative examples of this approach.

Table 11: Illustrative Example Scenarios and Potential Result in Determination of Material Change

Example Scenario	Potential Result
New clinical data is released showing increased clinical value for a greater number or new group of individuals who are prescribed a drug.	*Within the context of other section 1194(e)(2) information*, CMS determines this new data would likely meaningfully impact the section 1194(e)(2) adjustment. Therefore, this would be considered a material change.
Unit cost of production and distribution increases from $1.00 per unit to $1.50 per unit.	*Within the context of other section 1194(e)(1) factors*, CMS determines this change would not likely meaningfully impact the section 1194(e)(1) adjustment. Therefore, this would not be considered a material change.
New clinical data is released showing increased clinical value; two additional, less costly therapeutic alternatives come to market.	While the new clinical data would increase the section 1194(e)(2) adjustment, the availability of additional therapeutic alternatives would decrease the section 1194(e)(2) adjustment. The two changes might effectively cancel out one another. If so, *within the context of all section 1194(e)(2) factors*, the change would not be considered material.

CMS will review publicly available information pertaining to section 1194(e)(1) and section 1194(e)(2) factors to determine if there is a material change. CMS will also consider any

voluntary submission by a Primary Manufacturer of the information discussed in section 130.3.1 of this draft guidance.

130.2 Selection of Drugs for Renegotiation for Initial Price Applicability Year 2028

Section 1194(f)(3) of the Act directs CMS to select drugs for renegotiation from the identified renegotiation-eligible drugs (described in section 130.1 of this draft guidance). Sections 1194(f)(3)(A) and (B) of the Act require all drugs eligible for renegotiation due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug, as described in sections 130.1.1 and 130.1.2 of this draft guidance, be selected for renegotiation. Section 1194(f)(3)(C) of the Act requires that among the remaining renegotiation-eligible drugs (i.e., selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), CMS shall select renegotiation-eligible drugs for which CMS expects renegotiation is "likely to result in a significant change in the maximum fair price otherwise negotiated." Section 1194(f)(3)(C) provides CMS with the discretion to make determinations on when a renegotiation is "likely to result in a significant change" in the MFP. Further, in accordance with section 1198(4) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1194(f)(3) of the Act.

This section describes how CMS will approach making a determination about whether renegotiation is likely to result in a significant change in the MFP otherwise negotiated.

130.2.1 Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs due to a New Indication or a Material Change in a Section 1194(e) Factor

In accordance with section 1194(f)(3)(C) of the Act, CMS will select remaining renegotiation-eligible drugs (i.e., selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), for renegotiation if CMS expects renegotiation is "likely to result in a significant change" in the MFP. This applies to renegotiation-eligible drugs that are not automatically selected for renegotiation due to a change in monopoly status.

To determine whether renegotiation is likely to result in a significant change in the MFP, CMS will consider two criteria, as discussed in greater detail below. CMS' review of these two criteria will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug. First, CMS will consider the likelihood that the new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP upon engaging in renegotiation with the Primary Manufacturer. Second, CMS will consider whether such a change in the MFP for the renegotiation-eligible drug would have a significant impact on the Medicare Program. Importantly, CMS does not presume that the result of a renegotiation will reflect these approximations, rather, these criteria serve to support CMS in making a selection determination in alignment with the requirements set forth in section 1194(f)(3)(C) of the Act. CMS' review of these two criteria will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug, including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act, and will support CMS' determination of whether renegotiation is likely to result in a significant change to the MFP for the renegotiation-eligible drug. The scope of information considered may extend

beyond the scope of information reviewed for renegotiation eligibility to include a CMS-led review of the information sources discussed in section 50 of this draft guidance pertaining to section 1194(e)(1) and section 1194(e)(2) factors.

CMS will consider both of these criteria when determining whether a renegotiation-eligible drug will be selected for renegotiation and believes each of these criteria are of equal importance when considering whether renegotiation is likely to result in a significant change in the MFP otherwise negotiated. CMS believes that when considering drug selection for renegotiation from among renegotiation-eligible drugs, described above, such review will indicate that renegotiation is both likely to change the MFP and that the change in MFP will be significant, pursuant to section 1194(f)(3)(C) of the Act.

In establishing the first criterion (the likelihood that the new indication or material change would result in a renegotiated MFP, which would likely represent a 15 percent or greater change relative to the current MFP) CMS reviewed sections 1194(c)(3)(A) through (C) of the Act, which provide the applicable percentage of non-FAMP used to establish a ceiling during negotiation. The applicable percentages are 75 percent for short-monopoly drugs and vaccines, 65 percent for extended-monopoly drugs, and 40 percent for long-monopoly drugs (as described further in section 60.2 of this draft guidance).

Given that, under section 1194(c)(3)(A) through (C) of the Act, a change in monopoly status is associated with a percent reduction in the ceiling for negotiation and that such change in monopoly status of a selected drug results in selection for renegotiation, CMS believes this range of percent change is informative for deciding when renegotiation is likely to result in a significant and large enough change to the MFP to warrant CMS and the Primary Manufacturer investing the resources to renegotiate. For the first cycle of renegotiations for initial price applicability year 2028, CMS plans to select drugs for which renegotiation would likely result in a 15 percent or greater change in the MFP. This amount of change is consistent with the range of percent reductions in the ceiling that is statutorily defined for drugs selected for renegotiation due to monopoly status changes. Further, this criterion of considering the likelihood that the new indication or material change to a section 1194(e) factor would result in a renegotiated MFP that would represent a 15 percent or greater change relative to the current MFP can help provide clarity for when CMS may select remaining renegotiation-eligible drugs pursuant to section 1194(f)(3)(C) of the Act.

With regard to the second criterion for determining whether renegotiation is likely to result in a significant change in the MFP, CMS will consider the impact on the Medicare program of such a change in the renegotiated MFP. For example, if CMS determined there was a likelihood that the new indication or material change could result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP, CMS would consider the financial impact to the Medicare program and Medicare beneficiaries by reviewing associated changes in expenditures and beneficiary cost-sharing. In doing so, CMS seeks to incorporate consideration of whether such change in MFP warrants the time and resource investment by the Primary Manufacturers and CMS in the renegotiation process. As an example, consider a scenario where a selected drug becomes renegotiation-eligible and there was a likelihood that the percent change in the MFP would be greater than 15 percent. However, in this scenario patents on the selected drug will

have expired before a renegotiated MFP would take effect, and CMS determines that this patent expiration will likely result in the introduction of generic competition and therefore (1) a substantial price drop in the market price for the selected drug unrelated to a renegotiated MFP; and (2) the drug no longer being a selected drug on January 1, 2028 as it would no longer be single-source. As such, CMS would not select this hypothetical selected drug for renegotiation since the impact to the Medicare program would be minimal and does not warrant the considerable investment of time and resources by the Primary Manufacturer or CMS.

CMS will consider the totality of other available information to determine whether renegotiation is likely to result in a change in MFP of 15 percent or greater and that such change would have a significant impact on the Medicare program. This will include a preliminary review of the evidence available for a renegotiation-eligible drug. This holistic consideration of the available information and circumstances for renegotiation drug selection provides for the consideration of drug- and fact-specific circumstances. This approach also maintains consistency with CMS' process for developing the initial offer which considers the totality of available evidence as described in section 60.3 of this draft guidance.

CMS notes that no criteria to select drugs for renegotiation can predict the actual outcome of a renegotiation. A determination by CMS that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation. Any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in MFP, decrease in MFP, or no change in MFP. Further, the magnitude of the change in MFP could be higher or lower than 15 percent. Similarly, CMS does not presume that the result of a renegotiation will reflect these approximations, for example, with respect to the impact of a renegotiated MFP on the Medicare program. These criteria only serve to support CMS in making a selection determination in alignment with the requirements set forth in section 1194(f)(3)(C) of the Act.

Table 12 provides illustrative examples of how CMS may consider these criteria to determine whether a renegotiation-eligible drug will be selected.

Table 12: Illustrative Example Scenarios and Potential Result for Selection of Renegotiation-Eligible Drugs due to a New Indication or Change in a Section 1194(e) Factor

Example Scenario	Potential Result
New comparative clinical effectiveness data has become available that is favorable for the selected drug compared to therapeutic alternatives (e.g., a study is published showing the selected drug has a greater positive effect on clinical outcomes relative to therapeutic alternatives), but the ceiling* represents a <15% increase in the MFP.	It is not possible for renegotiation to result in a 15% increase in the MFP (because the ceiling* is less than 15% higher than current MFP), so the selected drug would not be selected for renegotiation.

Example Scenario	Potential Result
New comparative clinical effectiveness data has become available that is **unfavorable** for the selected drug compared to its therapeutic alternatives (e.g., a study is published showing the therapeutic alternative has a greater positive effect on clinical outcomes relative to the selected drug) and the MFP is much higher than competitors' prices. If such data were used during renegotiation with the Primary Manufacturer, the renegotiated MFP would likely **decrease** by 15% or more compared to the original MFP.	The selected drug would be selected for renegotiation if consideration of the other criterion supports the determination that renegotiation is likely to result in a significant change to the MFP.
New comparative clinical effectiveness data has become available that is **favorable** for the selected drug compared to therapeutic alternatives (e.g., a study is published showing the selected drug's therapeutic alternative has a greater positive effect on clinical outcomes relative to the selected drug), and the ceiling represents a >15% increase in the MFP. Upon renegotiating with the Primary Manufacturer, the renegotiated MFP would likely **increase** by 15% or more compared to the original MFP.	

*See section 130.4.1 of this draft guidance for additional detail on the ceiling that will be used for renegotiation

CMS also notes that renegotiation eligibility and selection will begin approximately 15 months after the end of the negotiation period for initial price applicability year 2026 selected drugs (August 1, 2024) and immediately after the end of the negotiation period for initial price applicability year 2027 (November 2025). Given this relatively short amount of time between the conclusion of negotiation and selection for renegotiation, CMS does not expect that it would be likely that renegotiation would result in a significant change to the agreed-upon MFP for drugs selected for initial price applicability years 2026 and 2027 except in unanticipated or unusual circumstances (e.g., a new indication is added shortly after the end of the negotiation period or a unit cost of production and distribution increased significantly due to a shortage of a key ingredient shortly after the end of the negotiation period, and either situation would have a significant impact and renegotiation would likely result in a significant change to the MFP).

CMS is soliciting comments on the selection approach described in this section, including the adoption of a holistic inquiry of the two criteria described in this section 130.2.1 (i.e., CMS' consideration of the likelihood that the new indication or material change to a section 1194(e) factor would result in a renegotiated MFP that would represent a 15 percent or greater change relative to the current MFP and that such change would have a significant impact on the Medicare program).

In the alternative, CMS would conduct a holistic review of the available information and circumstances for each renegotiation-eligible drug due to a new indication or a material change to a section 1194(e) factor to determine if CMS expects renegotiation is likely to result in a significant change to the MFP, without specific reliance on the two criteria discussed in this section 130.2.1.

Finally, CMS is soliciting comments on ways to increase transparency in the renegotiation selection process.

130.2.2 Publication of List of Drugs Selected for Renegotiation
CMS will publish the list of drugs selected for renegotiation at the same time as the publication of the selected drug list for negotiation for initial price applicability year 2028, as described in section 30.4 of this draft guidance.

130.3 Data Collection to Inform Renegotiation Drug Eligibility, Selection, and Renegotiation of the MFP for Initial Price Applicability Year 2028
In order for CMS to: determine which selected drugs are renegotiation-eligible drugs (in accordance with sections 1194(f)(1) and (2) of the Act as described in section 130.1 of this draft guidance); select drugs for renegotiation (in accordance with section 1194(f)(3) of the Act as described in section 130.2 of this draft guidance); and renegotiate the MFP of drugs selected for renegotiation (in accordance with section 1194(f)(4) of the Act as described in section 130.4 of this draft guidance), CMS will collect certain data from Primary Manufacturers and other interested parties necessary for each step in the renegotiation process as discussed in this section 130.3.

130.3.1 Voluntary Information Submission from Primary Manufacturers to Inform Renegotiation Drug Eligibility and Selection
Selected drugs with agreed-upon MFPs that have a change to long-monopoly status, as described in section 130.1.2 of this draft guidance, will automatically be selected for renegotiation per section 1194(f)(3)(B) of the Act. Since the addition of a new indication or a material change in any section 1194(e) factor does not need to be considered for a monopoly status change, as described in section 130.1.2 of this draft guidance, CMS does not need to collect or consider data related to the addition of a new indication or material change in a section 1194(e) factor prior to selection for renegotiation for these selected drugs.

Section 1194(f) of the Act does not require CMS to collect data from Primary Manufacturers to determine if a new indication has been added to the selected drug or if there has been a material change in any of the section 1194(e) factors. However, CMS believes that it may be helpful to permit submission of new information regarding the addition of a new indication to the selected drug or new information regarding the section 1194(e) factors prior to the CMS determination of renegotiation eligibility and selection. Therefore, CMS will collect a subset of new section 1194(e)(1) data as a voluntary submission from Primary Manufacturers of selected drugs that do not have a change to long-monopoly status, as described in section 130.1.2 of this draft guidance, based on a structured and limited set of CMS-specified questions with data points and free response fields prior to determining renegotiation eligibility and selection. CMS includes instructions and questions for Primary Manufacturers to answer and submit via Box if they

choose to do so via the Drug Selection ICR. The Drug Selection ICR includes a free response opportunity for Primary Manufacturers of a selected drug to also voluntarily provide new information about section 1194(e)(2) data for CMS' consideration for purposes of renegotiation eligibility and selection.

To provide CMS with the voluntary information, a Primary Manufacturer will need to email CMS via IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit the information described in this section by the date and time to be specified by CMS upon approval from the Office of Management and Budget for this information collection. Primary Manufacturers are encouraged to use the email template included in the Drug Selection ICR. Once CMS receives notification of the Primary Manufacturer's intent to provide the information, CMS will respond by providing access to a Box folder specific to the Primary Manufacturer. No parties other than the Primary Manufacturer and CMS and its contractors will have access to this folder. To voluntarily provide CMS with information prior to renegotiation eligibility determination and selection, the Primary Manufacturer must have uploaded its submission to the Box folder or using an alternative submission approach approved by CMS by the date and time to be specified by CMS upon approval from the Office of Management and Budget for the Drug Selection ICR. If a Primary Manufacturer is unable to use Box, it should include an explanation in its initial notification email to CMS and request an alternative submission method.

130.3.2 Data Collection from Primary Manufacturers and Other Interested Parties for Renegotiation

Once a renegotiation-eligible drug is selected for renegotiation, CMS will collect new information for all section 1194(e)(1) data elements from all Primary Manufacturers with a drug selected for renegotiation (in addition to any voluntary information provided for the process of selecting the drug for renegotiation as set forth in section 130.3.1 of this draft guidance). This includes all drugs selected for renegotiation regardless of the basis for the drug's renegotiation eligibility or selection. CMS will collect the new section 1194(e)(1) factor data for renegotiation post-selection consistent with the submission process and submission due date used for negotiation and the Drug Price Negotiation ICR, which is described in sections 50 and 50.1 of this draft guidance. The data collection for Primary Manufacturers will include NDC-11s of the selected drug that may be payable under Part B (if any) but are not covered under Part D, consistent with the collection of NDC-11s discussed in section 50.1 of this draft guidance.

Section 40.2.1 of this draft guidance applies to data submitted as part of the renegotiation process. If CMS believes the data provided by a Primary Manufacturer may be incomplete or inaccurate, CMS will follow the process established in section 40.2.3 of this draft guidance to seek clarification from the Primary Manufacturer.

Additionally, once a renegotiation-eligible drug is selected for renegotiation, CMS will solicit new data for all section 1194(e)(2) factors from the Primary Manufacturer and other interested parties who choose to submit. This solicitation and collection of data will include all drugs selected for renegotiation regardless of the basis for the drug's renegotiation eligibility or selection. CMS will collect the new section 1194(e)(2) data for renegotiation post-selection consistent with the process used for negotiation and the Drug Price Negotiation ICR, which is described in sections 50 and 50.2 of this draft guidance.

130.4 Renegotiation Process

As stated in section 1194(f)(4)(B) of the Act, CMS shall, to the extent practicable, establish a renegotiation process that is consistent with the negotiation process under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. Section 130.4.1 of this draft guidance describes how the ceiling will be calculated for renegotiation. The methodology for developing an initial offer for renegotiation is described in section 130.4.2 of this draft guidance, and the renegotiation process is described in section 130.4.3 of this draft guidance. Finally, plans for publication of the renegotiated MFP and an explanation of the renegotiated MFP are discussed in sections 130.4.4 and 130.4.5 of this draft guidance, respectively.

130.4.1 Determining the Ceiling

Consistent with section 1194(b)(2)(F)(i) of the Act, in renegotiating the MFP of a selected drug, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling determined under section 1194(c) of the Act, and adjusted, if applicable, and as described below. To determine the ceiling for renegotiation, CMS will maintain the underlying data that was used to calculate the amounts considered for the ceiling at the time of negotiation in accordance with section 1194(c) of the Act but will make the following adjustments to the calculations: (1) incorporate Part B data in accordance with sections 60.2.1, 60.2.2.3, and 60.2.3 of this draft guidance, as applicable (i.e., for selected drugs for initial price applicability years 2026 and 2027 that are also payable under Part B and selected for renegotiation); (2) update the applicable percent applied to the average non-FAMP amount(s) to reflect the appropriate monopoly status with respect to the initial price applicability year for which an agreed-upon MFP after renegotiation will apply (i.e., initial price applicability year 2028), as applicable; and (3) adjust the amounts considered for the ceiling (i.e., the sum of the plan-specific enrollment amounts and the average non-FAMP amount) for inflation (percent increase in CPI-U as explained below).

Prior to adjusting the applicable percent applied to the average non-FAMP amount (as necessary) or adjusting for inflation as described below, CMS will update the amounts considered for the ceiling to incorporate NDC-11s that may be payable under Part B if a drug that was originally selected for initial price applicability year 2026 or 2027 (and so did not include such NDC-11s in its original ceiling calculations since such drugs were not considered negotiation-eligible drugs under section 1192(d)(1) of the Act) is selected for renegotiation and has such NDC-11s. Specifically, CMS will:

- Calculate the payment amount under section 1847A(b)(4) of the Act using ASP/WAC and Part B claims data from the calendar year three years prior to the initial price applicability year of the MFP previously agreed upon (to mimic what the payment amount under section 1847A(b)(4) of the Act would have been if CMS had calculated it at the time of negotiation), as described in section 60.2.2.2 of this draft guidance;
- Calculate the payment amount for Selected Drugs Covered under Both Part D and Part B using ASP/WAC and Part B claims data from the calendar year three years prior to the initial price applicability year of the MFP previously agreed upon with the Part D data previously used to calculate the sum of the plan-specific enrollment weighted amounts at the time of negotiation, as described in 60.2.2.3 of this draft guidance; and
- Calculate the average non-FAMP amount using the non-FAMP and Part B utilization data for calendar year 2021 (or the first full year following market entry of the selected

drug) and 2024 (for initial price applicability year 2027 selected drugs) for NDC-11s of the selected drug that are not covered under Part D but may be payable under Part B with the non-FAMP and Part D utilization data previously used (or the non-FAMP amounts currently used, newly incorporating Part B utilization as well, for NDCs that are both covered under Part D and payable under Part B) to calculate the average non-FAMP at the time of negotiation, as described in section 60.2.3 of this draft guidance.

In cases where a selected drug's monopoly status with respect to the initial price applicability year of the negotiated price is different than the selected drug's monopoly status with respect to the initial price applicability year to which a renegotiated price would apply, CMS will update the applicable percent in accordance with section 1194(f)(4)(B) of the Act which specifies that CMS should apply the applicable percentage described in section 1194(c)(3)(B) of the Act for purposes of calculating the non-FAMP ceiling under section 1194(c)(1)(C) for drugs selected for renegotiation due to a change to extended-monopoly status, and should apply the applicable percent under section 1194(c)(3)(C) for purposes of calculating the non-FAMP ceiling under section 1194(c)(1)(C) for drugs selected for renegotiation due to a change to long-monopoly status. The applicable percent applied to the average non-FAMP amount(s) is as follows:

- Short-monopoly drugs and vaccines (a selected drug other than a long-monopoly drug): 75 percent.
- Long-monopoly drugs (a selected drug for which, with respect to the initial price applicability year for which an agreed-upon MFP after renegotiation would apply, at least 16 years have elapsed since the date of approval of such drug under section 505(c) of the FD&C Act or since the date of licensure of such drug under section 351(a) of the PHS Act, as applicable[127]): 40 percent.

CMS will also increase the ceiling amounts by the percent increase in the CPI-U from July of the calendar year that is two years prior to the initial price applicability year of the most recent MFP to which CMS and the Primary Manufacturer has agreed through July of the calendar year prior to the calendar year in which the drug is selected for renegotiation. This approach is consistent with sections 1194(f)(3)(C) and 1195(b)(1)(A) of the Act. Under section 1195(b)(1)(A) of the Act, for each selected drug for which there was an MFP, for each year subsequent to the first initial price applicability year of the price applicability period, CMS will publish an updated MFP no later than November 30 of the year that is two years prior to such subsequent year which is the previous MFP increased by the annual percentage increase in the CPI-U for the 12-month period ending with the July immediately preceding such November 30. For example, if a drug was selected for negotiation for initial price applicability year 2026, CMS and the Primary Manufacturer agreed upon an MFP, and the drug was selected in early 2026 for renegotiation for initial price applicability year 2028, CMS would increase the amounts considered for the ceiling that were applicable to the initial price applicability year 2026 negotiation (incorporating any Part B data as applicable) by the increase in CPI-U from July 2024 through July 2025. This increase represents the cumulative inflation adjustment that CMS would have applied to the initial price applicability year 2026 MFP through the most recent published MFP files at the time that the drug is selected for renegotiation (which would be the files for MFPs effective January 1, 2027, published in November 2025). If CMS did not similarly increase the amounts considered

[127] The first approval date under section 505(c) of the FD&C Act or the earliest licensure date under section 351(a) of the PHS Act, as applicable, is the approval or licensure date as identified in section 30.1 of this draft guidance.

for the ceiling by the same inflation adjustment that CMS applies to the MFP under section 1195(b)(1)(A) of the Act, the inflation-adjusted MFP would, over time, approach and/or exceed the original ceiling amount. This could preclude CMS' ability to select for renegotiation, and renegotiate MFPs for, selected drugs for which CMS expects renegotiation would be likely to result in an increase in the MFP due to changes to factors listed in sections 1194(e)(1) and 1194(e)(2) of the Act. This limitation on CMS's ability to renegotiate increased MFPs would be inconsistent with section 1194(f)(3)(C) of the Act, which does not limit selection for renegotiation to instances exclusively in which renegotiation would likely result in a decrease in the MFP and thus contemplates that renegotiation may be appropriate where CMS expected renegotiation would be likely to result in an increased MFP.

130.4.2 Methodology for Developing an Initial Offer

In accordance with section 1194(f)(4)(B) of the Act, CMS shall, to the extent practicable, establish a renegotiation process that is consistent with the methodology and process established for negotiation under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. With respect to the methodology for developing an initial offer for the purpose of renegotiating an MFP for a selected drug, CMS will follow the process described in section 60.3 of this draft guidance. CMS will: (1) identify a 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 the Net Part D Plan Payment and Beneficiary Liability for the therapeutic alternative(s), and/or the lower of ASP or WAC for a therapeutic alternative(s), or the MFP for any selected drug negotiated in a prior initial price applicability year that is a therapeutic alternative 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 comparative effectiveness of the selected drug and therapeutic alternatives, including the selected drug's impact on specific populations, the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need, the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) and the cost of such therapeutic alternative(s), and the prescribing information approved by the FDA for the selected drug and its therapeutic alternatives, as described in section 60.3.3 of this 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 and collected in accordance with section 130.3.3 of this draft guidance) to determine the initial offer price.

130.4.3 Renegotiation Process

In accordance with section 1194(f)(4)(B) of the Act, CMS intends, to the extent practicable, for the renegotiation process to conform to the procedures, structure, and timing established under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act as set forth in section 60.4 of this draft guidance. CMS may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for negotiation or host separate events specifically for drugs selected for renegotiation.

If the Primary Manufacturer is delayed in meeting one or more deadlines, such as submitting the written counteroffer for renegotiation, CMS will continue to engage in the renegotiation process

and will complete the established process as described in section 60.4 of this draft guidance. During the period of time from when the Primary Manufacturer fails to meet a deadline until the date the Primary Manufacturer comes into compliance with the renegotiation process, CMS will consider the Primary Manufacturer in violation of the Agreement and the Primary Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act and as described in section 100 of this draft guidance. Additionally, if the failure to meet a deadline results in the failure of CMS and the Primary Manufacturer to reach an MFP following renegotiation, this may result in certain sales of the selected drug being subject to a potential excise tax (see 26 U.S.C. § 5000D(b)(3)).

As CMS implements the first year of the renegotiation process, CMS is considering whether conforming to the procedures, structure, and timing of the negotiation process is practicable for the renegotiation process and is soliciting comments on whether there are specific aspects of the negotiation process that may not be practicable for the renegotiation process.

130.4.4 Publication of the MFP

For drugs for which there is agreement on a renegotiated MFP, CMS will publish and update the renegotiated MFP and related information in accordance with section 60.6 of this draft guidance.

130.4.5 Explanation for the MFP

CMS will release a public explanation for each selected drug with a renegotiated MFP following the completion of the renegotiation process in accordance with section 60.6.1 of this draft guidance and in accordance with the confidentiality policy described in sections 40.2.1 and 50.2 of this draft guidance. CMS does not intend to include redacted information from any voluntary information submitted by a Primary Manufacturer to CMS in response to the Drug Selection ICR if the selected drug of the Primary Manufacturer is selected for renegotiation and there is an agreement for a renegotiated MFP, in accordance with section 130.3.1 of this draft guidance. If the selected drug is then selected for renegotiation and the Primary Manufacturer submits the same information the Primary Manufacturer provided in response to the Drug Selection ICR also in response to the Drug Price Negotiation ICR, in accordance with section 130.3.2 of this draft guidance, CMS may redact and include information provided in response to the Drug Price Negotiation ICR in the public explanation of a renegotiated MFP in accordance with section 60.6.1 of this draft guidance and in accordance with the confidentiality policy described in sections 40.2.1 and 50.2 of this draft guidance

If an agreement for a renegotiated MFP is not reached for a drug selected for renegotiation by the same statutory deadline as the negotiation process, i.e., November 1, 2026, CMS will follow the procedures outlined in section 60.4.6 of this draft guidance and the Primary Manufacturer may be subject to potential excise tax liability (see 26 U.S.C. § 5000D(b)(3)). Additionally, if there is no agreed-upon MFP then neither a renegotiated MFP nor a public explanation for the renegotiated MFP will be published. Instead, CMS will indicate on the CMS website that a renegotiated MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where a renegotiated MFP is finalized after the statutory deadline for the conclusion of negotiations, for which CMS is adopting the same statutory deadline as the negotiation process, i.e., November 1, 2026, the renegotiated MFP and the public explanation for the renegotiated MFP will be posted in accordance with section 60.8 of this draft guidance.

Appendix A: Definitions for Purposes of Collecting Data for the Negotiation Program

For the purposes of describing the data at sections 1194(e)(1), 1194(e)(2), 1193(a)(4)(A), and 1194(f) of the Act to be collected for use in the Negotiation Program, as described in sections 40.2, 50.1, 50.2, and 130 of this draft guidance, CMS will apply the following definitions and standards to the Drug Selection ICR and the Drug Price Negotiation ICR, and to this draft guidance, for initial price applicability year 2028.[128] As described in sections 30.1.2 and 30.3.1 of this draft guidance, CMS is publishing the Drug Selection ICR concurrent with the publication of this draft guidance for a 60-day public comment period, and CMS intends to publish a revised version of the Drug Selection ICR for a 30-day comment period in Fall 2025. Additionally, as described in section 50 of this draft guidance, CMS intends to publish the Drug Price Negotiation ICR for a 60-day public comment period in Summer 2025, and CMS intends to publish a revised version of the Drug Price Negotiation ICR for a 30-day public comment period in Fall 2025. The Drug Price Negotiation ICR will include instructions on how Primary Manufacturers and members of the public may submit relevant data for initial price applicability year 2028, including the optional data described in this Appendix (relating to Evidence About Alternative Treatments).

CMS is also soliciting comments on opportunities to streamline the definitions included in Appendix A, including, in particular related to the Primary Manufacturer's research and development costs.

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[128] CMS includes instructions specifying the applicable reporting period for data under the Drug Selection ICR and Drug Price Negotiation ICR within the instructions for the applicable ICR. Therefore, this information was removed from definitions previously included the reporting periods because the reporting time periods are distinct for each ICR. Additionally, Appendix A reflects revisions to the definitions related to the reporting of research and development (R&D) costs because CMS includes a streamlined set of questions for reporting of R&D costs and recoupment within the Drug Selection ICR and Drug Price Negotiation ICR. Specifically, CMS has removed the separate question regarding acquisition costs because, among other impacts on the data, CMS understands that acquisitions costs are generally driven by the estimated net of the present value that is assessed based on the future revenue expectations for a drug, and that acquisition costs are not driven by R&D. Additionally, CMS is combining the reporting of all other R&D costs related to the selected drug (including basic pre-clinical research for all FDA-approved indications of the selected drug, post-IND costs for all FDA-approved indications of the selected drug and other allowable costs) in order to reduce the number of separate categories the Primary Manufacturer is required to report to CMS in response to feedback that the previous separation of categories may not reflect how Primary Manufacturers track R&D investments made by the company from which the drug is being acquired. Further, CMS has expanded the collection of data for basic pre-clinical research costs, post-investigational new drug costs, and costs of failed and abandoned drugs to include costs that are related to indications that have not been approved by the FDA because CMS observed in response collected for previous initial price applicability years that these costs may cover significant periods of time prior to FDA approval of an indication, if such indication is approved at all. CMS has revised the definition of which products are considered failed or abandoned products for basic pre-clinical research and post-IND costs because CMS did not intend to suggest different products would be considered failed or abandoned products for each category of R&D and in response to responses collected for previous initial price applicability years which suggested that therapeutic class was not a sufficiently clear term. Also, when calculating monetary values, there will no longer be an adjustment for cost of capital because CMS observed that in responses collected for previous initial price applicability years, Primary Manufacturers' approaches to adjustments varied and CMS is responding to feedback that applying an adjustment is inconsistent with Generally Accepted Accounting Principles.

General

- When calculating monetary values, do not adjust for cost of capital.

Selected Drug Information

- Average Manufacturer Price (AMP) unit: The unit type, as reported monthly by the manufacturer, used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, or microcurie.
- Drug sample: A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug (Section 503(c)(1) of the Federal Food, Drug, and Cosmetics Act).
- Labeler code: The first segment of the FDA-assigned NDC (21 C.F.R. § 207.33(b)(1)(i)). Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under 21 C.F.R. Part 207 must apply for an NDC labeler code (21 C.F.R. § 207.33(c)(1)).
- Private label distributor: With respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed (21 C.F.R. § 207.1).
- Total AMP Units per Package: The total number of AMP units per NDC-11 package size.
- Total NCPDP Units per Package: The total number of NCPDP units per NDC-11 package size.

Non-FAMP

- Non-FAMP: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) for the four calendar quarters of the year involved.[129] For initial price applicability year 2028, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and 2025 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2026). When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such drug. When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021, the Primary Manufacturer should submit 2021 data—to the extent that it exists—for all NDC-11s of the selected drug. For a given NDC-11 of such drug, when there are at least 30 days of commercial sales but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) or 2025, the non-FAMP reported by the Primary Manufacturer to CMS should reflect the temporary non-FAMP predicated upon the first 30 days of commercial

[129] 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).

sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2025 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585.[130] Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.

- Non-FAMP package: Non-FAMP package is the package unit as described in 38 U.S.C. § 8126(h)(6) and represents the NDC-11 package (e.g., for an NDC-11 that represents a bottle of 30 tablets, the non-FAMP package would be the bottle; for an NDC-11 that represents a carton containing 25 mg/mL in a single dose vial, the non-FAMP package would be the vial).

Research and Development (R&D) Costs
R&D costs mean a combination of costs incurred by the Primary Manufacturer for indications[131] of a drug falling into the two categories below, and excluding (a) prior Federal financial support and (b) costs associated with applying for and receiving foreign approvals:

1. R&D: Costs Related to the Selected Drug, Including Basic Pre-Clinical Research for Indications of the Selected Drug, Post-IND Costs for Indications of the Selected Drug and Other Allowable Costs
2. R&D: Costs for Failed and Abandoned Products Related to the Selected Drug

Acquisition costs are excluded from R&D costs. CMS is including both the global and U.S. net revenue for the selected drug in its consideration of the extent to which the Primary Manufacturer has recouped R&D costs.

3. Recoupment: Global and U.S. Net Revenue for the Selected Drug

The definitions for these terms are included below.

Definitions for 1. R&D: Basic Pre-Clinical Research Related to the Selected Drug

- Basic pre-clinical research costs are the sum of (1) direct research expenses; and (2) the appropriate proportion, as instructed in the applicable information collection request, of indirect research expenses.
- Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (monetary and non-monetary compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research,

[130] See: https://www.va.gov/opal/docs/nac/fss/pl102585-2025-pbm-fcp-guidance-for-new-covered-drugs.pdf. Archived Dear Manufacturer Letters from the VA are available at: https://www.va.gov/opal/nac/fss/publicLaw.asp.
[131] For purposes of this ICR and the Negotiation Data Elements and Drug Price Negotiation Process ICR, CMS distinguishes between the use of the word "indication" and the term "FDA-approved indication" such that "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s), and "indication" refers to the condition or disease state for which the selected drug is used.

and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.

- Indirect basic pre-clinical research costs and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological products.

Other Allowable Costs:

- Other allowable costs for all new costs related to the selected drug are defined as direct costs associated with conducting FDA-required postmarketing trials and other FDA postmarketing requirements and commitments that were not completed, direct costs associated with Phase IV postmarketing studies for FDA-approved indications that were not required by FDA, direct post-IND costs for indications that did not receive FDA approval (following the definitions for direct post-IND costs below), direct costs associated with researching and utilizing devices for the selected drug, and direct costs associated with generating real-world evidence that was submitted to FDA to support the safety or effectiveness of a selected drug and direct costs to support or satisfy a postmarketing requirement or commitment.
- Direct costs for other allowable costs include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting Phase IV and postmarketing trials.

Definitions for 2. R&D: Costs of Failed or Abandoned Products Related to the Selected Drug

- Failed or abandoned product costs include direct *basic pre-clinical research* costs on drugs with the same mechanism of action as the selected drug that did not make it to clinical trials.
    - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
    - Direct research expenses include personnel (monetary and non-monetary compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned product costs include direct *post-IND costs* for drugs with the same mechanism of action 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.
- Acquisition costs for failed or abandoned products or devices are not allowable.

Additional Definitions for 1 and 2.

- Post-IND costs are defined as direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication. Post-IND costs also include all direct costs associated with completed FDA-required, postmarketing trials that are conducted after the FDA has approved a product.

- Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel (compensation for investigators and staff) researching the selected drug, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, postmarketing trial.
- Personnel, patient recruitment, and per-patient costs include monetary and non-monetary compensation. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided

Definitions for 3. Global and U.S. Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. 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 3a. Global, including U.S., Net Revenue for the Selected Drug

- Global net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

Definitions for 3b. U.S. Net Revenue for the Selected Drug

- U.S. net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

Current Unit Costs of Production and Distribution

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (e.g., capsule or tablet, milligram of molecules, grams, international units) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS).[132] 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.

[132] 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);
    - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
    - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third-party vendors (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
    - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug do not include:
    - R&D costs;
    - Marketing costs; and
    - Transfer prices.
- "Marketing costs" are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, including providing free products to health professionals or patients, and other paid promotion.
- "Transfer prices" are defined as prices charged for goods, services, or other intangible assets in transactions between two members of the same controlled group of the Primary Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property.

For the purposes of the definition of transfer prices, "controlled group" of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of the Treasury regulations thereunder.

Prior Federal Financial Support

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 includes the manufacturer's reasonable estimate of the dollar value of in-kind contributions and Cooperative Research and Development Agreements (CRADAs) that do not have a readily ascertainable value.
- Direct prior federal financial support costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of indications of the selected drug.

Patents, Exclusivities, and Approvals

- CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
    - All patents issued by the United States Patent and Trademark Office (USPTO), both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents relevant to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
- Patents and patent applications relevant to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book;[133] patents that claim the drug product (e.g., the final product taken by or administered to a patient), drug substance (active ingredient) or other chemicals related to the active ingredient of a selected drug (e.g., crystalline forms,

[133] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.

polymorphs, salts, metabolites, or intermediates); patents that claim a formulation of the drug; method-of-use patents (e.g., patents that claim an indication or use of the drug for treating a particular disease); process patents (e.g., patents that claim technologies and method(s) of manufacturing the drug); device patents (e.g., patents that claim the device used to administer the selected drug); and design patents (e.g., patents that claim a design on the packaging of the selected drug).

- Relevant patents and patent applications do not include patent applications that were denied by the USPTO.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays on the submission or approval of applications for competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[134]
    - New Chemical Entity Exclusivity (NCE);[135]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[136]
    - New Clinical Investigation Exclusivity (NCI);[137]
    - Pediatric Exclusivity (PED);[138] and
    - Reference Product Exclusivity for Biological Products.[139]
- Active and pending FDA applications and approvals include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided.

Market Data and Revenue and Sales Volume Data

- Wholesale Acquisition Cost (WAC) unit price: The manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-11 level.
- The three NCPDP BUS[140] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS will request units be reported using the NCPDP BUS for all but Medicaid best price to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- 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

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[134] Section 527 of the FD&C Act.
[135] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[136] Section 505E(a) of the FD&C Act.
[137] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[138] Section 505A(b) & (c) of the FD&C Act.
[139] Section 351(k)(7) of the PHS Act.
[140] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

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.[141] 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.
- 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 following items should be deducted from gross revenue in your calculation: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The following items should not be deducted from gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price is reported at the NDC-11 level.
- Manufacturer U.S. commercial average net unit price─ net of patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price─ net of patient assistance, the following items should be deducted from the gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The following items should not be deducted from gross revenue in your calculations: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer 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 following items should be deducted from gross revenue in your calculations: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by

[141] See: https://department.va.gov/administrations-and-offices/acquisition-logistics-and-construction/freedom-of-information-act-requests/#toc_Historical_VA_Pharmaceutical_Prices.

the Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers. The following items should not be deducted from the gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price─ best is reported at the NDC-11 level.

- Manufacturer net Medicare Part D average unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price as calculated by the Primary Manufacturer. This manufacturer net Medicare Part D average unit price would include specific data, including coverage gap discounts for calendar years prior to the calendar year date specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale discounts) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price is reported at the NDC-11 level.
- Manufacturer net Medicare Part D average unit price – best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest manufacturer net Medicare Part D average unit price offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any Part D plan sponsors in the U.S. This manufacturer net Medicare Part D average unit price – best would include specific data, including coverage gap discounts for calendar years prior to the calendar year specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale discounts) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price – best is reported at the NDC-11 level.

Evidence About Alternative Treatments **(Optional)**

- Therapeutic Advance: CMS intends to examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression) and will consider the costs of the selected drug and its therapeutic alternative(s). CMS may consider the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for an indication(s) when determining the extent to which a selected drug represents a therapeutic advance. For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS will consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.
- Therapeutic Alternative: A therapeutic alternative must be a pharmaceutical product or group of pharmaceutical products that is clinically comparable to the selected drug (in

other words, a medicine other than the selected drug that may be used to treat the same condition or disease state). CMS intends to consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS intends to identify therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action and then also consider therapeutic alternatives in different pharmacologic classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug.

- Outcomes: Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes of interest to CMS may include direct clinical outcomes (e.g., cure, mortality) and/or validated or reasonably likely surrogate endpoints (e.g., serum hemoglobin A1c). In determining outcomes of interest, CMS will consider patient-reported outcomes and outcomes of importance to patients, if available. CMS may also consider additional outcomes and contextual factors, such as health-related quality of life or patient/caregiver preferences regarding treatment, to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternatives. The caregiver perspective may be considered to the extent it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.
- Patient-centered outcome: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves.[142]
- Specific populations: Specific populations may include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries.
- Unmet medical need: A circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition.[143] For purposes of the Negotiation program, anytime CMS considers an unmet medical need, CMS will consider the extent to which the drug represents an unmet medical need at the time of consideration based on all available information at such time of consideration. Under section 1194(e)(2) of the Act, CMS intends to consider the extent to which a selected drug and its therapeutic alternatives address an unmet medical need.
- Indication: Indication refers to the condition or disease state that the selected drug treats. An indication may include any FDA-approved indication included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s) and off-label use(s) that are

[142] 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).

[143] 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.

included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication covered under Part D or Part B, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice. For the purpose of an ICR submission, a respondent may combine FDA-approved indications (e.g., identical adult and pediatric indications) and off-label use(s). The respondent may also choose not to report on certain FDA-approved indications or off-label uses.

- Off-label Use: Off-label use means a use of a selected drug or therapeutic alternative that is not approved by the FDA but is included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted use covered under Part D or Part B, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

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

Table 13 contains the list of DDPS edits that CMS identified as directly relating to the determination and verification of MFP eligibility for the purposes of the Negotiation Program. As described in section 40.4.2.1 of this draft guidance, if a claim has any of the DDPS edits that are included on this list of edits directly related to MFP eligibility, the MTF DM will not transmit the claim-level data elements to the Primary Manufacturer because it has not been verified that the selected drug of the Primary Manufacturer was dispensed to an MFP-eligible individual. CMS is soliciting comments on this compilation of DDPS edits for its stated purpose and suggestions for DDPS edits to include or exclude.

Table 13: DDPS Edits that Directly Relate to the Determination and Verification of MFP Eligibility for the Purposes of the Negotiation Program[144]

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
603	Missing/ Invalid	Medicare Beneficiary Identifier (MBI)	MBI is missing. The Medicare Beneficiary Identifier must not be <SPACE>.
607	Missing/ Invalid	Date of Service (DOS)	DOS is missing or invalid. DOS must be in CCYYMMDD format and be a valid date.
608	Missing/ Invalid	Date of Service (DOS)	The DOS must be on/after 1/1/2006.
609	Missing/ Invalid	Date of Service (DOS)	DOS must be on or before PDE submission date.
612	Missing/ Invalid	Prescription Service Reference Number	Prescription Number Service Reference Number is missing or invalid. Prescription Service Reference Number must be numeric.
613	Missing/ Invalid	Product Service ID	Product Service ID is missing. Product Service ID must not be <SPACE>.
614	Missing/ Invalid	Service Provider ID Qualifier, Non-Standard Format Code	Service Provider ID Qualifier is missing or invalid. Service Provider ID Qualifier must be '01', '06', '07', '08', '11', or '99'for non-standard format PDEs or ’01’ or ‘07’ for standard format PDEs.
615	Missing/ Invalid	Service Provider ID	The Service Provider ID is missing or invalid.

[144] The full list of DDPS edits is located at https://www.csscoperations.com/internet/csscw3.nsf/T/Prescription%20Drug%20Program%20(Part%20D)~References.

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
616	Missing/ Invalid	Fill Number	Fill Number is missing or invalid. Fill Number must be a value between ‘00’ and ‘99’.
618	Missing/ Invalid	Compound Code	Compound Code is missing or invalid. Compound Code must be ‘0’, ‘1’ or ‘2’.
620	Missing/ Invalid	Quantity Dispensed	Quantity Dispensed is missing or invalid. Quantity Dispensed must be >= ‘0.001’.
621	Missing/ Invalid	Days Supply	Days Supply is missing or invalid. Days Supply must be a value between ‘000’ and ‘999’.
622	Missing/ Invalid	Prescriber ID Qualifier	Prescriber ID Qualifier is missing. Prescriber ID Qualifier must not be <SPACE>.
623	Missing/ Invalid	Prescriber ID Qualifier	Prescriber ID Qualifier is invalid. Prescriber ID Qualifier must be '01'.
624	Missing/ Invalid	Prescriber ID	The Prescriber ID is missing. Prescriber ID must not be <SPACE>.
626	Missing/ Invalid	Adjustment Deletion Code	Adjustment Deletion Code is invalid. Adjustment Deletion Code must be ‘A’, ‘D’or<SPACE>.
627	Missing/ Invalid	Non-Standard Format Code	Non-Standard Format Code is invalid. Non-Standard Format Code must be 'A', 'B', 'C', 'P', 'X' or <SPACE>. Effective 10/24/2022, 'A' is a valid value.
641	Missing/ Invalid	Filler	Filler fields are invalid. Filler fields must be<SPACE>.
662	Adj/Del	Adjustment Deletion Code	Deletion PDE not permitted. Existing PDE is deleted. Only an original PDE can be submitted.
700	Eligibility	MBI	MBI does not exist. Medicare Beneficiary Identifier does not match an existing beneficiary record.
701	Eligibility	MBI, Date of Birth (DOB)	DOB submitted does not match the beneficiary record. DOB is optional. If DOB is reported, matching to the beneficiary record is performed on month and year only.
703	Eligibility	MBI, DOB, Date of Service (DOS)	DOS must be > DOB.
704	Eligibility	MBI, DOS, Pharmacy Service Type, Patient Residence	DOS must be <= date of death (DOD) + 32 days. Applies when Pharmacy Service Type <> '01' and Patient Residence <> '01'.

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
705	Eligibility	MBI, DOS	Beneficiary must be enrolled in Part D on DOS.
713	Eligibility	Contract Number, Plan Benefit Package (PBP) ID, DOS	Submitting Contract and PBP ID does not offer Part D on DOS.
735	NDC	Product Service ID	NDC not found in NDC database. NDC not found on First Databank and/or MediSpan.
738	NDC	Product Service ID, Drug Coverage Status Code	NDC is a non-covered drug. NDC not covered by Part D. Refer to the subcategory reject code returned in the Exclusion Reason Code field from the PDE Outbound File for more information.
742	NDC	Product Service ID, Drug Coverage Status Code, Vaccine Administration Fee or Additional Dispensing Fee	Vaccine Administration Fee or Additional Dispensing Fee must be $0 for non-qualifying drugs. NDC must qualify as a valid Part D vaccine when Vaccine Administration Fee or Additional Dispensing Fee > $0. Applies to covered drugs only (Drug Coverage Status Code = 'C'). Effective 03/01/2022, edit is bypassed for oral antiviral drugs procured by the U.S. Government.
744	NDC	DOS, Product Service ID, Compound Code, Drug Coverage Status Code, Reported Gap Discount	NDC not covered under Part D on DOS. This drug is not covered under Part D because the FDA-assigned Marketing Category is NDA or BLA, and no Coverage Gap Discount Program agreement is on file for the manufacturer responsible for this labeler code for the given DOS. Applies to covered drugs only (Drug Coverage Status Code = 'C'). Edit is bypassed for compound drugs.
745	NDC	Product Service ID, Quantity Dispensed, Days Supply, Drug Coverage Status Code	NDC not covered under Part D for submitted strength and days supply. Coverage under Part D allows for 1-2 tablets per day of Cialis in 2.5 milligram strength and one-half or 1 tablet per day of Cialis in 5 milligram strength when prescribed to treat benign prostatic hyperplasia. Applies to covered drugs only (Drug Coverage Status Code = 'C').

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
746	NDC	Product Service ID, Drug Coverage Status Code	NDC not found on NSDE file. NDC not found on current FDA NDC SPL Data Element file. Applies to covered drugs only (Drug Coverage Status Code = 'C').
747	NDC	DOS, Product Service ID, Drug Coverage Status Code	NDC not effective on DOS. NDC found on current FDA NDC SPL Data Element file, but is not effective for the given DOS. Applies to covered drugs only (Drug Coverage Status Code = 'C').
748	NDC	DOS, Product Service ID, Compound Code, Drug Coverage Status Code, Reported Manufacturer Discount	NDC not covered under Part D on DOS. For DOS >= 01/01/2025, this drug is not covered under Part D because the FDA-assigned Marketing Category is NDA or BLA, and no Manufacturer Discount Program agreement is on file for the manufacturer responsible for this labeler code for the given DOS. Applies to covered drugs only (Drug Coverage Status Code = 'C'). Edit is bypassed for compound drugs.
753	Eligibility	MBI, DOS, Pharmacy Service Type, Patient Residence	DOS must be <= DOD + 14 days. Applies when Pharmacy Service Type = '01' and Patient Residence = '01'.
777	Misc	Contract number, DOS, Prescription Service Reference Number, Service Provider ID, Fill Number, Adjustment Deletion Code	Duplicate PDE record exists. Applies when Adjustment Deletion Code on submitted PDE = <SPACE>, but a match is found with an existing accepted original or adjustment PDE. Prior accepted PDE must be deleted in order to submit a new original.
781	Misc	Product Service ID, Service Provider ID	Service Provider ID not found on provider file. Edit is bypassed for vaccines.
783	Misc	DOS, Service Provider ID	Service Provider ID not active on DOS. Applies when DOS > store closure date plus six months.

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
784	Misc	Contract number, DOS, Prescription Service Reference Number, Service Provider ID Qualifier, Service Provider ID, Fill Number, Adjustment Deletion Code	Duplicate PDE record exists from a different Submitting Contract. Applies when Adjustment Deletion Code on submitted PDE = <SPACE>, but a match is found with an existing accepted original or adjustment PDE from a different Submitting Contract. Refer to Original Submitting Contract field from the PDE Outbound File for the contract that submitted the previously accepted PDE.
785	Misc	Contract number, PDP ID, DOS, Prescription Service Reference Number, Service Provider ID Qualifier, Service Provider ID, Fill Number	Duplicate PDE record exists on this File ID. Applies when a duplicate PDE is found on the same File ID from the PDE Inbound File submission.
789	Misc	Prescriber ID Qualifier, Prescriber ID	Prescriber ID is listed on OIG's List of Excluded Individuals and Entities and is not assigned an active sanctioned provider waiver.
790	Misc	Service Provider ID Qualifier, Service Provider ID	Service Provider ID is listed on OIG's List of Excluded Individuals and Entities and is not assigned an active sanctioned provider waiver.
833	Missing/ Invalid	Prescriber ID Qualifier, Prescriber ID	Prescriber ID not found on NPI database. NPI must be Type 1 (individual) and be found in current NPPES data.
834	Missing/ Invalid	Prescriber ID Qualifier, Prescriber ID, DOS	Prescriber ID not active on DOS. NPI must be active in current NPPES data for the given DOS. Edit is bypassed when DOS is within one year of NPI Deactivation Date when there is no NPI Reactivation Date available in current NPPES data.

Error Number	Edit Category	Data Element to be Edited	Message to be Reported and Comments/Rationale
835	Missing/ Invalid	Non-Standard Format Code, Pharmacy Service Type	Pharmacy Service Type is missing or invalid. Pharmacy Service Type must be '01', '02', '03', '04', '05', '06', '07', '08' or '99'. May be <SPACE> on COB PDEs (Non-Standard Format Code = 'C'). Effective 09/18/2023, may be <SPACE> on Medicaid subrogation PDEs (Non-Standard Format Code = 'A' and CPP = GDCB + GDCA).
844	Missing/ Invalid	Service Provider ID Qualifier, Service Provider ID, Adjustment Deletion Code	Service Provider ID is invalid. Service Provider ID must be 'PAPERCLAIM' when Service Provider ID Qualifier = '99' and submitted Service Provider ID value is non-numeric. Edit is bypassed for adjustment PDEs.
998	Misc	N/A	Internal CMS system issue regarding Contract/PBP of Record encountered. CMS issue encountered with retrieving Contract and PBP of Record. Please resubmit PDE until edit is no longer returned.
999	Misc	N/A	Internal CMS system issue encountered. CMS issue encountered with retrieving necessary data for PDE editing. Please resubmit PDE until edit is no longer returned.